Veterans Health Administration (VHA)

Coronavirus Disease 2019 (COVID-19)

Response Report - Annex D Interim

April 10, 2023

U.S. Department of Veterans Affairs
Veterans Health Administration

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FOREWORD

It is our solemn honor to care for the people who serve this country. Even as the pandemic continues to bring unique challenges to our doorstep, it has not stopped the people of the Veterans Health Administration (VHA) from working tirelessly to protect Veterans and their caregivers. I am beyond proud of the innovation, dedication and honor VHA has brought to the fight against COVID-19.

The Annex D Interim Report covers the period from April 1, 2022, through July 31, 2022. It is a shorter time period than past reports, which allows us to provide interim snapshots on important topics. An additional report, which extends the review period through January 31, 2023, is scheduled to be published later in 2023.

During the Interim Review Period, confirmed COVID-19 cases rose among employees and Veterans. Staffing shortages were compounded by the number of employees who were unable to work due to COVID-19. The Omicron variants caused less-severe symptoms in many of the infected, but sadly, hospitalizations and deaths continued throughout the United States, impacting Veterans and the entire Nation.

To combat the ongoing spread of the virus and its subsequent illness, VHA expanded our Virtual Test to Treat programming, collaborated with multiple agencies to ensure the best in therapeutic care for those who were ill with COVID-19, planned ahead to prevent future supply chain issues with innovative 3D-printing techniques and published more than 300 research papers on topics to help stem the tide of COVID-19. We also stand at the forefront of discoveries regarding both Long COVID and COVID-19 rebound after Paxlovid treatment.

VHA is a learning organization; we are dedicated to improving our care, our processes and our responses to the challenges we face. A careful look at how we managed the COVID-19 pandemic will inform how we provide care in the future, both in the endemic state and in future public health emergencies.

With that in mind, I present the Annex D Interim COVID-19 Response Report. I hope you will find it informative and helpful as we continue to fight this virus together.

Sincerely,

Shereef Elnahal, M.D., MBA
Under Secretary for Health

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EXECUTIVE SUMMARY

The Annex D Interim Report (the Interim Report) provides a picture of the VHA COVID-19 response from April 1, 2022, through July 31, 2022. Because this report covers a shorter time frame than past reports, it is considered an Interim report. The full Annex D report will be released later in 2023.

The Interim Report also includes a literature review that provides high-level summary findings of evidence on the impact of COVID-19 among this Veteran population by race/ethnicity, rurality and gender. The review summarizes findings from 12 selected studies spanning the course of the pandemic. All of the studies in the literature review used VHA data to examine COVID-19 and health equity in the Veteran population receiving care from VHA.

During the Interim Report Review Period, VHA worked to combat COVID-19 by caring for Veterans and their caregivers and by continuing policies designed to protect employees. In laboratories and health care facilities across the country, VHA has conducted research, fostered innovation and expanded Virtual Test to Treat and Long COVID Care programs in support of the fight against the SARS-CoV-2 virus.

VHA also continued to provide COVID-19 support for ongoing work under the Fourth Mission; however, the volume of Fourth Mission activity was lower in the Interim Report Review Period than in previous periods, and there were no new FEMA Mission Assignments.

Method

VHA leadership provided most of the information contained in the Interim Report. Data and insights were obtained from these leaders through interviews and information requests. Data was also collected from centralized VHA databases. For the literature review, information was collected from the published results of the 12 selected studies, which were chosen for inclusion in coordination with the VHA Office of Health Equity (OHE).

Publicly available information was also used to create this report, such as briefings, press releases and published articles from government sources—including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the White House—as well as medical journals and university publications.

Endnotes throughout the report will take the reader to the source of that information. References include hyperlinks if the source is available to the public.

VHA leadership reviewed and approved the Interim Report before it was posted publicly on the VHA website. Making this information available to everyone is part of VHA's commitment to shared learning and collaborative solutions. Only by sharing our experiences and knowledge can we adjust and prepare for future health care emergencies.

All VHA COVID-19 Response Reports are available here: https://www.publichealth.va.gov/n-coronavirus/COVID_19_Response_Reports.asp.

Guiding Principles

The VHA Steering Committee for the Interim Report established the following guiding principles. They are identical to those in Annex A, B and C, and they continue to be followed throughout the Annex D Interim Report:

- Working as a collaborative health care system is critical to the success of VHA. Our facilities and networks work as a team, focused on a common goal—quality care for our Veterans.
- Reporting and assessment of the COVID-19 response is essential to VHA as a learning organization and can be applied to agencies outside VHA, as well as private health care systems.
- Accurate documentation of the evolution of the pandemic and essential elements of the response is imperative to informing future VHA readiness and planning for VHA emergency responses.
- Readiness and planning will be essential to effective future responses because VHA's role in the Fourth Mission requires close coordination and collaboration with multiple components of government.
- Data, observations and experiences in response to a crisis are all important to identifying issues that are key to learning from the response.
- Identification of root causes for complex process problems is essential to improvement and often requires a focused analysis by subject matter experts.
- Questions identified in the response for which answers require new knowledge will be approached via research, applying the scientific method.
- A systems-oriented approach to process solutions is important to identifying reliable solutions.

