

**February 5, 2023**

**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.

## Contents

<b>I. Relevant Background and Qualifications</b>	<b>3</b>
<b>II. Methodology</b>	<b>5</b>
<b>III. Executive Summary</b>	<b>6</b>
<b>IV. COVID-19 and Vulnerable Groups</b>	<b>9</b>
A. What is COVID-19 and How Is It Spread?	9
B. Older People Are Among the Most Vulnerable	11
C. SARS-CoV-2 Variants	16
<b>V. Effectiveness and Fair Allocation of Covid-19 Vaccines</b>	<b>19</b>
A. Vaccines Are Safe and Effective, Particularly For Aged 65 Years and Older	19
The vaccine known as Pfizer-BioNTech (BNT162b2) or Comirnaty	27
The vaccine known as AstraZeneca (ChAdOx1-SARS- COV-2), or Vaxzevria	29
The vaccine known as Moderna (mRNA-1273), or Spikevax	31
The vaccine known as J&J/Janssen (Ad26.COVS.S), or Jcovden	32
B. Vaccine Policies are Determined by States and Regional Bodies	37
C. Vaccine Prioritization	38
D. Vaccination Allocation and Distribution	43
E. The Case of Bulgaria	45
<b>VI. Public Health Campaign and Communication regarding Covid-19 Vaccination</b>	<b>54</b>
<b>VII. Conclusion/Summary</b>	<b>58</b>

**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.<sup>1</sup>

---

<sup>1</sup> 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."<sup>2</sup>

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...”<sup>3</sup> By March 2020, SARS-CoV-2 was declared a pandemic.<sup>4</sup>

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.<sup>5</sup> True counts are likely even higher due to

---

<sup>2</sup> World Health Organization. Director-General's remarks at the media briefing on 2019-nCoV on 11 February 2020. <http://www.who.int/dg/speeches/detail/who-director-general-s-remarks-at-the-media-briefing-on-2019-ncov-on-11-february-2020>. Accessed December 2022.

<sup>3</sup> “World Health Organization Statement on the meeting of the International Health Regulations Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV)” (Jan. 23, 2020), [https://www.who.int/news-room/detail/23-01-2020-statement-on-the-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-\(2019-ncov\)](https://www.who.int/news-room/detail/23-01-2020-statement-on-the-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)).

<sup>4</sup> WHO Director-General's opening remarks at the media briefing on COVID19 -March 2020; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7569573/#ref1>. Accessed December 2022.

<sup>5</sup> “Coronavirus (COVID-19) Dashboard, World Health Organization, January 10, 2023, <https://covid19.who.int/>. Accessed January 10, 2023.

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.<sup>6</sup> 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.<sup>7,8,9</sup> 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.<sup>10,11,12,13</sup> 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

---

<sup>6</sup> Eric Meyerowitz et al, "Transmission of SARS-CoV-2: A Review of Viral, Host, and Environmental Factors," *Ann Intern Med* 174, no. 1 (September 2020). doi: 10.7326/M20-5008.

<sup>7</sup> Daphne Duval et al, "Long distance airborne transmission of SARS-CoV-2: rapid systematic review," *BMJ* 377 (June 2022). doi: 10.1136/bmj-2021-068743.

<sup>8</sup> Prateek Bahl et al, "Airborne or Droplet Precautions for Health Workers Treating Coronavirus Disease 2019," *J Infect Dis* 225, no. 9 (May 2022):1561-1568. doi:10.1093/infdis/jiaa189.

<sup>9</sup> Valentyn Stadnytskyi et al, "The airborne lifetime of small speech droplets and their potential importance in SARS-CoV-2 transmission," *Proc Natl Acad Sci USA* 117, no.22 (June 2020):11875-11877. doi:10.1073/pnas.2006874117

<sup>10</sup> Roman Wölfel et al, "Virological assessment of hospitalized patients with COVID-2019," *Nature* 588, no 7839 (May 2020): 465-469. doi:10.1038/s41586-020-2196-x.

<sup>11</sup> Tara Bouton et al, "Viral dynamics of Omicron and Delta SARS-CoV-2 variants with implications for timing of release from isolation: a longitudinal cohort study," *Clin Infect Dis* 510, (June 2022). doi:10.1093/cid/ciac510

<sup>12</sup> Julie Boucau et al, "Duration of Shedding of Culturable Virus in SARS-CoV-2 Omicron (BA.1) Infection," *N Engl J Med* 387, no.3 (June 2022):275-277. doi:10.1056/NEJMc2202092

<sup>13</sup> "Active epidemiological investigation on SARS-CoV-2 infection caused by Omicron variant (Pango lineage B.1.1.529) in Japan: preliminary report on infectious period," National Institute of Infectious Diseases Disease Control and Prevention Center, National Center for Global Health and Medicine, January 5, 2022. <https://www.niid.go.jp/niid/en/2019-ncov-e/10884-covid19-66-en.html>. Accessed December 2022.

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)<sup>14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27</sup>
- For example, individuals aged less than 65 years account for 4.5–11.2% of all COVID-19 deaths in European countries and Canada.<sup>28</sup>
- B. Male Gender<sup>29, 30, 31, 32, 33, 34, 35, 36, 37, 38</sup>
- C. Comorbid conditions:

<sup>14</sup> Fei Zhou et al, "Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study," *Lancet* 395, no.10229 (March 2020):1054-1062. doi:10.1016/S0140-6736(20)30566-3

<sup>15</sup> Eboni Price-Haywood, "Hospitalization and Mortality among Black Patients and White Patients with Covid-19," *N Engl J Med* 382, no. 26 (May 2020):2534-2543. doi:10.1056/NEJMsa2011686

<sup>16</sup> Tao Chen et al, "Clinical characteristics of 113 deceased patients with coronavirus disease 2019: retrospective study," *BMJ* 368, 1091(March 2020):. doi:10.1136/bmj.m1091

<sup>17</sup> Israel Júnior Borges do Nascimento, "Novel Coronavirus Infection (COVID-19) in Humans: A Scoping Review and Meta-Analysis," *J Clin Med* 9, no.4 (March 2020):941.doi:10.3390/jcm9040941

<sup>18</sup> Elizabeth Williamson et al, "Factors associated with COVID-19-related death using OpenSAFELY," *Nature* 584, no. 7821 (August 2020):430-436. doi:10.1038/s41586-020-2521-4

<sup>19</sup> Andrew Levin et al, "Assessing the age specificity of infection fatality rates for COVID-19: systematic review, meta-analysis, and public policy implications," *Eur J Epidemiol* 35, no: 12 (December 2020):1123-1138. doi:10.1007/s10654-020-00698-1

<sup>20</sup> Mohammad Parohan et al, "Risk factors for mortality in patients with Coronavirus disease 2019 (COVID-19) infection: a systematic review and meta-analysis of observational studies," *Aging Male* 23, no. 5 (December 2020):1416-1424. doi:10.1080/13685538.2020.1774748

<sup>21</sup> 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," *Aging* 12, no. 24 (December 2020):24522-24534. doi:10.18632/aging.202307

<sup>22</sup> Mattia Bellan et al, "Fatality rate and predictors of mortality in an Italian cohort of hospitalized COVID-19 patients," *Sci Rep* 10, no.1 (November 2020):20731. doi:10.1038/s41598-020-77698-4

<sup>23</sup> 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," *Br J Gen Pract* 70, no. 701 (November 2020):e890-e898. doi:10.3399/bjgp20X713393

<sup>24</sup> Paola Michelozzi et al, "Mortality impacts of the coronavirus disease (COVID-19) outbreak by sex and age: rapid mortality surveillance system, Italy, 1 February to 18 April 2020," *Euro Surveill* 25, no.19 (May 2020):2000620. doi:10.2807/1560-7917.ES.2020.25.19.2000620

<sup>25</sup> Mohamed Mohamed et al "Sex Differences in Mortality Rates and Underlying Conditions for COVID-19 Deaths in England and Wales," *Mayo Clin Proc* 95, no.10 (October 2020):2110-2124. doi:10.1016/j.mayocp.2020.07.009

<sup>26</sup> Christopher Petrilli et al, "Factors associated with hospital admission and critical illness among 5279 people with coronavirus disease 2019 in New York City: prospective cohort study," *BMJ* 369 (May 2020):m1966.doi:10.1136/bmj.m1966

<sup>27</sup> John Ioannidis, Cathrine Axfors, Despina Contopoulos-Ioannidis, "Population-level COVID-19 mortality risk for non-elderly individuals overall and for non-elderly individuals without underlying diseases in pandemic epicenters," *Environ Res* 188 (September 2020):109890. doi:10.1016/j.envres.2020.109890

<sup>28</sup> Ioannidis, "Population-level COVID-19," 109890.

<sup>29</sup> Zhou, "Clinical course and risk factors,"1054-1062.

<sup>30</sup> Nascimento, "Novel Coronavirus Infection," 941

<sup>31</sup> Jian-Min Jin et al, "Gender Differences in Patients With COVID-19: Focus on Severity and Mortality," *Front Public Health* 8, no. 152 (April 2020) doi:10.3389/fpubh.2020.00152

<sup>32</sup> Williamson, "Factors associated with COVID-19," 430-436.

<sup>33</sup> Cangiano, "Mortality Italian nursing home," 24522-24534.

<sup>34</sup> Joy, "Excess mortality first COVID," e890-e898.

<sup>35</sup> Michelozzi, "Mortality impacts coronavirus," 2000620.

<sup>36</sup> Mohamed, "Sex Differences in Mortality," 2110-2124.

<sup>37</sup> Aline Mendes et al, "Predictors of In-Hospital Mortality in Older Patients With COVID-19: The COVIDAge Study," *J Am Med Dir Assoc* 21, no.11 (November 2020):1546-1554.e3. doi:10.1016/j.jamda.2020.09.014

<sup>38</sup> Petrilli, "Factors associated hospital admission," 1966.

- **Cardiovascular Disease** <sup>39, 40, 41, 42, 43, 44, 45, 46, 47</sup>
  - 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.<sup>48</sup>
- **Diabetes** <sup>49, 50, 51, 52, 53</sup>
- **Chronic lung disease** <sup>54, 55, 56, 57</sup>
- **Obesity** <sup>58, 59, 60</sup>
- **Cancer** <sup>61, 62, 63, 64, 65</sup>
- **Chronic kidney disease** <sup>66, 67, 68</sup>

---

<sup>39</sup> Zhou, "Clinical course and risk factors," 1054-1062.

<sup>40</sup> Maurizio Cecconi et al, "Early Predictors of Clinical Deterioration in a Cohort of 239 Patients Hospitalized for Covid-19 Infection in Lombardy, Italy," *J Clin Med* 9, no. 5 (May 2020):1548. doi:10.3390/jcm9051548

<sup>41</sup> Petrilli, "Factors associated hospital admission," 1966.

<sup>42</sup> Zhe Zhu et al, "Clinical value of immune-inflammatory parameters to assess the severity of coronavirus disease 2019," *Int J Infect Dis* 95, (June 2020):332-339. doi:10.1016/j.ijid.2020.04.041

<sup>43</sup> Chen, "Clinical characteristics deceased patients," 1091.

<sup>44</sup> Tomasz Guzik et al, "COVID-19 and the cardiovascular system: implications for risk assessment, diagnosis, and treatment options," *Cardiovasc Res* 116, no.10 (August 2020):1666-1687. doi:10.1093/cvr/cvaa106

<sup>45</sup> Mohammad Parohan et al, "Risk factors for mortality in patients with Coronavirus disease 2019 (COVID-19) infection: a systematic review and meta-analysis of observational studies," *Aging Male* 23, no. 5 (December 2020):1416-1424. doi:10.1080/13685538.2020.1774748

<sup>46</sup> Williamson, "Factors associated with COVID-19," 430-436.