Summary of Events During the Annex D Interim Period

Public health policy during the Annex D Interim Report Review Period (April 1, 2022, through July 31, 2022) reflected the Nation's movement from pandemic to a potential endemic state. Mask restrictions and social distancing constraints were lifted. Reporting of key data points changed, with many states reducing their COVID-19 reporting to once per week.

Most public health policy practices regarding COVID-19 were re-focused on a three-tiered community risk system, defined and recommended by CDC. The system allowed communities to adjust their public health mitigations based on the quantity of new COVID-19 infections and the number of hospitalizations in a given area. This

change in policy was designed to keep illness from overwhelming health care systems.

Despite public policy geared toward a potential endemic state, the Review Period saw a gradual and steady increase in COVID-19 cases. The new infections were driven predominantly by Omicron strain BA.5, which comprised nearly 82% of all U.S. COVID-19 cases during the reporting period.[1]

Weekly new cases of COVID-19 rose over the course of the Interim Report Review Period, with the highest rate on July 27, 2022 (approximately 274 weekly cases per 100,000 people).[2] This high point was still significantly lower than the peak new case rate in the Annex C period, which surpassed 1,676 in January 2022.[3] The Annex C Reporting Period covered events from August 1, 2021, through March 31, 2022.

In May 2022, the White House issued a call to action, leveraging the increased availability of self-tests and prescription drugs available to prevent infection and reduce hospitalizations from COVID-19, particularly among those at increased risk for severe illness.[4] The President of the United States released a briefing, encouraging the expansion of Test to Treat sites where people could access prescription medications.[5]

In June 2022, FDA issued Emergency Use Authorizations (EUAs) for vaccinations for children starting at 6 months of age, which made vaccinations available to 20 million children across the United States.[6] The EUAs were issued to Moderna (6 months through 17 years old) and Pfizer-BioNTech (6 months through 4 years old). Before June 2022, no vaccines were available for children under five years of age.[7]

Updates to VHA Strategic Challenges and Actions

As the pandemic began to turn endemic, VHA grew its expertise, bolstered its capabilities and worked to maintain and expand support for Veterans through its national integrated health system.

Aware of the increasing popularity of self-testing, VHA broadened its Virtual Test to Treat programming during the Interim Report Review Period, allowing more patients to self-test and obtain treatment for COVID-19 without an in-person encounter.

A VHA facility in Boston, Massachusetts, was one of the first to identify a condition associated with Paxlovid. Those who experience this condition—called COVID-19 rebound—have reported that their COVID-19 symptoms returned several days after they completed Paxlovid treatment.[8] VA used its clinical genomic sequencing

capability to investigate and confirm that COVID-19 rebound was associated with the same viral variant that produced the patient's recently treated infection.

Other progress during this period is described in the following sections.

A Geriatric Scholar, part of a team working to narrow the digital divide by improving Veteran access to VA Video Connect. (Photo credit: VA)

Test to Treat

On April 1, 2022, VHA launched a pilot Virtual Test to Treat program, which allowed Veterans and their families to perform self-tests and obtain prescriptions for COVID-19 treatment without in-person appointments. This program was particularly important because the pharmaceutical medications used to treat COVID-19 were at their most effective in the early days of illness.

Using procedures that are standard in Clinical Contact Centers (CCCs), the pilot started in Veterans Integrated Services Network (VISN) 1 and then expanded to include 9 of the 18 VISNs.

Research and Innovation

As VHA continued its research and innovation work related to COVID-19, the organization leveraged its array of partnerships, academic affiliations and interagency relationships to develop new initiatives.

Over the course of the pandemic, research and innovation professionals adjusted their processes to generate studies that could swiftly address urgent clinical questions and translate new knowledge into clinical care. This change, brought on by the urgency of the COVID-19 public health emergency, has allowed VHA to expand its research and innovation capabilities. VHA data continued to be a cornerstone of VHA's national response.

From April 1, 2022, through July 31, 2022, VHA collaborated on 316 published articles related to COVID-19, initiated 2 new clinical trials and continued to support 8 trials that were initiated prior to the reporting period. VHA also launched a real-world evidence (RWE) study to assess the effectiveness of COVID-19 vaccines.

To address past supply chain issues, VHA expanded its innovation capabilities into digital stockpiling. Using 3D printers and a shelf-stable powder, VHA explored ways to print much-needed products, including specialized nasal swabs for testing, face masks and shields. The use of 3D printing may help to prepare VHA for future shortages during emergencies.

Literature Review

The literature review is a comprehensive look at 12 research studies that used VHA data to conduct COVID-19 research over the course of the pandemic. The review addresses a single research question: How did the impact of COVID-19 (specifically, rates of infection, hospitalization and mortality) vary among Veterans of different racial/ethnic groups, rurality and sex/gender?

The findings of these selected studies indicated that COVID-19 infection and mortality rates varied by race/ethnicity, rurality and sex/gender; however, the impact changed as the pandemic progressed. Early in the pandemic, urban residents had a higher risk of testing positive for COVID-19, but later in the pandemic, rural areas had a higher risk. Similarly, Black and American Indian/Alaska Native (AI/AN) Veterans experienced a higher risk of testing positive and dying of COVID-19 at the start of the pandemic, but that disparity faded with time.

Therapeutics

During the Interim Report Review Period, VHA prescribed six different medications to combat COVID-19. Two were offered for oral use (Paxlovid and Lagevrio), and the others were injectable (Veklury, Evusheld, Bebtelovimab and Dexamethasone Sodium Phosphate).[9]

Over the course of the Interim Report Review Period, outpatient treatment with medications increased; Paxlovid was the most used.[10]

Long COVID

Long COVID is a condition in which symptoms of COVID-19 (new, ongoing or recurring) continue for four weeks or longer after initial infection. Symptoms can include fatigue, rash, joint or muscle pain, shortness of breath, dizziness and brain fog (also known as cognitive symptoms).

As of July 31, 2022, VHA estimated that tens of thousands of Veterans had experienced (or were experiencing) Long COVID. As health care providers for these individuals, many VHA facilities identified Long COVID as a concern and established independent treatment guidelines within their practices. During the Interim Report Review Period, VHA aimed to provide comprehensive and cohesive treatment for the condition for Veterans, developing over-arching guidelines for VHA Long COVID Care programs across the country.

In treating Veterans with Long COVID, many facilities offered either all-virtual or hybrid (virtual and in-person) care.

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ACKNOWLEDGMENTS

The COVID-19 Response Reporting Team would like to thank the VA Secretary and Deputy Secretary for their support in creating the team's fifth COVID-19 report, the Annex D Interim. The completion of this document was made possible with guidance from the Steering Group: Dr. Carolyn Clancy and Mr. James Tranoris. The Acting Under Secretary for Health contributed to Annex D, as did VHA senior leaders, VISN Directors and VHA personnel. The Annex D Interim team is greatly appreciative to VA for its ongoing work to protect and care for America's Veterans through the pandemic and beyond.

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OVERVIEW

The Annex D Interim Report (the Interim Report) documents the efforts of the Veteran Health Administration (VHA) to support and care for Veterans in response to the COVID-19 pandemic. The report covers the period from April 1, 2022, through July 31, 2022.

Consistent with all prior reports, VHA activities encompass care delivery (including clinical and supply chain operations), VHA's academic missions (including research and publication), Veteran-centered innovations motivated by pandemic challenges and VHA's role as the Nation's safety net during public health emergencies.

This report is the fifth of its kind, following these four reports:

- The Initial Report: January 1, 2020, through June 30, 2020
- Annex A: July 1, 2020, through January 1, 2021
- Annex B: January 1, 2021, through July 31, 2021
- Annex C: August 1, 2021, through March 31, 2022

This Interim Report will provide an update on the following:

- The ongoing VHA response to COVID-19, including the Omicron variant
- Preparations for moving toward an endemic state, including optimization of health services to Veterans
- Mitigation of health consequences associated with deferred care and other responses to the COVID-19 public health emergency

All of the reports are available at the VA Public Health website: https://www.publichealth.va.gov/n-coronavirus/COVID_19_Response_Reports.asp.

Progression of the Pandemic in Veteran Populations

During the Annex D Interim Review Period, fewer Veterans were hospitalized and fewer Veterans died, compared to the previous reporting period (covered by the Annex C Report).[11] On a cumulative basis since February 1, 2020, more than 83,000 Veterans Using VHA Services had been hospitalized with COVID-19, and more than 22,000 of that Veteran population died, in addition to 258 VHA employees. For details, see **Table 1.1**.[12]

Veteran & VHA Employee Vaccinations

Table 1.1 also shows the vaccination status for Veterans and VHA employees.[13] Vaccination status was accurate and true to the best of VHA's knowledge as of the

publication of this report, but these counts may not reflect all vaccinations received outside the Department of Veterans Affairs (VA).