<sup>47</sup> 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

<sup>48</sup> "COVID-19 Clinical Guidance For the Cardiovascular Care Team," American College of Cardiology, March 2020. <https://www.acc.org/~/media/Non-Clinical/Files-PDFs-Excel-MS-Word-etc/2020/02/S20028-ACC-Clinical-Bulletin-Coronavirus.pdf>. Accessed December 2022.

<sup>49</sup> Weina Guo et al, "Diabetes is a risk factor for the progression and prognosis of COVID-19," *Diabetes Metab Res Rev* 36, no.7 (March 2020):e3319. doi:10.1002/dmrr.3319

<sup>50</sup> Williamson, "Factors associated with COVID-19," 430-436.

<sup>51</sup> Guzik, "COVID-19 and cardiovascular system," 1666-1687.

<sup>52</sup> Parohan, "Risk factors for mortality," 1416-1424.

<sup>53</sup> Petrilli, "Factors associated hospital admission," 1966.

<sup>54</sup> Williamson, "Factors associated with COVID-19," 430-436.

<sup>55</sup> Guzik, "COVID-19 and cardiovascular system," 1666-1687.

<sup>56</sup> Parohan, "Risk factors for mortality," 1416-1424.

<sup>57</sup> Joy, "Excess mortality first COVID," e890-e898.

<sup>58</sup> Williamson, "Factors associated with COVID-19," 430-436.

<sup>59</sup> Bellan, "Fatality rate predictors mortality," 20731.

<sup>60</sup> Petrilli, "Factors associated hospital admission," 1966.

<sup>61</sup> Williamson, "Factors associated with COVID-19," 430-436.

<sup>62</sup> Guzik, "COVID-19 and cardiovascular system," 1666-1687.

<sup>63</sup> Parohan, "Risk factors for mortality," 1416-1424.

<sup>64</sup> Bellan, "Fatality rate predictors mortality," 20731.

<sup>65</sup> Fan Yang et al, "Clinical characteristics and outcomes of cancer patients with COVID-19," *J Med Virol* 92, no. 19 (October 2020):2067-2073. doi:10.1002/jmv.25972

<sup>66</sup> Williamson, "Factors associated with COVID-19," 430-436.

<sup>67</sup> Joy, "Excess mortality in COVID-19," 890-898.

<sup>68</sup> Petrilli, "Factors associated hospital admission," 1966.

- Liver Disease <sup>69</sup>
- Neurological diseases such as stroke or dementia <sup>70, 71</sup>
- Immunosuppression <sup>72</sup>
- Learning disability <sup>73</sup>
- Socioeconomic factors, such as residence in a low-income area or communal living <sup>74, 75, 76</sup>

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 <sup>77, 78, 79, 80, 81, 82</sup>

B. Male Gender <sup>83</sup>

C. Comorbid conditions:

---

<sup>69</sup> Williamson,, "Factors associated with COVID-19," 430-436.

<sup>70</sup> Ibid

<sup>71</sup> Bielza, "Clinical Characteristics, Frailty, Mortality," 245-252.

<sup>72</sup> Williamson,, "Factors associated with COVID-19," 430-436.

<sup>73</sup> Joy, "Excess mortality in COVID-19," 890-898

<sup>74</sup> Bielza, "Clinical Characteristics, Frailty, Mortality," 245-252.

<sup>75</sup> Chiara Di Girolamo et al, "Socioeconomic inequalities in overall and COVID-19 mortality during the first outbreak peak in Emilia-Romagna Region (Northern Italy)," *Epidemiol Prev* 44, no.5-6 (September 2020):288-296. doi:10.19191/EP20.5-6.S2.129

<sup>76</sup> Joy, "Excess mortality in COVID-19," 890-898

<sup>77</sup> Roohallah Alizadehsani et al, "Risk factors prediction, clinical outcomes, and mortality in COVID-19 patients," *J Med Virol* 93, no.4 (April 2021):2307-2320 doi:10.1002/jmv.26699

<sup>78</sup> Abdulrahman Alharthy et al, "Clinical Characteristics and Predictors of 28-Day Mortality in 352 Critically Ill Patients with COVID-19: A Retrospective Study," *J Epidemiol Glob Health* 11, no.1 (March 2021):98-104. doi:10.2991/jegh.k.200928.001

<sup>79</sup> Gokhan Aksel et al, "Early predictors of mortality for moderate to severely ill patients with Covid-19," *Am J Emerg Med* 45, (July 2021):290-296. doi:10.1016/j.ajem.2020.08.076

<sup>80</sup> Mustapha Mohammed et al, "Risk Factors Associated with Mortality Among Patients with Novel Coronavirus Disease (COVID-19) in Africa," *J Racial Ethn Health Disparities* 8, no. 5 (2021):1267-1272. doi:10.1007/s40615-020-00888-3

<sup>81</sup> Krishnan Bhaskaran et al, "Factors associated with deaths due to COVID-19 versus other causes: population-based cohort analysis of UK primary care data and linked national death registrations within the OpenSAFELY platform," *Lancet Reg Health Eur* 6, (July 2021):100109. doi:10.1016/j.lanep.2021.100109

<sup>82</sup> Linda Ahrenfeldt et al, "Sex and age differences in COVID-19 mortality in Europe," *Wien Klin Wochenschr* 133, no 7-8 (April 2021):393-398. doi:10.1007/s00508-020-01793-9

<sup>83</sup> Bielza, "Clinical Characteristics, Frailty, Mortality," 245-252.

- Cardiovascular Disease<sup>84, 85, 86</sup>
- Diabetes<sup>87, 88</sup>
- Chronic Lung Disease<sup>89, 90</sup>
- Obesity<sup>91</sup>
- Cancer<sup>92, 93, 94</sup>
- Chronic renal failure<sup>95</sup>

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.<sup>96</sup>

---

<sup>84</sup> Mariam Ayed et al, "Assessment of Clinical Characteristics and Mortality-Associated Factors in COVID-19 Critical Cases in Kuwait," *Med Princ Pract* 30, no.2 (2021):185-192. doi:10.1159/000513047

<sup>85</sup> Roohallah Alizadehsani, "Risk factors prediction, mortality," 2307-2320.

<sup>86</sup> Aksel, "Early predictors of mortality," 290-296.

<sup>87</sup> John Dennis et al, "Type 2 Diabetes and COVID-19-Related Mortality in the Critical Care Setting: A National Cohort Study in England, March-July 2020," *Diabetes Care* 44, no.1 (January 2021):50-57. doi:10.2337/dc20-1444

<sup>88</sup> Elinor Tan et al, "Global Impact of Coronavirus Disease 2019 Infection Requiring Admission to the ICU: A Systematic Review and Meta-analysis," *Chest* 159, no.2 (February 2021):524-536. doi:10.1016/j.chest.2020.10.014

<sup>89</sup> Alharthy, "Clinical Characteristics Predictors Mortality," 98-104.

<sup>90</sup> Aksel, "Early predictors mortality," 290-296.

<sup>91</sup> Bhaskaran, "Factors associated with deaths," 100109.

<sup>92</sup> Alizadehsani, "Risk factors prediction, mortality," 2307-2320.

<sup>93</sup> Michael Lunski et al, "Multivariate mortality analyses in COVID-19: Comparing patients with cancer and patients without cancer in Louisiana," *Cancer* 127, no. 2 (January 2021):266-274. doi:10.1002/cncr.33243

<sup>94</sup> Aksel, "Early predictors of mortality," 290-296.

<sup>95</sup> Ibid

<sup>96</sup> "Distribution of total COVID-19 deaths in the United States as of December 21, 2022, by age group," Statista, December 2022. <https://www.statista.com/statistics/1254488/us-share-of-total-covid-deaths-by-age-group/>. Accessed December 2022.

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.<sup>97, 98, 99, 100, 101, 102, 103</sup>
36. It is important to note that Bulgaria has a large share of people aged 65 years and above (nearly 21% of the population).<sup>104</sup>
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.<sup>105</sup> More specific and scientific nomenclature systems, such as the Pango, GISAID, and Nextstrain, are typically used by researchers,

<sup>97</sup> Omid Dadras et al, "COVID-19 mortality and its predictors in the elderly: A systematic review," *Health Sci Rep* 5, no. 3 (May 2022):e657. doi:10.1002/hsr2.657

<sup>98</sup> Katarzyna Wilk-Sledziewska et al, "The Impact of Cardiovascular Risk Factors on the Course of COVID-19," *J Clin Med* 11, no.8 (April 2022):2250. doi:10.3390/jcm11082250

<sup>99</sup> Constantine Vardavas et al, "Prognostic factors for mortality, intensive care unit and hospital admission due to SARS-CoV-2: a systematic review and meta-analysis of cohort studies in Europe," *Eur Respir Rev* 31, no.166 (November 2022):220098. doi:10.1183/16000617.0098-2022

<sup>100</sup> Garyfallia Pepera et al, "Epidemiology, risk factors and prognosis of cardiovascular disease in the Coronavirus Disease 2019 (COVID-19) pandemic era: a systematic review," *Rev Cardiovasc Med* 23, no.1 (January 2022):28. doi:10.31083/j.rcm2301028

<sup>101</sup> Sina Tazerji et al, "Global data analysis and risk factors associated with morbidity and mortality of COVID-19," *Gene Rep* 26 (January 2022):101505. doi:10.1016/j.genrep.2022.101505

<sup>102</sup> Catalina Torres et al, "Identifying age- and sex-specific COVID-19 mortality trends over time in six countries," *Int J Infect Dis* 128 (December 2022):32-40. doi:10.1016/j.ijid.2022.12.004

<sup>103</sup> Jin-Jin Zhang et al, "Risk and Protective Factors for COVID-19 Morbidity, Severity, and Mortality," *Clin Rev Allergy Immunol* 19 (January 2022):1-18. doi:10.1007/s12016-022-08921-5

<sup>104</sup> "Data explorer," Our World in Data, metric: sorted by share aged 65+, January 2023.

[https://ourworldindata.org/explorers/coronavirus-data-explorer?facet=none&pickerSort=desc&pickerMetric=aged\\_70\\_older&Metric=Confirmed+deaths&Interval=7-day+rolling+average&Relative+to+Population=true&Color+by+test+positivity=false&country=~OWID\\_WRL](https://ourworldindata.org/explorers/coronavirus-data-explorer?facet=none&pickerSort=desc&pickerMetric=aged_70_older&Metric=Confirmed+deaths&Interval=7-day+rolling+average&Relative+to+Population=true&Color+by+test+positivity=false&country=~OWID_WRL)

<sup>105</sup> "Tracking SARS-CoV-2 variants," World Health Organization, last updated January 23, 2023.

<https://www.who.int/activities/tracking-SARS-CoV-2-variants/>. Accessed January 30, 2023.



public health agencies and in academia.<sup>106, 107</sup> 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.<sup>108</sup> 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).<sup>109,110</sup>
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).<sup>111</sup>
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.<sup>112</sup> 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

---

<sup>106</sup> "Nexstrain", Nexstrain, no date, <https://nextstrain.org/>. Accessed January 30, 2023

<sup>107</sup> "Pango Lineages: Latest epidemiological lineages of SARS-CoV-2," Cov-lineages, no date. <https://cov-lineages.org/>. Accessed January 30, 2023

<sup>108</sup> "SARS-CoV-2 Variant Classifications and Definitions," Centers for Disease Control and Prevention, April 26, 2022. <https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-classifications.html>. Accessed February 5, 2023.