The majority of Veterans Using VHA Services (58.6%and VHA employees (84.1%) completed their initial vaccination series as recommended by CDC to reduce the risk of severe COVID-19 infection, hospitalization and death.[14] Of Veterans who came to VHA for services in the last year, there was a higher rate of vaccination—65.2%.[15]

As of July 31, 2022, more than 30% of Veteran Using VHA Services had received their first vaccine booster dose, and 4.3% had completed their second vaccine booster dose. The second booster (available as of March 29, 2022) was offered only to those over 50 years old during the Interim Review Period.[16]

Table 1.1: *COVID-19 Summary Statistics, as of July 31, 2022**

Category	Number	Percent of Population
Veterans Using VHA Services	7,457,269	
Veteran COVID-19 Cases	591,508	7.9%
Veteran COVID-19 Inpatients	83,651	1.1%
Veteran Deaths (COVID-19 associated)	22,212	0.3%
At Least 1 Dose of Vaccine	4,528,943	60.7%
Initial Vaccination Series Complete	4,369,653	58.6%
1st Vaccine Booster Dose	2,306,244	30.9%
2nd Vaccine Booster Dose for Veterans Over 50	318,766	4.3%
VHA Employees	393,572	
Employee COVID-19 Cases	88,104	22.4%
Employee Deaths (COVID-19 associated)	258	0.1%
At Least 1 Dose of Vaccine	351,050	89.2%
Initial Vaccination Series Complete	331,112	84.1%
1st Vaccine Booster Dose	148,741	37.8%

Note: Veterans Using VHA Services are Veterans who used VHA services from 10/1/2019 through 7/31/2022. COVID-19 cases and deaths among Veterans were Veterans who used VHA services from 10/1/2019 through 7/31/2022 and were alive as of 1/1/2020. Those values did not include Veterans who were VHA employees during this timeframe. Veteran COVID-19 cases include VHA-conducted tests and Veteran self-reported lab test results to VHA. Veteran COVID-19 Cases are the cumulative total number of unique Veterans Using VHA Services who have tested positive for COVID-19 since the start of the pandemic. COVID-19-associated Veteran Deaths refers to Veterans Using VHA Services who died within 30 days of an established lifetime first COVID-19 case (the date of the first case confirmed by VHA testing or the date when the first positive test outside of VHA was reported to VHA).

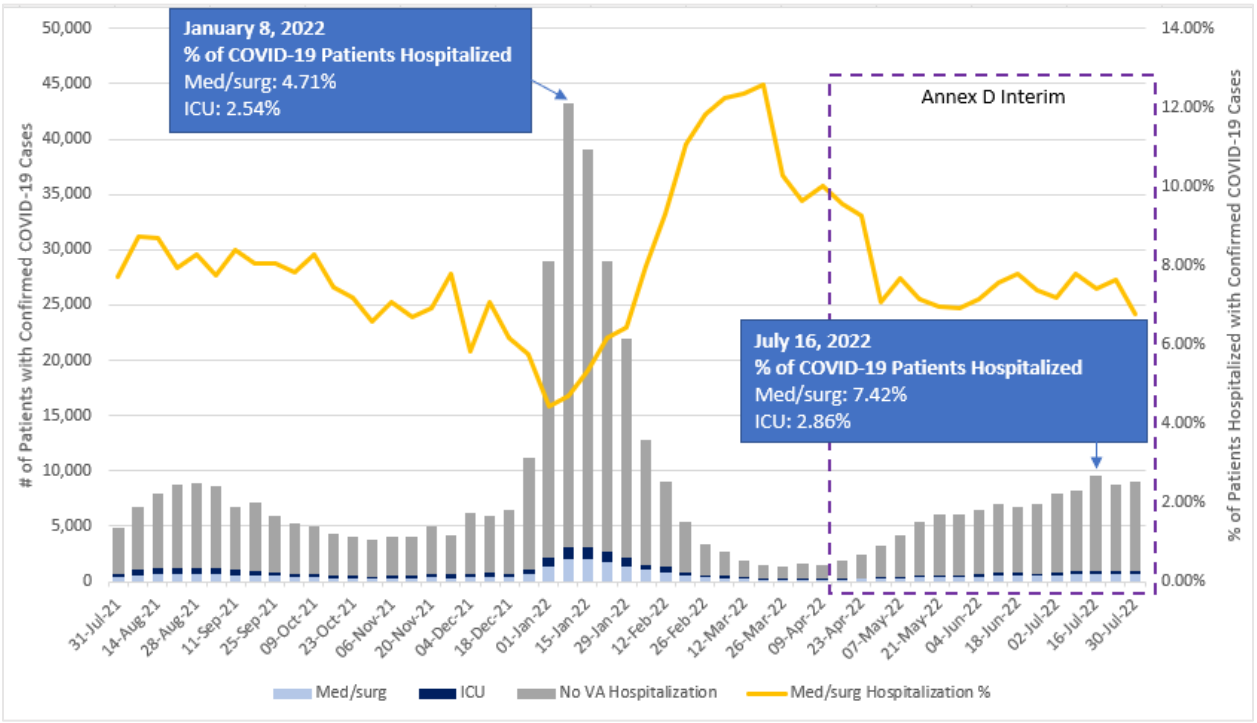
Completed initial vaccination series refers to those who received their second dose of either the Moderna or Pfizer COVID-19 vaccine or their single dose of the J&J COVID-19 vaccine. 1st and 2nd Vaccine Booster Doses refer to those who received an initial vaccination series and an additional dose of Moderna, Pfizer or J&J COVID-19 vaccine. Veteran vaccination counts are for Veterans Using VHA Services. The total number of vaccinations and boosters administered does not include vaccinations for individuals vaccinated by sources outside VHA in which records were not provided to VHA. Vaccination numbers may change depending on when the data is accessed because VHA may retroactively update vaccination status. Employee numbers

include only paid VHA employees and VHA Veteran-employees; VISN contractors and volunteers are not included.
*For data availability reasons, numbers for "VHA Employees" are as of August 27, 2022, "Employee COVID-19 Cases" are as of August 1, 2022, and "Employee Deaths (COVID-19-associated)" are as of October 6, 2022. Ref. D216, Ref. D227, Ref D229
Sources: VHA, CDW, NST Dataset, Veteran Population accessed on 10/26/2022; VHA, CDW, NST Dataset, Cases accessed 10/26/2022; VHA, CDW, NST Dataset, Inpatients accessed 10/26/2022; VHA, CDW, NST Dataset, Deaths accessed 10/26/2022; VHA, CDW Database, VHA, CDW, VSSC Dataset, Veteran Vaccinations, accessed 3/28/2023; VHA, HOC, Employee Population response to data call 9/22/2022; Access to Care Dashboard, Employee Deaths accessed 10/6/2022; VHA, HOC, Employee Vaccination response to data call 10/4/2022. Employee Cases, VHA, response to data request, 11/17/2022.

Veteran Hospitalizations

Figure 1.1 shows the hospitalization status of Veterans with confirmed cases of COVID-19 from July 31, 2021, through July 30, 2022.[17] The highest rate of Veteran hospitalization during the Interim Review Period occurred on July 16, 2022.[18] On that date, the rate of Veterans hospitalized—both in med/surg and intensive care unit (ICU) facilities—was higher than it was at the peak of the Omicron wave on January 8, 2022.[19]

Figure 1.1: *VA Lab-confirmed COVID-19 Cases, by Hospitalization Status, July 31, 2021 – July 30, 2022*



Source: VHA, HOC, response to data call, 9/22/2022. Ref. D218
Note: Data represent weekly hospitalization counts and not unique admissions. Veteran patients with confirmed COVID-19 cases who died or were not hospitalized in a VA med-surg or ICU were included in the "No VA Hospitalization" status.

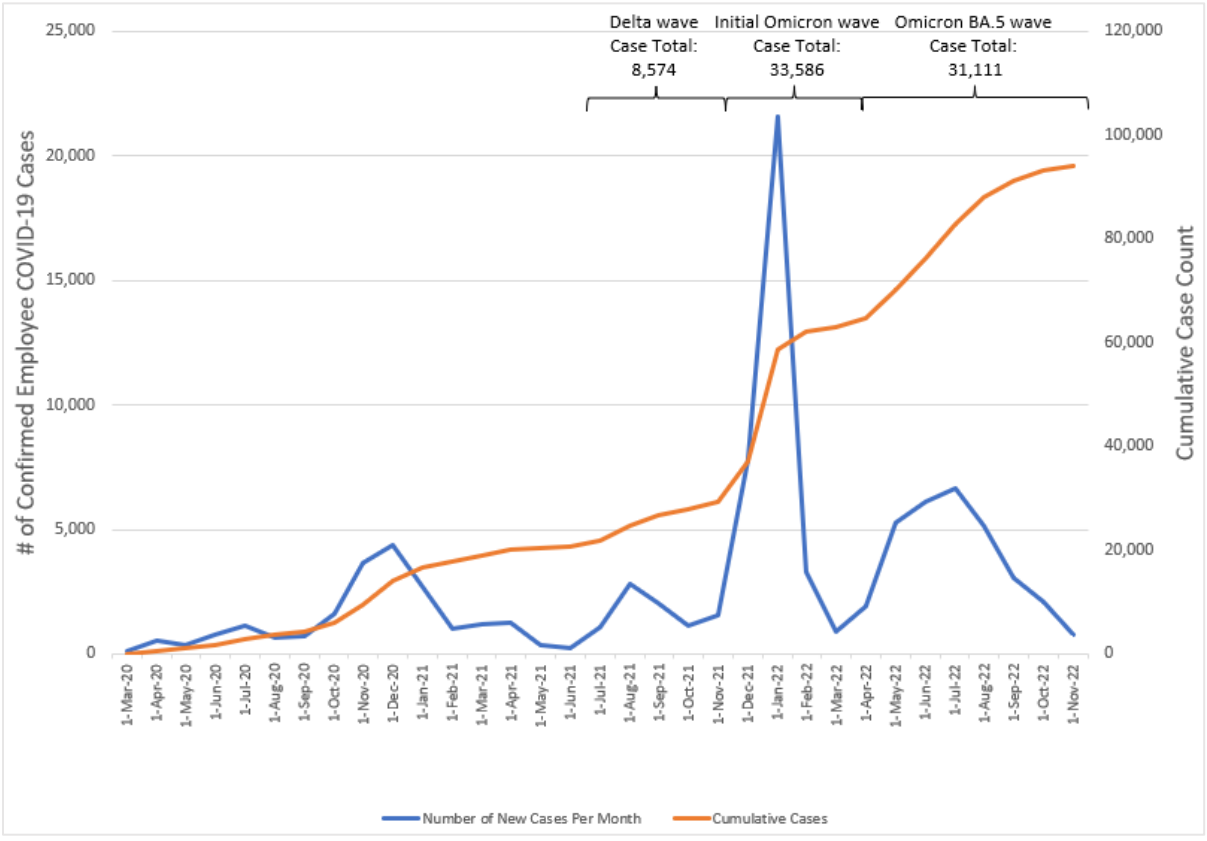
The increased use of self-tests may have impacted hospitalization percentages; self-tests were not included in the number of confirmed Veteran COVID-19 cases.[20] In the broader U.S. population, CDC found minimal reporting of self-test data.[21] For more information on self-tests, see the U.S. Epidemiology section.