<sup>109</sup> Weekly epidemiological update on COVID-19 – 1 February 2023," World Health Organization, February 1, 2023. <https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---1-february-2023>. Accessed February 1, 2023.

<sup>110</sup> World Health Organization, "Tracking SARS-CoV-2 variants"

<sup>111</sup> Ibid

<sup>112</sup> Ibid

than the original SARS-CoV-2 strain due to mutations in the spike protein, as well as causing more severe disease and death.<sup>113, 114</sup>

43. The Alpha variant accounted for the majority of sequences in Bulgaria between January 2021 and July 2021.<sup>115, 116</sup>
44. In May 2021, the WHO labeled the Delta variant (B.1.617.2) a VOC.<sup>117</sup> Delta quickly spread worldwide and remained globally dominant between approximately July 2021 through December 2021.<sup>118, 119</sup> It was estimated to be 80-90% more transmissible than the Alpha variant, and more severe, especially for unvaccinated people.<sup>120</sup>
45. The Delta variant was dominant in Bulgaria between approximately July 2021 and January 2022.<sup>121, 122</sup>
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.<sup>123</sup> Within a few months Omicron spread worldwide. By the first week of January 2022, Omicron already accounted for 58% of reported sequences globally.<sup>124</sup> By January 25<sup>th</sup>, Omicron accounted

---

<sup>113</sup> Kathy Katella and Nathan Grubaugh, "Omicron, Delta, Alpha, and More: What To Know About the Coronavirus Variants," Yale Medicine, updated January 6, 2023. <https://www.yalemedicine.org/news/covid-19-variants-of-concern-omicron>. Accessed January 30, 2023.

<sup>114</sup> Marharyta Sobczak and Rafal Pawliczak, "COVID-19 mortality rate determinants in selected Eastern European countries," *BMC Public Health* 22, no.1 (November 2022):2088. doi: 10.1186/s12889-022-14567-x

<sup>115</sup> Our World in Data, "Sequences by Variant"

<sup>116</sup> "Overview of Variants/Mutations," CoVariants, last updated January 2023. <https://covariants.org/per-variant?country=Bulgaria>. Accessed January 30, 2023

<sup>117</sup> World Health Organization, "Tracking SARS-CoV-2 variants"

<sup>118</sup> Our World in Data, "Sequences by Variant"

<sup>119</sup> World Health Organization, "Weekly epidemiological update on COVID-19, 14 December 2021." <https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---14-december-2021>.

<sup>120</sup> Katella and Grubaugh, "Coronavirus Variants".

<sup>121</sup> CoVariants, "Overview Variants/Mutations"

<sup>122</sup> Our World in Data, "Sequences by Variant"

<sup>123</sup> World Health Organization, "Tracking SARS-CoV-2 variants"

<sup>124</sup> Weekly epidemiological update on COVID-19 – 11 January 2022," World Health Organization, January 11, 2022. <https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---11-january-2022>

for over 98% of reported sequences globally.<sup>125</sup> 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.<sup>126, 127</sup> The Omicron variant has been characterized by multiple subvariants/sublineages with new genetic mutations.<sup>128, 129</sup>

48. The Omicron variant became dominant in Bulgaria in January 2022.

## **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

---

<sup>125</sup> Weekly epidemiological update on COVID-19 – 25 January 2022,” World Health Organization, January 25, 2022. <https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---25-january-2022>

<sup>126</sup> Ibid

<sup>127</sup> Manish Dhawan et al, “Omicron variant (B.1.1.529) and its sublineages: What do we know so far amid the emergence of recombinant variants of SARS-CoV-2?” *Biomed Pharmacother* 154 (October 2022):113522. doi: 10.1016/j.biopha.2022.113522

<sup>128</sup> Jacqueline Houtman et al, “Variants, Sublineages, and Recombinants,” The Rockefeller Foundation, March 25, 2022.

<https://www.rockefellerfoundation.org/case-study/variants-sublineages-and-recombinants-the-constantly-changing-genome-of-sar-s-cov-2/>. Accessed January 30, 2023.

<sup>129</sup> World Health Organization, "Tracking SARS-CoV-2 variants"

higher burden of death compared to the original "wild-type" virus<sup>130, 131, 132, 133, 134, 135, 136, 137, 138, 139</sup>

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.<sup>140</sup>
- 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.<sup>141</sup>

<sup>130</sup> Martina Patone et al, "Mortality and critical care unit admission associated with the SARS-CoV-2 lineage B.1.1.7 in England: an observational cohort study," *Lancet* 21, no. 11 (November 2021): 1518-1528. [https://doi.org/10.1016/S1473-3099\(21\)00318-2](https://doi.org/10.1016/S1473-3099(21)00318-2)

<sup>131</sup> Peter Bager et al, "Risk of hospitalisation associated with infection with SARS-CoV-2 lineage B.1.1.7 in Denmark: an observational cohort study," *Lancet* 21, no.11 (November 2021):1507-1517. [https://doi.org/10.1016/S1473-3099\(21\)00290-5](https://doi.org/10.1016/S1473-3099(21)00290-5)

<sup>132</sup> Lixin Lin et al, "The Disease Severity and Clinical Outcomes of the SARS-CoV-2 Variants of Concern," *Front Public Health* 30, no.9 (November 2021).doi: 10.3389/fpubh.2021.775224

<sup>133</sup> Linda Geddes, "From Alpha to Omicron: Everything you need to know about SARS-CoV-2 variants of concern," GAVI, December 6, 2021.

<https://www.gavi.org/vaccineswork/alpha-omicron-everything-you-need-know-about-coronavirus-variants-concern>

<sup>134</sup> David Pascall et al, "The SARS-CoV-2 Alpha variant is associated with increased clinical severity of COVID-19 in Scotland: a genomics-based retrospective cohort analysis," *medRxiv preprint* (August 2022). <https://doi.org/10.1101/2021.08.17.21260128>

<sup>135</sup> Nicholas Davies et al, "Estimated transmissibility and impact of SARS-CoV-2 lineage B.1.1.7 in England," *Science* 372, no.6538 (March 2021). doi:10.1126/science.abg3

<sup>136</sup> Thomas Michaelsen et al, "Introduction and transmission of SARS-CoV-2 lineage B.1.1.7, Alpha variant, in Denmark," *Genome Med* 14, no.1 (May 2022):47. doi: 10.1186/s13073-022-01045-7

<sup>137</sup> Raju Mukherjee and Rohit Satardekar, "Why are some coronavirus variants more infectious?," *J Biosci* 46, no.4 (2021). doi: 10.1007/s12038-021-00221-y

<sup>138</sup> Matteo Vassallo et al, "Patients Admitted for Variant Alpha COVID-19 Have Poorer Outcomes than Those Infected with the Old Strain," *J Clin Med* 10, no.16 (August 2021):3550. doi: 10.3390/jcm10163550

<sup>139</sup> Daniel Grint et al, "Severity of Severe Acute Respiratory System Coronavirus 2 (SARS-CoV-2) Alpha Variant (B.1.1.7) in England," *Clin Infect Dis* 75, no. 1 (August 2022):e1120-e1127. doi: 10.1093/cid/ciab754

<sup>140</sup> Victoria Jane Hall et al, "COVID-19 vaccine coverage in health-care workers in England and effectiveness of BNT162b2 mRNA vaccine against infection (SIREN): a prospective, multicentre, cohort study," *Lancet* 397, no. 10286 (May 2021): 1725-1735. [https://doi.org/10.1016/S0140-6736\(21\)00790-X](https://doi.org/10.1016/S0140-6736(21)00790-X)

<sup>141</sup> Emma Pritchard et al, "Impact of vaccination on new SARS-CoV-2 infections in the United Kingdom," *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.<sup>142</sup>
- 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.<sup>143</sup>

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."<sup>144</sup>

145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155

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

<sup>142</sup> 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

<sup>143</sup> Mark W Tenforde et al, "Sustained Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Associated Hospitalizations Among Adults - United States, March-July 2021," *MMWR Morb Mortal Wkly Rep* 70, no. 34 (August 2021):1156-1162. doi: 10.15585/mmwr.mm7034e2

<sup>144</sup> 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>

<sup>145</sup> Frank Esper et al, "Alpha to Omicron: Disease Severity and Clinical Outcomes of Major SARS-CoV-2 Variants," *J Infect Dis*, (October 2022). doi: 10.1093/infdis/jiac411

<sup>146</sup> Lin, "Disease Severity Clinical Outcomes"

<sup>147</sup> Geddes, "Alpha to Omicron variants"

<sup>148</sup> Adeel Butt et al, "Severity of Illness in Persons Infected With the SARS-CoV-2 Delta Variant vs Beta Variant in Qatar," *JAMA* 182, no.2 (December 2021):197-205. doi:10.1001/jamainternmed.2021.7949

<sup>149</sup> Rebecca Earnest et al, "Comparative transmissibility of SARS-CoV-2 variants Delta and Alpha in New England, USA," *medRxiv preprint* (October 2021). doi: 10.1101/2021.10.06.21264641

<sup>150</sup> Camino Trobajo-Sanmartin 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). doi: 10.1128/spectrum.00008-22

<sup>151</sup> William Hart et al, "Generation time of the alpha and delta SARS-CoV-2 variants: an epidemiological analysis," *Lancet Infect Dis* 22, no.5 (May 2022):603-610. doi: 10.1016/S1473-3099(22)00001-9

<sup>152</sup> Kerstin Klaser 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* 12, no.1 (June 2022):10904. doi: 10.1038/s41598-022-14016-0

<sup>153</sup> "Delta Variant Is 60 Percent More Contagious Than Original Virus and Evades Immunity" Columbia Mailman School of Public Health, August 17,

2021. <https://www.publichealth.columbia.edu/public-health-now/news/delta-variant-60-percent-more-contagious-original-virus-and-evades-immunity>. Accessed December 2022

<sup>154</sup> Mukherjee and Satardekar, "Why are variants"

<sup>155</sup> Sobczak and Pawliczak, "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.<sup>156</sup>
- 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.<sup>157</sup>
- 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.<sup>158</sup>
- 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.<sup>159</sup>
- 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.<sup>160</sup>

---

<sup>156</sup> Karan Pattni 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

<sup>157</sup> Pouwels, "Effect Delta variant"

<sup>158</sup> Butt, "Severity Illness Delta Variant,"

<sup>159</sup> David Eyre et al, "Effect of Covid-19 Vaccination on Transmission of Alpha and Delta Variants," *N Engl J Med* 386, no. 8 (February 2022):744-756. doi: 10.1056/NEJMoa2116597

<sup>160</sup> Juan Corchado-Garcia et al, "Analysis of the Effectiveness of the Ad26.COV2.S Adenoviral Vector Vaccine for Preventing COVID-19," *JAMA Netw Open* 4, no.11 (November 2021):e2132540. doi: 10.1001/jamanetworkopen.2021.32540

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.<sup>161, 162</sup> 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.<sup>163, 164, 165, 166, 167, 168, 169, 170, 171, 172</sup>
- 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

<sup>161</sup> Zhou Zhou, Yimiao Zhu and Ming Chu, "Role of COVID-19 Vaccines in SARS-CoV-2 Variants," *Front Immunol* 13. (May 2022). doi: 10.3389/fimmu.2022.898192

<sup>162</sup> Mohammad Shah Alam, "Insight into SARS-CoV-2 Omicron variant immune escape possibility and variant independent potential therapeutic opportunities," *Heliyon* 9, no.2 (2023):e13285. doi: 10.1016/j.heliyon.2023.e13285

<sup>163</sup> Alexander Muik et al, "Neutralization of SARS-CoV-2 Omicron by BNT162b2 mRNA vaccine-elicited human sera," *Science* 375, no.6581 (February 2022):678-680. doi: 10.1126/science.abn7591