VHA Employee COVID-19 Cases

Figure 1.2 shows the number of employees who had confirmed cases of COVID-19 over the course of the pandemic. As of March 31, 2022, the cumulative case count for employees was 60,667.[22] As of August 1, 2022 (one day after the end of the Interim Review Period), cumulative employee cases had increased by 45.2% to 88,104.[23] By November 1, 2022, the cumulative case count had risen to 94,033—an almost 55% increase in less than 7 months.[24]

As shown in **Figure 1.2**, in January 2022, the initial Omicron wave generated the highest peak in new monthly employee cases—21,602 new cases.[25] The second Omicron wave (BA.5), by comparison, reached a peak of 6,678 new monthly cases in June 2022.[26]

Figure 1.2: *COVID-19 Confirmed Case Counts for VA Employees, March 1, 2020 – November 1, 2022*



Note: The time periods for each wave are defined as: Delta wave: July 1, 2021, through November 30, 2021; initial Omicron wave: December 1, 2021, through March 31, 2022; and second Omicron wave: April 1, 2022, through November 1, 2022.
Source: VHA, response to data request, 11/17/2022. Ref. D227

Despite the difference in their peaks, the longer duration of the second Omicron wave resulted in nearly as many total employee cases as the initial Omicron wave (31,111 and 33,586 cases, respectively).[27] The total employee cases in the second Omicron wave were also over 3.5 times higher than the employee cases in the Delta wave (8,574 from July 1, 2021, through November 30, 2021).[28]

The Annex D Interim Report Review Period typically covers only the period from April 1, 2022, through July 31, 2022, but a broader picture was critical to show the impact of the second Omicron (BA.5) wave on staffing. For more information on the spread of Omicron BA.5 nationally, see the U.S. Epidemiology section.

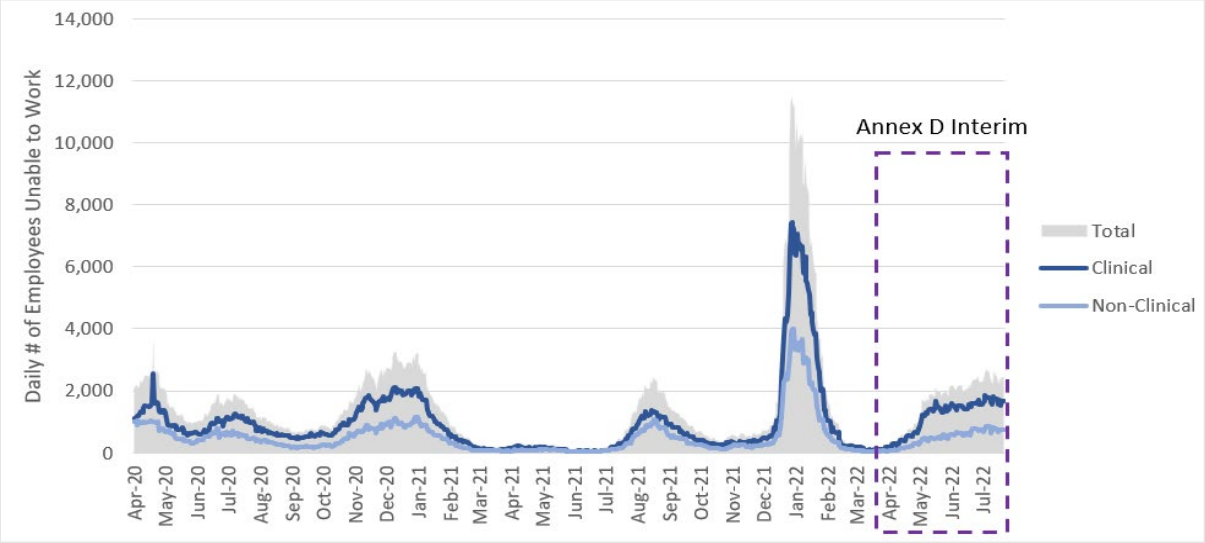
This Army Veteran spent 6 months on a ventilator due to complications related to COVID-19. VA supported him through the process of re-learning skills like walking, talking and playing music. (Photo credit: VA)