<sup>164</sup> 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

<sup>165</sup> Emma Accorsi et al, "Association Between 3 Doses of mRNA COVID-19 Vaccine and Symptomatic Infection Caused by the SARS-CoV-2 Omicron and Delta Variants," *JAMA* 327, no.7 (February 2022): 639-651. doi: 10.1001/jama.2022.0470

<sup>166</sup> Venkata-Viswanadh Edara et al, "mRNA-1273 and BNT162b2 mRNA vaccines have reduced neutralizing activity against the SARS-CoV-2 omicron variant," *Cell Rep Med* 3, no.2 (January 2022): 100529. doi: 10.1016/j.xcrm.2022.100529

<sup>167</sup> Jihye Um et al, "Booster BNT162b2 COVID-19 Vaccination Increases Neutralizing Antibody Titers Against the SARS-CoV-2 Omicron Variant in Both Young and Elderly Adults," *J Korean Med Sci* 37, no.9 (March 2022) :e70. doi: 10.3346/jkms.2022.37.e70

<sup>168</sup> Yuntao Zou et al, "The Vaccine Efficacy Against the SARS-CoV-2 Omicron: A Systemic Review and Meta-Analysis," *Front Public Health* 10 (July 2022). doi: 10.3389/fpubh.2022.940956

<sup>169</sup> Daniele Focosi and Fabrizio Maggi, "Do We Really Need Omicron Spike-Based Updated COVID-19 Vaccines? Evidence and Pipeline," *Viruses* 11, no.11 (November 2022): 2488. doi: 10.3390/v14112488

<sup>170</sup> Tommy Nyberg et al, "Comparative analysis of the risks of hospitalisation and death associated with SARS-CoV-2 omicron (B.1.1.529) and delta (B.1.617.2) variants in England: a cohort study," *Lancet* 399, no.10332 (April 2022): 1303-1312. doi: 10.1016/S0140-6736(22)00462-7

<sup>171</sup> Chih-Hsien Chuang et al, "Titers and breadth of neutralizing antibodies against SARS-CoV-2 variants after heterologous booster vaccination in health care workers primed with two doses of ChAdOx1 nCov-19: A single-blinded, randomized clinical trial," *J Clin Virol* 157 (December 2022):105328. doi: 10.1016/j.jcv.2022.105328

<sup>172</sup> Kirsten Lyke et al, "Rapid decline in vaccine-boosted neutralizing antibodies against SARS-CoV-2 Omicron variant," *Cell Rep Med* 3, no.7 (July 2022):100679. doi: 10.1016/j.xcrm.2022.100679

against COVID-19-associated hospitalizations was 81%, 57%, and 90% after one, two, and three doses respectively.<sup>173</sup>

- 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.<sup>174</sup> 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%.<sup>175</sup> 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

---

<sup>173</sup> Mark Thompson et al, "Effectiveness of a Third Dose of mRNA Vaccines Against COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance - VISION Network, 10 States, August 2021-January 2022," *MMWR Morb Mortal Wkly Rep* 71, no.4 (January 2022):139-145. doi: 10.15585/mmwr.mm7104e3.

<sup>174</sup> Alam, "Insight into SARS-CoV-2"

<sup>175</sup> Rontgene Solante et al, "Expert review of global real-world data on COVID-19 vaccine booster effectiveness and safety during the omicron-dominant phase of the pandemic," *Expert Rev Vaccines* 22, no.1 (January 2023):1-16. doi: 10.1080/14760584.2023.2143347



evolve.<sup>176, 177, 178, 179, 180, 181, 182, 183</sup> Slowing the spread of SARS-CoV-2 is the best way to slow the rise of new variants; increased replication and transmission fosters viral mutation.<sup>184, 185,</sup>  
186

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/Comirnaty or Moderna/Spikevax had a 94% reduced risk of COVID-19 related hospitalization.<sup>187</sup> 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.<sup>188</sup> Subsequently, booster doses have become especially important for elderly people because additional doses have shown to boost antibody response and increase protection from the virus.<sup>189</sup> Given that age is known

<sup>176</sup> "Without Global Vaccinations, Further Variants Ahead," HUB Johns Hopkins University, December 21, 2021. <https://hub.jhu.edu/2021/12/21/global-vaccination-prevents-variants-durbin-moss/>. Accessed February 5, 2023.

<sup>177</sup> Michael Head, "Omicron Is Here: A Lack of COVID Vaccines Is Partly Why," *Scientific American*, November 30, 2021. <https://www.scientificamerican.com/article/omicron-is-here-a-lack-of-covid-vaccines-is-partly-why1/>. Accessed February 5, 2023.

<sup>178</sup> "What's Ahead? Viral Mutations and Global Vaccinations," Johns Hopkins Bloomberg School of Public Health, December 17, 2021. <https://publichealth.jhu.edu/2021/whats-ahead-viral-mutations-and-global-vaccinations>. Accessed February 5, 2023.

<sup>179</sup> Richard Oehler and Vivian Vega, "Worldwide vaccine inequality threatens to unleash the next COVID-19 variant," *Int J Infect Dis* 123 (October 2022):133-135. doi: 10.1016/j.ijid.2022.08.010

<sup>180</sup> "Vaccine Equity," World Health Organization, no date. <https://www.who.int/campaigns/vaccine-equity>. Accessed January 5, 2023

<sup>181</sup> Nicoletta Lanese, "Omicron's not the last variant we'll see. Will the next one be bad?" *LiveScience*, January 12, 2022. <https://www.livescience.com/coronavirus-variants-after-omicron-2022>. Accessed January 5, 2023.

<sup>182</sup> "How to Keep New Variants From Emerging, and Ending the Pandemic," Cedars Sinai Newsroom, March 16, 2022. <https://www.cedars-sinai.org/newsroom/how-to-keep-new-variants-from-emerging-and-ending-the-pandemic/#:~:text=Vail%3A%20The%20number%20one%20thing,And%20that's%20with%20vaccinations>. Accessed January 5, 2023

<sup>183</sup> Joia Mukherjee, Haniya Abbasi and Michelle Morse, "Global Vaccine Inequity Led To The COVID-19 Omicron Variant: It's Time For Collective Action," *Health Affairs Forefront*, January 2022. <https://www.healthaffairs.org/doi/10.1377/forefront.20220124.776516/>. Accessed January 30, 2023

<sup>184</sup> "The effects of virus variants on COVID-19 vaccines," World Health Organization, March 1, 2021. <https://www.who.int/news-room/feature-stories/detail/the-effects-of-virus-variants-on-covid-19-vaccines>

<sup>185</sup> David Hunter et al, "Addressing Vaccine Inequity — Covid-19 Vaccines as a Global Public Good," *N Engl J Med* 386 (March 2022):1176-1179. doi: 10.1056/NEJMe2202547

<sup>186</sup> 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>

<sup>187</sup> Centers for Disease Control and Prevention, "COVID-19 Risks and Vaccine Information for Older Adults," Centers for Disease Control and Prevention, 2021. <https://www.cdc.gov/aging/covid19-guidance.html>. Accessed December 2022

<sup>188</sup> Juliet Bartleson et al, "SARS-CoV-2, COVID-19 and the Ageing Immune System," *Nat Aging* 1, no.9 (September 2021):769-782. doi:10.1038/s43587-021-00114-7

<sup>189</sup> Sara Hagg and Dorota Religa, "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.<sup>190, 191, 192, 193, 194, 195,</sup>

196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208

<sup>190</sup> Fernando Polack et al, "Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine," *N Engl J Med* 383, no.27 (December 2020):2603-2615. doi:10.1056/NEJMoa2034577

<sup>191</sup> Mark Mulligan et al, "Phase I/II study of COVID-19 RNA vaccine BNT162b1 in adults," *Nature* 586, no.7844 (October 2020):589-593.doi:10.1038/s41586-020-2639-4

<sup>192</sup> Lindsey Baden et al, "Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine," *N Engl J Med* 384, no. 5 (December 2020): 403-416. <https://doi.org/10.1056/NEJMoa2035389>

<sup>193</sup> Laurence Chu et al, "A preliminary report of a randomized controlled phase 2 trial of the safety and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine," *Vaccine* 39, no.20 (May 2021):2791-2799.doi:10.1016/j.vaccine.2021.02.007

<sup>194</sup> Pedro M Folegatti et al, "Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial," *Lancet* 396, no.10249 (August 2020):467-478. doi:10.1016/S0140-6736(20)31604-4

<sup>195</sup> Merryn Voysey et al, "Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK," *Lancet* 397, no.10269 (2021):99-111. doi:10.1016/S0140-6736(20)32661-1

<sup>196</sup> Jerald Sadoff et al, "Interim Results of a Phase 1-2a Trial of Ad26.COV2.S Covid-19 Vaccine," *N Engl J Med* 384, no.19 (May 2021):1824-1835. doi:10.1056/NEJMoa2034201

<sup>197</sup> Jerald Sadoff et al, "Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19," *N Engl J Med* 384, no.23 (April 2021):2187-2201. doi:10.1056/NEJMoa2101544

<sup>198</sup> Fulvia Pimpinelli et al, "Fifth-week immunogenicity and safety of anti-SARS-CoV-2 BNT162b2 vaccine in patients with multiple myeloma and myeloproliferative malignancies on active treatment: preliminary data from a single institution," *J Hematol Oncol* 14, no.1 (May 2021): 81. doi:10.1186/s13045-021-01090-6

<sup>199</sup> Katherine R W Emary et al, "Efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine against SARS-CoV-2 variant of concern 202012/01 (B.1.1.7): an exploratory analysis of a randomised controlled trial," *Lancet* 397, no.10282 (April 2021):1351-1362. doi:10.1016/S0140-6736(21)00628-0

<sup>200</sup> Kathryn E Stephenson et al, "Immunogenicity of the Ad26.COV2.S Vaccine for COVID-19," *JAMA* 325, no.15 (April 2021):1535-1544. doi: 10.1001/jama.2021.3645

<sup>201</sup> Renuka Kadali et al, "Side effects of BNT162b2 mRNA COVID-19 vaccine: A randomized, cross-sectional study with detailed self-reported symptoms from healthcare workers," *Int J Infect Dis* 106 (May 2021):376-381. <https://doi.org/10.1016/j.ijid.2021.04.047>

<sup>202</sup> Lisa Jackson et al, "An mRNA Vaccine against SARS-CoV-2 - Preliminary Report," *N Engl J Med* 383, no. 20 (November 2020):1920-1931. doi: 10.1056/NEJMoa2022483

<sup>203</sup> Ugur Sahin et al, "COVID-19 vaccine BNT162b1 elicits human antibody and TH1 T cell responses," *Nature* 586, no. 7830 (October 2020): 594-599. doi: 10.1038/s41586-020-2814-7

<sup>204</sup> Edward Walsh et al, "Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates," *N Engl J Med* 383, no. 25 (December 2020): 2439-2450. <https://doi.org/10.1056/NEJMoa2027906>

<sup>205</sup> Federico Gobbi et al, "Antibody Response to the BNT162b2 mRNA COVID-19 Vaccine in Subjects with Prior SARS-CoV-2 Infection," *Viruses* 13, no. 3 (March 2021):422. doi: 10.3390/v13030422

<sup>206</sup> Evan Anderson et al, "Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults," *N Engl J Med* 383, no.25 (December 2020):2427-2438. doi: 10.1056/NEJMoa2028436

<sup>207</sup> 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

<sup>208</sup> 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.<sup>209</sup>
  - 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.<sup>210</sup>
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.<sup>211</sup>