Figure 1.3 shows the number of VHA employees who were unable to work during the Interim Review Period due to COVID-19.[29] The employees are shown by service type—clinical and non-clinical.[30] Clinical staff participated in patient-related services,

and non-clinical staff worked in affiliated areas, education, administration and research.[31]

The number of VHA employees who were unable to work due to COVID-19 dropped after January 2022, but the numbers began to rise again during the Interim Review Period.[32] By July 2022, the number of employees unable to work surpassed 2,000 a day.[33]

Figure 1.3: *Daily Number of VHA Employees Unable to Work by Clinician Status, April 10, 2020 – July 31, 2022*

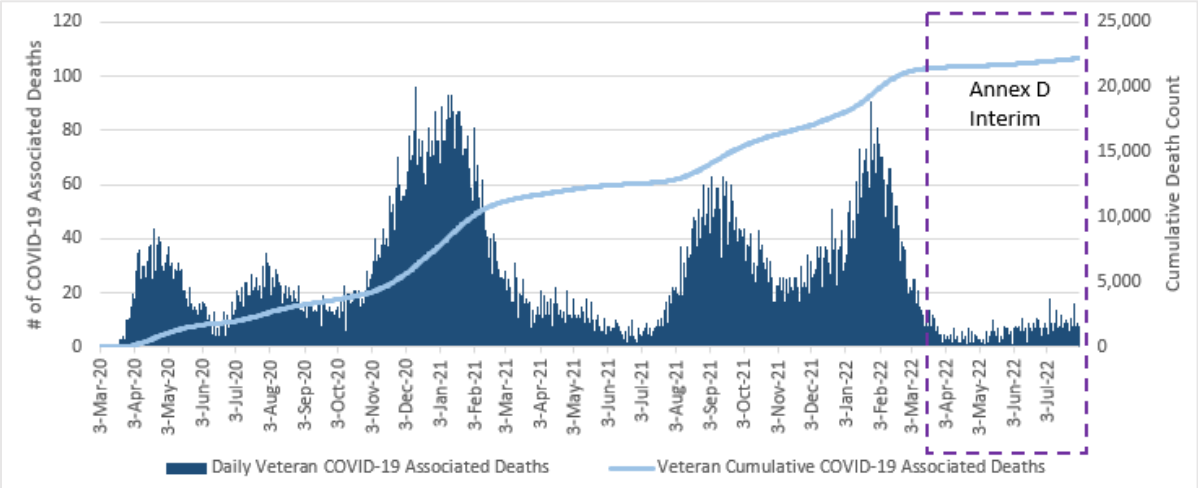


Source: VHA, HOC, response to data call, 9/22/2022. Ref. D219

Veteran COVID-19-associated Deaths

The number of Veterans with COVID-19-associated deaths began to climb during the Interim Review Period although fewer Veterans died in this period than in previous review periods, as shown in **Figure 1.4**.[34] There was an uptick of the number of clinical and non-clinical employees unable to work in the later part of the Interim Report Review Period (from April 1, 2022, through July 31, 2022).[35]

Figure 1.4: *Veteran COVID-19-associated Deaths, through July 31, 2022*



Source: VHA, CDW, NST Dataset: Daily Death Counts, accessed 10/24/2022. Ref. D217

Summary of Adjustments to VHA Approach

During the Interim Report Review Period, VHA continued to work to protect Veterans, their families and VHA employees from the SAR-CoV-2 virus. The organization focused on increasing personnel and improving operating procedures across VHA facilities.[36]

Looking toward an endemic state, VHA emphasized the importance of preparing health care facilities and personnel to respond to the ebbs and flows of the COVID-19 pandemic.[37] For more information on this topic, see the Public Policy section of this report.