---

<sup>209</sup> European Medicines Agency, “Cormirnaty: EPAR-Product Information,” European Medicines Agency, January 01, 2021, <https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty>

<sup>210</sup> Polack, "Safety and Efficacy BNT162b2"

<sup>211</sup> Jamie Lopez Bernal et al, "Effectiveness of the Pfizer-BioNTech and Oxford-AstraZeneca vaccines on covid-19 related symptoms, hospital admissions, and mortality in older adults in England: test negative case-control study," *BMJ* 373 (2021):n1088. doi:10.1136/bmj.n1088

- b) People aged over 80 years had an 80% lower risk of hospitalization for COVID-19 than those who were not vaccinated.<sup>212</sup>
- 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  $\geq 80$  years old, and 96% against COVID-related mortality.<sup>213</sup>

### 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.<sup>214</sup>
- 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.<sup>215</sup>
- 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

<sup>212</sup> "COVID-19 vaccines - safety and effectiveness in older adults," Australian Government Department of Health and Aged Care, March 10, 2021, <https://www.tga.gov.au/news/safety-alerts/covid-19-vaccines-safety-and-effectiveness-older-adults>. Accessed December 2022

<sup>213</sup> Nunes Baltazar et al, "mRNA vaccine effectiveness against COVID-19-related hospitalisations and deaths in older adults: a cohort study based on data linkage of national health registries in Portugal, February to August 2021," *Euro Surveill* 26, no.38 (2021). <https://doi.org/10.2807/1560-7917.ES.2021.26.38.2100833>

<sup>214</sup> 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

<sup>215</sup> Leonardo Arregocés-Castillo et al, "Effectiveness of COVID-19 vaccines in older adults in Colombia: a retrospective, population-based study of the ESPERANZA cohort," *Lancet Healthy Longev* 3, no.4 (April 2022):e242-e252. doi:10.1016/S2666-7568(22)00035-6

series was 81.2% for infection, 85.3% for COVID-related death, and 63.7% for all-cause mortality.<sup>216</sup>

d) A systematic review using data through November 2021, demonstrated that Comirnaty compared to placebo:<sup>217</sup>

- (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.

*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%.<sup>218</sup>

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.<sup>219</sup>

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

---

<sup>216</sup> 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

<sup>217</sup> Carolina Graña et al, "Efficacy and safety of COVID-19 vaccines," *Cochrane Database Syst Rev* 12, no.12 (December 2022):CD015477.doi:10.1002/14651858.CD015477

<sup>218</sup> European Medicines Agency, "Vaxzevria: EPAR-Product Information," European Medicines Agency, February 18, 2021, <https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria/#product-information-section>

<sup>219</sup> 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.<sup>220</sup>
  - b) People aged over 80 years had an 80% lower risk of hospitalization for COVID-19 than those who were not vaccinated.<sup>221</sup>
  - c) Among people greater than 80 years of age, vaccine efficacy against symptomatic COVID-19 was 80.4% after only 1 dose.<sup>222</sup>
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.<sup>223</sup>
  - b) A systematic review using data through November 2021, demonstrated that Vaxzevria compared to placebo:<sup>224</sup>
    - (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

---

<sup>220</sup> Lopez Bernal, "Effectiveness Pfizer-and AstraZeneca," 1088.

<sup>221</sup> "COVID-19 vaccines - safety and effectiveness in older adults," Australian Government Department of Health and Aged Care, March 10, 2021, <https://www.tga.gov.au/news/safety-alerts/covid-19-vaccines-safety-and-effectiveness-older-adults>. Accessed December 2022

<sup>222</sup> Catherine Hyams et al, "Effectiveness of BNT162b2 and ChAdOx1 nCoV-19 COVID-19 vaccination at preventing hospitalisations in people aged at least 80 years: a test-negative, case-control study," *The Lancet Infect Dis* 21, no. 11 (June 2021):1539-1548. [https://doi.org/10.1016/S1473-3099\(21\)00330-3](https://doi.org/10.1016/S1473-3099(21)00330-3)

<sup>223</sup> Arregocés-Castillo, "Effectiveness vaccines older adults," 242-252.

<sup>224</sup> 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.<sup>225</sup>
  - 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.<sup>226</sup>
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.<sup>227</sup>
3. Example of what is known now:
  - a) A systematic review using data through November 2021, demonstrated that Spikevax compared to placebo:<sup>228</sup>
    - (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

---

<sup>225</sup> Baden, "Efficacy and Safety mRNA-1273"

<sup>226</sup> European Medicines Agency, "Spikevax EPAR-Product Information," European Medicines Agency, January 1, 2021, <https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax>. Accessed December 2022

<sup>227</sup> Baltazar, "mRNA vaccine effectiveness"

<sup>228</sup> 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.<sup>229</sup> 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.<sup>230</sup>
  
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.<sup>231</sup> 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:<sup>232</sup>
    - (1) reduced the incidence of symptomatic COVID-19 with a vaccine efficacy of 66.9%, with a high grade of evidence

---

<sup>229</sup> European Medicines Agency, "Jcovden: EPAR-Product Information," European Medicines Agency, March 3, 2021, <https://www.ema.europa.eu/en/medicines/human/EPAR/jcovden-previously-covid-19-vaccine-janssen>. Accessed December 2022

<sup>230</sup> Sadoff, "Safety Efficacy Single-Dose Ad26.COV2.S"

<sup>231</sup> Arregocés-Castillo, "Effectiveness vaccines older adults," 242-252.

<sup>232</sup> 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.<sup>233, 234, 235, 236, 237, 238, 239, 240, 241, 242</sup>

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.<sup>243</sup> In the United States, 75% of cumulative deaths have been in people over the age of 65.<sup>244</sup> In fact, the differing case fatality rates between countries has been linked to the proportion of elderly people:

<sup>233</sup> Clare Brown, Sean Young, and George Pro, "COVID-19 vaccination rates vary by community vulnerability: A county-level analysis," *Vaccine* 39, no.31 (July 2021):4245-4249. doi:10.1016/j.vaccine.2021.06.038

<sup>234</sup> "Vulnerability — how well a community handles the repercussions of a COVID-19 outbreak — matters," Precision For Covid, 2021, <https://precisionforcovid.org/ccvi>. Accessed December 2022

<sup>235</sup> Leonardo Bastos et al, "Primary healthcare protects vulnerable populations from inequity in COVID-19 vaccination: An ecological analysis of nationwide data from Brazil," *Lancet Reg Health Am* 14 (October 2022):100335. doi:10.1016/j.lana.2022.100335

<sup>236</sup> Ying Chen et al, "Amplified effect of social vulnerability on health inequality regarding COVID-19 mortality in the USA: the mediating role of vaccination allocation," *BMC Public Health* 22, no.1 (November 2022):2131. doi:10.1186/s12889-022-14592-w

<sup>237</sup> Diego Cuadros et al, "Association Between Vaccination Coverage Disparity and the Dynamics of the COVID-19 Delta and Omicron Waves in the US," *Front Med* 9 (June 2022):898101. doi:10.3389/fmed.2022.898101

<sup>238</sup> 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," *BMJ Glob Health* 5, no.10 (October 2020):e003595. doi:10.1136/bmjgh-2020-003595

<sup>239</sup> Mohammad Bhuiyan et al, "Using the social vulnerability index to assess COVID-19 vaccine uptake in Louisiana," *GeoJournal*, (December 2022):1-10. doi:10.1007/s10708-022-10802-5

<sup>240</sup> David Finch and Adam Tinson, "The continuing impact of COVID-19 on health and inequalities," The Health Foundation, August 24, 2022, <https://www.health.org.uk/publications/long-reads/the-continuing-impact-of-covid-19-on-health-and-inequalities>. Accessed December 2022

<sup>241</sup> Ema Nye and Martin Blanco, "Characteristics of Homebound Older Adults: Potential Barriers to Accessing the COVID-19 Vaccine Issue Brief, Office of the Assistant Secretary For Planning and Evaluation, Health and Human Services, April 5, 2021, <https://aspe.hhs.gov/reports/characteristics-homebound-older-adults-potential-barriers-accessing-covid-19-vaccine-issue-brief>. Accessed December 2022

<sup>242</sup> "Countries need support to vaccinate their highest risk groups," Global COVID-19 Access Tracker, last updated December 2023. <https://www.covid19globaltracker.org/pillar/vaccination>. Accessed December 2022

<sup>243</sup> "Statement – Older people are at highest risk from COVID-19, but all must act to prevent community spread," World Health Organization, April 3, 2020, <https://www.who.int/europe/news/item/03-04-2020-statement-older-people-are-at-highest-risk-from-covid-19-but-all-must-act-to-prevent-community-spread>. Accessed December 2022

<sup>244</sup> "Number of coronavirus disease 2019 (COVID-19) deaths in the U.S., by age," Statista, December 2022, <https://www.statista.com/statistics/1191568/reported-deaths-from-covid-by-age-us/>. Accessed December 2022

countries with more elders have higher case fatality rates because elderly people account for the majority of deaths.<sup>245</sup>

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.<sup>246</sup>
- In England, between January 2021 and October 2021, unvaccinated people compared to vaccinated people (2 doses) had a 28 times higher mortality rate.<sup>247</sup>
- Public Health England estimated that between January 2021 and September 5, 2021, COVID-19 vaccinations prevented 230,800 hospitalizations in people over age 45.<sup>248</sup>
- 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.<sup>249</sup> The number of people whose health was impacted is certainly far higher as that estimate did not

<sup>245</sup> 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

<sup>246</sup> "COVID-19 Vaccination Associated with Reductions in COVID-19 Mortality and Morbidity in the United States, and an Approach to Valuing these Benefits," Office of the Assistant Secretary For Planning and Evaluation, Health and Human Services, December 2021, <https://aspe.hhs.gov/sites/default/files/documents/cfae1f63ba6d7eeda21d3fcf2a35c6bc/aspe-ib-association-of-vaccination-select-outcomes.pdf>. Accessed December 2022.

<sup>247</sup> "Deaths involving COVID-19 by vaccination status, England: deaths occurring between 1 January and 31 October 2021," Office For National Statistics, December 20, 2021, <https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsinvolvingcovid19byvaccinationstatusengland/deathsoccurringbetween1januaryand31october2021>. Accessed December 2022.

<sup>248</sup> "COVID-19 vaccine surveillance report published," Public Health England, May 14, 2021, <https://www.gov.uk/government/news/covid-19-vaccine-surveillance-report-published#full-publication-update-history>. Accessed December 2022.

<sup>249</sup> "WHO/ECDC: Nearly half a million lives saved by COVID-19 vaccination in less than a year," European Centre For Disease Prevention and Control, November 25, 2021, <https://www.ecdc.europa.eu/en/news-events/who-ecdc-nearly-half-million-lives-saved-covid-19-vaccination>. Accessed December 2022.

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.<sup>250</sup>
- 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.<sup>251</sup>
- 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.<sup>252</sup>
- 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  $\geq 80$  years.<sup>253</sup>

---

<sup>250</sup> Margaux Mi Meslé et al, "Estimated number of deaths directly averted in people 60 years and older as a result of COVID-19 vaccination in the WHO European Region, December 2020 to November 2021," *Euro Surveill* 26, no.47 (November 2021):2101021. doi:10.2807/1560-7917.ES.2021.26.47.2101021

<sup>251</sup> Amitabh Suthar et al, "Public health impact of covid-19 vaccines in the US: observational study," *BMJ* 377 (April 2022):e069317. doi:10.1136/bmj-2021-069317

<sup>252</sup> Oliver Watson et al, "Global impact of the first year of COVID-19 vaccination: a mathematical modelling study," *Lancet Infect Dis* 22, no.9 (September 2022):1293-1302. doi:10.1016/S1473-3099(22)00320-6

<sup>253</sup> "Impact of Vaccination on Risk of COVID-19–Related Mortality," Centers for Disease Prevention and Control, November 16, 2022, <https://www.cdc.gov/coronavirus/2019-ncov/science/data-review/vaccines.html>. Accessed December 2022.

- 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.<sup>254</sup>

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.<sup>255</sup> 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.<sup>256</sup> Since this review, more reports have emerged suggesting the benefit of vaccination against Long COVID.<sup>257, 258</sup>

---

<sup>254</sup> Meagan Fitzpatrick et al, "Two Years of U.S. COVID-19 Vaccines Have Prevented Millions of Hospitalizations and Deaths," The Commonwealth Fund, December 13, 2022, <https://www.commonwealthfund.org/blog/2022/two-years-covid-vaccines-prevented-millions-deaths-hospitalizations>. Accessed December 2022.

<sup>255</sup> Sarah Wulf Hanson et al, "Estimated Global Proportions of Individuals With Persistent Fatigue, Cognitive, and Respiratory Symptom Clusters Following Symptomatic COVID-19 in 2020 and 2021," *JAMA* 328, no.16 (October 2022):1604-1615. doi:10.1001/jama.2022.18931

<sup>256</sup> Kin Notarte et al, "Impact of COVID-19 vaccination on the risk of developing long-COVID and on existing long-COVID symptoms: A systematic review," *EClinicalMedicine* 53 (August 2022):101624. doi:10.1016/j.eclinm.2022.101624

<sup>257</sup> Elena Azzolini et al, "Association Between BNT162b2 Vaccination and Long COVID After Infections Not Requiring Hospitalization in Health Care Workers," *JAMA* 328, no.7 (August 2022):676-678. doi:10.1001/jama.2022.11691

<sup>258</sup> 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.<sup>259</sup>

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.<sup>260, 261</sup>

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.<sup>262</sup> 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.<sup>263</sup>

---

<sup>259</sup> "Guidance on "Long COVID" as a Disability Under the ADA, Section 504, and Section 1557," U.S Department of Health and Human Services, July 26, 2021, [https://www.hhs.gov/civil-rights/for-providers/civil-rights-covid19/guidance-long-covid-disability/index.html#footnote10\\_0ac8mdc](https://www.hhs.gov/civil-rights/for-providers/civil-rights-covid19/guidance-long-covid-disability/index.html#footnote10_0ac8mdc). Accessed December 2022.

<sup>260</sup> "COVID-19 Vaccines," European Vaccination Information Portal, last updated November 24, 2022. <https://vaccination-info.eu/en/covid-19/covid-19-vaccines>. Accessed December 2022.

<sup>261</sup> "COVID-19 Key Facts," European Medicines Agency, no date, <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-key-facts#vaccine-safety-section>. Accessed December 2022

<sup>262</sup> Panayiotis Ziakas et al, "Comparative Analysis of Mortality From Coronavirus Disease 2019 Across the European Union Countries and the Effects of Vaccine Coverage," *Open Forum Infect Dis* 9, no.3 (February 2022):ofac006. doi:10.1093/ofid/ofac006

<sup>263</sup> *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.<sup>264</sup>

### 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.<sup>265</sup>

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

---

<sup>264</sup> Alban Ylli et al, "COVID-19 excess deaths in Eastern European countries associated with weaker regulation implementation and lower vaccination coverage," *East Mediterr Health J* 28, no.10 (October 2022):776-780. doi: 10.26719/emhj.22.074

<sup>265</sup> "Partial COVID-19 vaccination, vaccination following SARS-CoV-2 infection and heterologous vaccination schedule: summary of evidence," European Centre for Disease Prevention and Control, July 22, 2021, <https://www.ecdc.europa.eu/en/publications-data/partial-covid-19-vaccination-summary>. Accessed December 2022.

individuals with comorbid conditions, such as cardiovascular disease and diabetes.<sup>266</sup>

- In May 2020, a Global Framework for equitable allocation of COVID-19 products was presented to member states and published.<sup>267</sup> 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.<sup>268</sup> 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.<sup>269</sup> 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

---

<sup>266</sup> "Statement – Older people are at highest risk from COVID-19, but all must act to prevent community spread," World Health Organization, April 3, 2020, <https://www.who.int/europe/news/item/03-04-2020-statement-older-people-are-at-highest-risk-from-covid-19-but-all-must-act-to-prevent-community-spread>. Accessed December 2022.

<sup>267</sup> "A Global Framework To Ensure Equitable And Fair Allocation Of Covid-19 Products," World Health Organization, May 2020, [https://www.campusvirtualsp.org/sites/default/files/5oct\\_access\\_and\\_allocation\\_of\\_covid\\_products\\_for\\_hss\\_meeting.pdf](https://www.campusvirtualsp.org/sites/default/files/5oct_access_and_allocation_of_covid_products_for_hss_meeting.pdf). Accessed December 2020.

<sup>268</sup> "A Global Framework To Ensure Equitable And Fair Allocation Of Covid-19 Products," World Health Organization, June 18, 2020, [https://apps.who.int/gb/COVID-19/pdf\\_files/18\\_06/Global%20Allocation%20Framework.pdf?utm\\_source=POLITICO.EU&utm\\_campaign=18fd118248-EMAIL\\_CAMPAIGN\\_2020\\_06\\_22\\_04\\_52\\_COPY\\_01&utm\\_medium=email&utm\\_term=0\\_10959edeb5-18fd118248-189787901](https://apps.who.int/gb/COVID-19/pdf_files/18_06/Global%20Allocation%20Framework.pdf?utm_source=POLITICO.EU&utm_campaign=18fd118248-EMAIL_CAMPAIGN_2020_06_22_04_52_COPY_01&utm_medium=email&utm_term=0_10959edeb5-18fd118248-189787901). Accessed December 2022.

<sup>269</sup> "Preventing and managing COVID-19 across long-term care services: Policy brief, 24 July 2020," World Health Organization, July 24, 2020, [https://www.who.int/publications/i/item/WHO-2019-nCoV-Policy\\_Brief-Long-term\\_Care-2020.1](https://www.who.int/publications/i/item/WHO-2019-nCoV-Policy_Brief-Long-term_Care-2020.1). Accessed December 2022.

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.<sup>270</sup> 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.<sup>271</sup>
  - 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.<sup>272</sup>

<sup>270</sup>"Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility," World Health Organization, September 9, 2020, <https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility>. Accessed December 2022.

<sup>271</sup>"High-risk groups for COVID-19," European Centre for Disease Prevention and Control, no date, <https://www.ecdc.europa.eu/en/covid-19/high-risk-groups>. Accessed December 2022.

<sup>272</sup>"Key aspects regarding the introduction and prioritisation of COVID-19 vaccination in the EU/EEA and the UK," European Centre for Disease Prevention and Control, October 26, 2020, <https://www.ecdc.europa.eu/en/publications-data/key-aspects-regarding-introduction-and-prioritisation-covid-19-vaccination>. Accessed December 2022.



- 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."<sup>273</sup>
- 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..."<sup>274</sup>
- In March 2021, guidance was issued for COVID-19 vaccine challenges and good practice.<sup>275</sup>
- In April 2021, guidance for vaccination strategies was published.<sup>276</sup> 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."

---

<sup>273</sup> COVID-19 vaccination and prioritisation strategies in the EU/EEA," European Centre for Disease Prevention and Control, December 22, 2020, <https://www.ecdc.europa.eu/en/publications-data/covid-19-vaccination-and-prioritisation-strategies-eueea>. Accessed December 2022.

<sup>274</sup> "Risk Assessment: Risk related to the spread of new SARS-CoV-2 variants of concern in the EU/EEA – first update, European Centre for Disease Prevention and Control, January 21, 2021, <https://www.ecdc.europa.eu/en/publications-data/covid-19-risk-assessment-spread-new-variants-concern-eueea-first-update>. Accessed December 2022.

<sup>275</sup> "Rollout of COVID-19 vaccines in the EU/EEA: challenges and good practice," European Centre for Disease Prevention and Control, March 29, 2021, <https://www.ecdc.europa.eu/en/publications-data/rollout-covid-19-vaccines-eueea-challenge-and-good-practice>. Accessed December 2022

<sup>276</sup> "Objectives of vaccination strategies against COVID-19, European Centre for Disease Prevention and Control, April 23, 2021, <https://www.ecdc.europa.eu/en/publications-data/objectives-vaccination-strategies-against-covid-19>. Accessed December 2022.

- 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.<sup>277,278,279</sup>
  - On December 1, 2020, Phase 1a included health care personnel and long-term care facility residents.<sup>280</sup> On December 20, Phase 1b included persons aged  $\geq 75$  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.

---

<sup>277</sup> Evidence Table for COVID-19 Vaccines Allocation in Phases 1b and 1c of the Vaccination Program," Centers for Disease Control and Prevention, last reviewed December 22, 2020, <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/evidence-table-phase-1b-1c.html>.; <https://stacks.cdc.gov/view/cdc/91980>. Accessed December 2022.

<sup>278</sup> COVID-19 ACIP Vaccine Recommendations," Centers for Disease Control and Prevention, last reviewed July 28, 2022. <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>. Accessed December 2022.

<sup>279</sup> Interim List of Categories of Essential Workers Mapped to Standardized Industry Codes and Titles," Centers for Disease Control and Prevention, last reviewed March 29, 2021, <https://www.cdc.gov/vaccines/covid-19/categories-essential-workers.html>. Accessed December 2022.

<sup>280</sup> "The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine — United States, December 2020," Centers for Disease Control and Prevention, December 22, 2020, [https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e2.htm#T1\\_down](https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e2.htm#T1_down). Accessed December 2022.

- 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.<sup>281, 282, 283</sup>

#### 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.<sup>284</sup>
- In May 2020, the United Nations Sustainable Development Group released a policy brief detailing the impact of COVID-19 on older persons.<sup>285</sup> 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.<sup>286</sup> This included priority groups for vaccination and

<sup>281</sup> "Statement on universal and equitable access to vaccines for the coronavirus disease (COVID-19)," UN Committee on Economic, Social and Cultural Rights, 2020, <https://digitallibrary.un.org/record/3897801?ln=en#record-files-collapse-header>. Accessed December 2022.

<sup>282</sup> "Democracies facing the Covid-19 pandemic," Council of Europe Parliamentary Assembly, 2020, <https://pace.coe.int/en/files/28773>. Accessed December 2022.

<sup>283</sup> "Communication From The Commission To The European Parliament And The Council Preparedness for COVID-19 vaccination strategies and vaccine deployment," European Union, October 15, 2020. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2020:0680:FIN>. Accessed December 2022.

<sup>284</sup> "No exceptions with COVID-19: "Everyone has the right to life-saving interventions" UN experts say," United Nations Office of the High Commissioner, March 26, 2020, <https://www.ohchr.org/en/press-releases/2020/03/no-exceptions-covid-19-everyone-has-right-life-saving-interventions-un>. Accessed December 2022.

<sup>285</sup> "The Impact of COVID-19 on older persons," United Nations, May 2020, <https://unsdg.un.org/sites/default/files/2020-05/Policy-Brief-The-Impact-of-COVID-19-on-Older-Persons.pdf>. Accessed December 2022.

<sup>286</sup> "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.<sup>287</sup> 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.<sup>288</sup>
- 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.<sup>289</sup>

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 mis and disinformation, and successful deployment would require significant communication with the public.<sup>290</sup> They highlighted vulnerable groups including

---

[https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE\\_Framework-Allocation\\_and\\_prioritization-2020.1-eng.pdf](https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf). Accessed December 2022.

<sup>287</sup> "Key aspects regarding the introduction and prioritisation of COVID-19 vaccination in the EU/EEA and the UK," European Centre for Disease Prevention and Control, October 26, 2020, <https://www.ecdc.europa.eu/en/publications-data/key-aspects-regarding-introduction-and-prioritisation-covid-19-vaccination>. Accessed December 2022.

<sup>288</sup> "Covid-19 vaccines: ethical, legal and practical considerations," Council of Europe Parliamentary Assembly, January 27, 2021, [https://pace.coe.int/en/files/29004/html?\\_\\_cf\\_chl\\_tk=4D\\_E\\_Cva7rJuCpQpqErOq.OmCmoPq13PqhjRu1zjKKs-1645095438-0-gaNycGzNCSU](https://pace.coe.int/en/files/29004/html?__cf_chl_tk=4D_E_Cva7rJuCpQpqErOq.OmCmoPq13PqhjRu1zjKKs-1645095438-0-gaNycGzNCSU). Accessed December 2022.

<sup>289</sup> "Supporting countries to prepare for and implement COVID-19 vaccination," World Health Organization, multiple dates, <https://www.who.int/europe/activities/supporting-country-preparedness-for-covid-19-vaccine-deployment-and-implementation>. Accessed December 2022.

<sup>290</sup> "Vaccine deployment: Behaviour, ethics, misinformation and policy strategies," The Royal Society, October 21, 2020, <https://royalsociety.org/-/media/policy/projects/set-c/set-c-vaccine-deployment.pdf?la=en-GB&hash=43073E5429C87FD2674201CA19280A8E>. Accessed December 2022.

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.<sup>291</sup>
- In November 2020, The Australian Government published a Vaccination Policy plan.<sup>292</sup> 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.<sup>293</sup> In response, Bulgaria and the Council of Ministers declared a state of emergency.<sup>294</sup> 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

---

<sup>291</sup> National Academies of Sciences, Engineering, and Medicine et al, "Framework for Equitable Allocation of COVID-19 Vaccine," *National Academies Press* (October 2020). doi: 10.17226/25917.

<sup>292</sup> "COVID-19 vaccination," Australian Government Department of Health and Aged Care, November 13, 2020, <https://www.health.gov.au/resources/publications/covid-19-vaccination-australian-covid-19-vaccination-policy?language=en>. Accessed December 2022.

<sup>293</sup> "Bulgaria, Moldova Report First Coronavirus Cases," RadioFreeEurope/RadioLiberty, March 8, 2020, <https://www.rferl.org/a/bulgaria-confirms-coronavirus-cases-amid-flu-outbreak/30475539.html>. Accessed January 2023.

<sup>294</sup> "13 March 2020-Nationwide State of Emergency," International Science Council, March 2020, <https://ingsa.org/covid-19-policy-tracker/europe/bulgaria/13-march-2020-nationwide-state-of-emergency-declared/>. Accessed January 2023.

of Health to introduce measures to "protect and preserve the life and health" of citizens.<sup>295,</sup>  
296, 297, 298, 299 300

75. It was not until early December 3, 2020, that the Bulgarian Council of Ministers introduced a National Pandemic Preparedness Plan.<sup>301</sup>

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.<sup>302</sup> 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

<sup>295</sup> "Decision No. 482 of the Cabinet of Ministers of 2020 to extend the period of the emergency epidemic situation announced by Decision No. 325 of the Council of Ministers of May 14, 2020, extended by Decision No. 378 and Decision No. 418," Unified Information Portal, 2020, <https://coronavirus.bg/bg/474>. Accessed December 2022.

<sup>296</sup> "Decision No. 378 of the Cabinet of Ministers of 2020 to extend the period of the emergency epidemic situation declared by the Cabinet of Ministers No. 325 of 2020," Unified Information Portal, 2020, <https://coronavirus.bg/bg/433>. Accessed December 2022.

<sup>297</sup> "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.

<sup>298</sup> "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.

<sup>299</sup> "Decision No. 609 of the Council of Ministers of 2020 to extend the period of the emergency epidemic situation declared by Decision No. 325 of the Council of Ministers of May 14, 2020, extended by RMS No. 378, RMS No. 418, RMS No. 482 and RMS No. 515," Unified Information Portal, 2020, <https://coronavirus.bg/bg/517>. Accessed December 2022.

<sup>300</sup> "Decision No. 673 of the Cabinet of Ministers of 2020 to extend the period of the emergency epidemic situation announced by Decision No. 325 of the Council of Ministers of May 14, 2020, extended by Decision No. 378, Decision No. 378, No. 418, No. 482, No. 525, No. 609, No. 673," Unified Information Portal, 2020, <https://coronavirus.bg/bg/390>. Accessed December 2022.

<sup>301</sup> "Decision No. 896 of the Council of Ministers of 2020 on the adoption of the National Vaccination Plan against COVID-19 (amended and supplemented)," Unified Information Portal, 2020, <https://coronavirus.bg/bg/663>. Accessed December 2022.

<sup>302</sup> "The national plan for vaccination against COVID-19 in our country will take place in 5 phases," BNT News, December 4, 2020, <https://bntnews.bg/news/nacionalniyat-plan-za-vaksinirane-sreshtu-covid-19-u-nas-shte-proteche-v-5-fazi-1085877news.html>. Accessed December 2022.

77. On December 26, 2020, the first shipment of vaccines arrived in Bulgaria (10,725 doses of Comirnaty/Pfizer mRNA vaccine).<sup>303</sup> 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.<sup>304,305</sup>
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.<sup>306</sup> 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.<sup>307</sup> 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.<sup>308</sup> 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

<sup>303</sup> "Information on domestically delivered COVID vaccines as of 11/22/2022," Ministry of Health, November 23, 2022, <https://www.mh.government.bg/bg/covid-19/dostaveni-v-stranata-vaksini/>. Accessed December 2022.

<sup>304</sup> "Overview of Variants in Countries," CoVariants, <https://covariants.org/per-country>. Accessed December 2022.

<sup>305</sup> "SARS-CoV-2 sequences by variant" Our World in Data, July 2021.

<https://ourworldindata.org/explorers/coronavirus-data-explorer?zoomToSelection=true&time=2021-07-05&facet=none&uniformYAxis=0&pickerSort=asc&pickerMetric=location&Metric=Variants&Interval=Cumulative&Relative=to+Population=true&Color+by+test+positivity=false&country=-BGR>. Accessed December 2022.

<sup>306</sup> "Decision No. 91 of the Council of Ministers of 2021 to supplement the National Plan for vaccination against COVID-19 in the Republic of Bulgaria, adopted by Decision No. 896 of the Council of Ministers of 2020.," Unified Information Portal, February 3, 2021, <https://coronavirus.bg/bg/777>. Accessed December 2022.

<sup>307</sup> "Decision No. 145 of the Cabinet of Ministers of 2021 amending the National Plan for Vaccination against COVID-19 in the Republic of Bulgaria, adopted by Decree No. 896 of 2020, supplemented by Decree No. 91 of 2021 and Decree No. 144 of 2021," Unified Information Portal, February 22, 2021, <https://coronavirus.bg/bg/780>. Accessed December 2022.

<sup>308</sup> "Joint ECDC-WHO Regional Office for Europe Weekly COVID-19 Surveillance Bulletin," ECDC and WHO, December 21, 2022, <https://worldhealthorg.shinyapps.io/euro-covid19/>. Accessed January 2023.

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:<sup>309</sup>

- 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.<sup>310</sup> 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.<sup>311</sup>

<sup>309</sup> "Excess mortality: Cumulative deaths from all causes compared to projection based on previous years," Our World in Data, June 30, 2021, [https://ourworldindata.org/explorers/coronavirus-data-explorer?zoomToSelection=true&time=earliest..2021-06-30&facet=none&pickerSort=desc&pickerMetric=aged\\_65\\_older&Metric=Excess+mortality+%28%25%29&Interval=Cumulative&Relative+to+Population=true&Color+by+test+positivity=false&country=AUT~BEL~BGR~CYP~CZE~DEU~DNK~ESP~EST~FIN~FRA~GRC~HRV~HUN~IRL~ITA~LTU~LUX~LVA~MLT~NLD~POL~PRT~ROU~SVK~SVN~SWE~EuropeanUnion](https://ourworldindata.org/explorers/coronavirus-data-explorer?zoomToSelection=true&time=earliest..2021-06-30&facet=none&pickerSort=desc&pickerMetric=aged_65_older&Metric=Excess+mortality+%28%25%29&Interval=Cumulative&Relative+to+Population=true&Color+by+test+positivity=false&country=AUT~BEL~BGR~CYP~CZE~DEU~DNK~ESP~EST~FIN~FRA~GRC~HRV~HUN~IRL~ITA~LTU~LUX~LVA~MLT~NLD~POL~PRT~ROU~SVK~SVN~SWE~EuropeanUnion). Accessed January 2023.

<sup>310</sup> "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%B08>. Accessed January 2023.

<sup>311</sup> "Data set: Statistics on the spread of COVID-19 in Bulgaria,' Deceased by age and sex groups," Open Data Portal, last modified January 7, 2023. [https://data.egov.bg/data/resourceView/18851aca-4c9d-410d-8211-0b725a70bcfd?per\\_page=100](https://data.egov.bg/data/resourceView/18851aca-4c9d-410d-8211-0b725a70bcfd?per_page=100). Accessed January 6, 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.<sup>312</sup>
- between June 2020 and December 2021, 30,474 people died from COVID-19, of which over 85% were people over the age of 60.<sup>313</sup>
- 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.<sup>314, 315</sup>

83. Between December 2020 and the end of June 2021, the cumulative uptake of a complete (2 dose) COVID-19 vaccine in Bulgaria was:<sup>316</sup>

- 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:<sup>317</sup>

- 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)

<sup>312</sup> "Data set: Statistics on the spread of COVID-19 in Bulgaria,' Deceased by age and sex groups," Open Data Portal, last modified January 7, 2023. [https://data.egov.bg/data/resourceView/18851aca-4c9d-410d-8211-0b725a70bcfd?per\\_page=100](https://data.egov.bg/data/resourceView/18851aca-4c9d-410d-8211-0b725a70bcfd?per_page=100). Accessed January 6, 2023.

<sup>313</sup> "Ibid

<sup>314</sup> "Dataset: Statistics on vaccinated people with COVID-19-Died Vaccinated," Open Data Portal, Last updated January 7, 2023, <https://data.egov.bg/data/resourceView/e6a72183-28e0-486a-b4e4-b5db8b60a900>. Accessed January 6, 2023

<sup>315</sup> "Data set: Statistics on the spread of COVID-19 in Bulgaria-Deceased by sex and age groups," Open Data Portal, last updated January 7, 2023, [https://data.egov.bg/data/resourceView/18851aca-4c9d-410d-8211-0b725a70bcfd?order=2&per\\_page=100](https://data.egov.bg/data/resourceView/18851aca-4c9d-410d-8211-0b725a70bcfd?order=2&per_page=100). Accessed January 6, 2023

<sup>316</sup> "Joint ECDC-WHO Regional Office for Europe Weekly COVID-19 Surveillance Bulletin," ECDC and WHO, June 27, 2021, <https://worldhealthorg.shinyapps.io/euro-covid19/>. Accessed January 2023.

<sup>317</sup> ibid

85. As of January 10, 2023 there have been 1,293,491 confirmed SARS-CoV-2 infections, and 38,127 deaths in Bulgaria.<sup>318</sup> There have been 26,309 confirmed cases in Medical Staff workers alone.<sup>319</sup>

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.<sup>320</sup> 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
- 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.<sup>321</sup>

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

---

<sup>318</sup> "Bulgaria," World Health Organization, January 10, 2023, <https://covid19.who.int/region/euro/country/bg>. Accessed January 10, 2023.

<sup>319</sup> "Current Statistics in Bulgaria," Unified Information Portal, 2023, <https://coronavirus.bg/bg/statistika>. Accessed January 10, 2023

<sup>320</sup> 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).

<sup>321</sup> "COVID-19 Vaccine Data Tracker," European Centre for Disease Prevention and Control, December 14, 2022, <https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab>.

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:<sup>322</sup>
  - 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:<sup>323</sup>
  - 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:<sup>324</sup>
  - 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

---

<sup>322</sup> "Explore the global situation," metrics: confirmed death, case fatality rate, vaccine doses, people fully vaccinated for the world, Our World In Data, January 2023. <https://ourworldindata.org/coronavirus#explore-the-global-situation>. Accessed January 31, 2023

<sup>323</sup> "Explore the global situation," metrics: confirmed death, case fatality rate, vaccine doses, people fully vaccinated, Our World In Data, January 2023. <https://ourworldindata.org/coronavirus#explore-the-global-situation>. Accessed January 30, 2023

<sup>324</sup> "Explore the global situation," metrics: confirmed death, case fatality rate, vaccine doses, people fully vaccinated for the European Union, Our World In Data, January 2023. <https://ourworldindata.org/coronavirus#explore-the-global-situation>. Accessed January 30, 2023

- 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:<sup>325, 326</sup>
  - 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.<sup>327</sup> Bulgaria has the lowest rate of primary series completion in the EU.<sup>328</sup> 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%.<sup>329</sup> Bulgaria is also significantly behind other EU countries in uptake of the first and second booster doses.<sup>330</sup>

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.<sup>331</sup> Completion of a primary series among adults aged 60 years and older is above 90% for more than half of EU

<sup>325</sup> "Classification and definition of regions," United Nations, no date,

<https://esa.un.org/MigFlows/Definition%20of%20regions.pdf>

<sup>326</sup> "Explore the global situation," metrics: confirmed death, case fatality rate, excess mortality rate, vaccine doses, people fully vaccinated for Eastern European countries, Our World In Data, January 2023.

<https://ourworldindata.org/coronavirus#explore-the-global-situation>. Accessed January 31, 2023

<sup>327</sup> "Bulgaria," World Health Organization, January 2023, <https://covid19.who.int/region/euro/country/bg>. Accessed January 10, 2023.

<sup>328</sup> "WHO Coronavirus Dashboard," World Health Organization, December 11, 2022, <https://covid19.who.int>. Accessed December 11, 2022.

<sup>329</sup> "COVID-19 Vaccine Tracker," European Centre for Disease Prevention and Control, December 14, 2022, <https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab>. Accessed January 2023.

<sup>330</sup> Ibid.

<sup>331</sup> "COVID-19 Vaccine Tracker," European Centre for Disease Prevention and Control, December 14, 2022, <https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab>. Accessed January 2023.

countries; Bulgaria has the lowest primary series completion at 38.4% of adults 60 years and older.<sup>332</sup>

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.<sup>333</sup> 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.<sup>334</sup> 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.<sup>335, 336</sup>
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.<sup>337</sup>

---

<sup>332</sup> Ibid

<sup>333</sup> Aleksandar Džakula et al, "A comparison of health system responses to COVID-19 in Bulgaria, Croatia and Romania in 2020," *Health Policy* 126, no.5 (May 2022):456-464. doi:10.1016/j.healthpol.2022.02.003

<sup>334</sup> Ibid

<sup>335</sup> 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

<sup>336</sup> Guihong Fan et al, "Impact of low vaccine coverage on the resurgence of COVID-19 in Central and Eastern Europe," *One Health* 14, (May 2022):100402. doi: 10.1016/j.onehlt.2022.100402

<sup>337</sup> "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.<sup>338</sup> A vaccines advisory group to WHO identified complacency, inconvenience in accessing vaccines, and lack of confidence as key reasons underlying hesitancy.<sup>339</sup> 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.<sup>340</sup> 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.<sup>341</sup>
99. People who distrust healthcare workers, health systems, or governmental institutions are also more likely to be vaccine hesitant.<sup>342</sup>

---

<sup>338</sup> "Ten threats to global health in 2019," World Health Organization, no date, <https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019>. Accessed December 2022.

<sup>339</sup>Ibid

<sup>340</sup> "Infodemic," World Health Organization, no date, [https://www.who.int/health-topics/infodemic#tab=tab\\_1](https://www.who.int/health-topics/infodemic#tab=tab_1). Accessed January 2023.

<sup>341</sup> World Health Organization, "Infodemic"

<sup>342</sup> 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:<sup>343</sup>

- 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.<sup>344</sup> In 2020, before COVID-19 vaccinations were available, a poll revealed that only 33% of Bulgarians were willing to receive a COVID-19 vaccine.<sup>345</sup>

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

---

<sup>343</sup> “Attitudes on vaccination against COVID-19,” Eurobarometer, June 2021, <https://europa.eu/eurobarometer/surveys/detail/2512>. Accessed January 2023.

<sup>344</sup> “Chapter 5: Attitudes to vaccines,” Wellcome Global Monitor 2018, 2018, <https://news.gallup.com/poll/348719/billion-unwilling-covid-vaccine.aspx>. Accessed January 2023

<sup>345</sup> Julie Ray, “Over 1 Billion Worldwide Unwilling to Take COVID-19 Vaccine,” Gallup, May 3, 2021, <https://news.gallup.com/poll/348719/billion-unwilling-covid-vaccine.aspx>. Accessed January 2023

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...”<sup>346</sup>

- In March 2020, an update on the above-named report on risk communication and community engagement, was provided.<sup>347</sup>
- 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.<sup>348</sup>
- In December 2020, a Global Risk Communication and Community Engagement Strategy was published.<sup>349</sup> 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.<sup>350</sup>

---

<sup>346</sup> “Risk communication and community engagement readiness and initial response for novel coronaviruses,” World Health Organization, January 10, 2020, [https://www.who.int/publications/i/item/risk-communication-and-community-engagement-readiness-and-initial-response-for-novel-coronaviruses-\(ncov\)](https://www.who.int/publications/i/item/risk-communication-and-community-engagement-readiness-and-initial-response-for-novel-coronaviruses-(ncov)). Accessed December 2022.

<sup>347</sup> “Risk communication and community engagement readiness and response to coronavirus disease (COVID-19): interim guidance,” World Health Organization, March 19, 2020, <https://www.who.int/publications/i/item/risk-communication-and-community-engagement-readiness-and-initial-response-for-novel-coronaviruses>. Accessed January 8, 2023.

<sup>348</sup> “1st WHO Infodemiology Conference,” World Health Organization, July 2020, <https://www.who.int/news-room/events/detail/2020/06/30/default-calendar/1st-who-infodemiology-conference>. Accessed December 2022.

<sup>349</sup> “COVID-19 Global Risk Communication and Community Engagement Strategy – interim guidance,” World Health Organization, December 23, 2020, <https://www.who.int/publications/i/item/covid-19-global-risk-communication-and-community-engagement-strategy>. Accessed December 2022.

<sup>350</sup> “Community needs, perceptions and demand: community assessment tool,” World Health Organization, February 5, 2021, [https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccination-community\\_assessment-tool-2021.1](https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccination-community_assessment-tool-2021.1). Accessed January 6, 2023.



- In May 2021, a tool for health worker communication and vaccination workflow was published.<sup>351</sup>
- In May 2021, guidance on critical actions for pandemic preparedness and response was published.<sup>352</sup> 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.<sup>353</sup>
- 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.<sup>354</sup>
- 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..."<sup>355, 356</sup>

<sup>351</sup> "Health worker communication for COVID-19 vaccination flow diagram," World Health Organization, May 13, 2021, <https://www.who.int/publications/m/item/health-worker-communication-for-covid-19-vaccination-flow-diagram>. Accessed January 3, 2023.

<sup>352</sup> "Critical preparedness, readiness and response actions for COVID-19," World Health Organization, May 27, 2021, <https://www.who.int/publications/i/item/critical-preparedness-readiness-and-response-actions-for-covid-19>. Accessed January 6, 2023

<sup>353</sup> "Coronavirus disease 2019 (COVID-19) in the EU/EEA and the UK – tenth update," European Center for Disease Prevention and Control, June 11, 2020, <https://www.ecdc.europa.eu/en/publications-data/rapid-risk-assessment-coronavirus-disease-2019-covid-19-pandemic-tenth-update>. Accessed January 4, 2023.

<sup>354</sup> "Risk assessment: SARS-CoV-2 - increased circulation of variants of concern and vaccine rollout in the EU/EEA, 14th update," European Centre for Disease Prevention and Control, February 15, 2021, <https://www.ecdc.europa.eu/en/publications-data/covid-19-risk-assessment-variants-vaccine-fourteenth-update-february-2021>. Accessed December 2022.

<sup>355</sup> "Countering online vaccine misinformation in the EU/EEA," European Center for Disease Prevention and Control, June 29, 2021, <https://www.ecdc.europa.eu/en/publications-data/countering-online-vaccine-misinformation-eu-eea>. Accessed January 4, 2023.

<sup>356</sup> "Countering online vaccine misinformation in the EU/EEA," European Centre for Disease Prevention and Control, June 29, 2021, <https://www.ecdc.europa.eu/en/publications-data/countering-online-vaccine-misinformation-eu-eea>. Accessed December 2022.

- C. The European Commission has included fighting disinformation as part of their Coronavirus response.<sup>357</sup>
- D. The American CDC has had a variety of health communication toolkits and resources published and updated throughout the pandemic.<sup>358, 359, 360</sup>
- E. In July 2020, the Organisation for Economic Co-operation and Development released a policy brief focusing on COVID-19, health communication, and disinformation.<sup>361</sup>

## **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

---

<sup>357</sup> “Fighting Disinformation,” European Commission, no date, [https://commission.europa.eu/strategy-and-policy/coronavirus-response/fighting-disinformation\\_en#online-resources-and-tools](https://commission.europa.eu/strategy-and-policy/coronavirus-response/fighting-disinformation_en#online-resources-and-tools). Accessed January 6, 2023.

<sup>358</sup> “Ways Health Departments Can Help Increase COVID-19 Vaccinations,” Centers for Disease Control and Prevention, last updated June 17, 2022, <https://www.cdc.gov/vaccines/covid-19/health-departments/generate-vaccinations.html>. Accessed January 4, 2023.

<sup>359</sup> “Communication Resources,” Centers for Disease Control and Prevention, last updated September 14, 2021, <https://www.cdc.gov/coronavirus/2019-ncov/communication/index.html>. Accessed January 4, 2023

<sup>360</sup> “Health Communication Gateway,” Centers for Disease Control and Prevention, last updated December 9, 2021, <https://www.cdc.gov/healthcommunication/index.html>. Accessed January 4, 2023

<sup>361</sup> “Transparency, communication and trust: The role of public communication in responding to the wave of disinformation about the new Coronavirus,” Organisation for Economic Co-operation and Development, July 3, 2020, <https://www.oecd.org/coronavirus/policy-responses/transparency-communication-and-trust-the-role-of-public-communication-in-responding-to-the-wave-of-disinformation-about-the-new-coronavirus-bef7ad6e/>. Accessed January 6, 2023.

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.



Ranit Mishori, MD, MHS, FAAFP



Brianna da Silva Bhatia, MD, MPH