Additional adjustments during this period included the following:

- Standardized operating procedures for diagnosis, treatment and rehabilitation for Veterans with Long COVID across VHA facilities. (All efforts in Long COVID were informed and inspired by an emerging community of practice led by approximately 22 VAMCs leaning forward to respond to the needs of Veterans with persistent symptoms.)
- Progressed in implementation of enhanced VHA Clinical Contact Center (CCC) support through VA Health Connect. (VHA leveraged modernized technology and consolidation of CCC management at the VISNs to help Veterans catch up on deferred care.[38] For more information on VA Health Connect and CCC, see the Test to Treat section of this report.)
- Developed, piloted and implemented Virtual Test to Treat programming to facilitate early treatment for mild-to-moderate COVID-19.[39]

- Applied recommended public health policies designed to mitigate risk of COVID-19 exposure, as recommended under CDC criteria for community risk levels.[40]

Fourth Mission and VHA Interagency Agreements

No new Federal Emergency Management Agency (FEMA) Mission Assignments (MAs) or VHA Interagency Agreements (IAAs) were initiated for COVID-19 support during the Interim Review Period.[41]

During the period, 11 Indian Health Service (IHS) IAAs were ongoing, focusing on enhancing bed capacity support and supplementing staff for IHS.[42] Seven-bed capacity support IAAs began in 2020, and 4 IAAs began in 2021 (2-bed capacity support and 2 staffing support).[43] For more details on these initiatives since the beginning of the pandemic, see the Annex C Report.

Clinical deployment teams (CDTs) are designed to support VHA's emergency staffing needs.[44] VHA leadership noted that efforts related to CDTs were in the early development phase and were not yet operational, as of July 31, 2022.[45]

COVID-19 Timeline[46]

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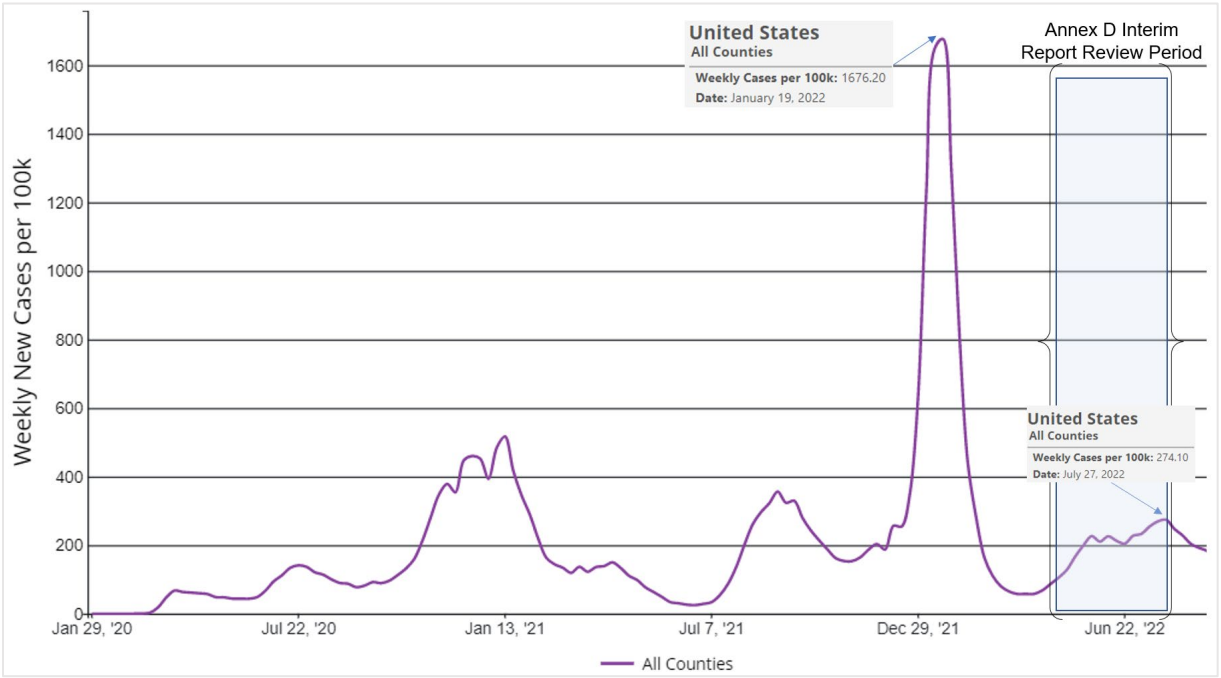
U.S. EPIDEMIOLOGY

This section of the Annex D Interim Report chronicles the changing nature of the SARS-CoV-2 virus and the COVID-19 pandemic throughout the United States from April 1, 2022, through July 31, 2022. This section does not contain specifics related to VHA's response, and it does not rely on VHA data; rather, it provides a high-level picture of the disease's spread, severity and changing nature throughout the United States over the course of the Interim Review Period.

As of July 27, 2022, reported COVID-19 cases in the United States totaled approximately 91 million—around 27% of the U.S. population.[47]

U.S. weekly new cases (per 100,000 people) rose during the Interim Report Review Period, as shown in **Figure 2.1**.[48] According to CDC, cases in this reporting period peaked in late July with a weekly new case rate of 274.[49] By comparison, the highest weekly rate in the Annex C period came in mid-January with a rate of 1,676.[50] Hospitalization rates increased during the Interim Report Review Period as well, particularly for those who were unvaccinated.[51]

Figure 2.1: *Weekly New Case Rate for COVID-19 Infection, per 100,000 People in the United States*



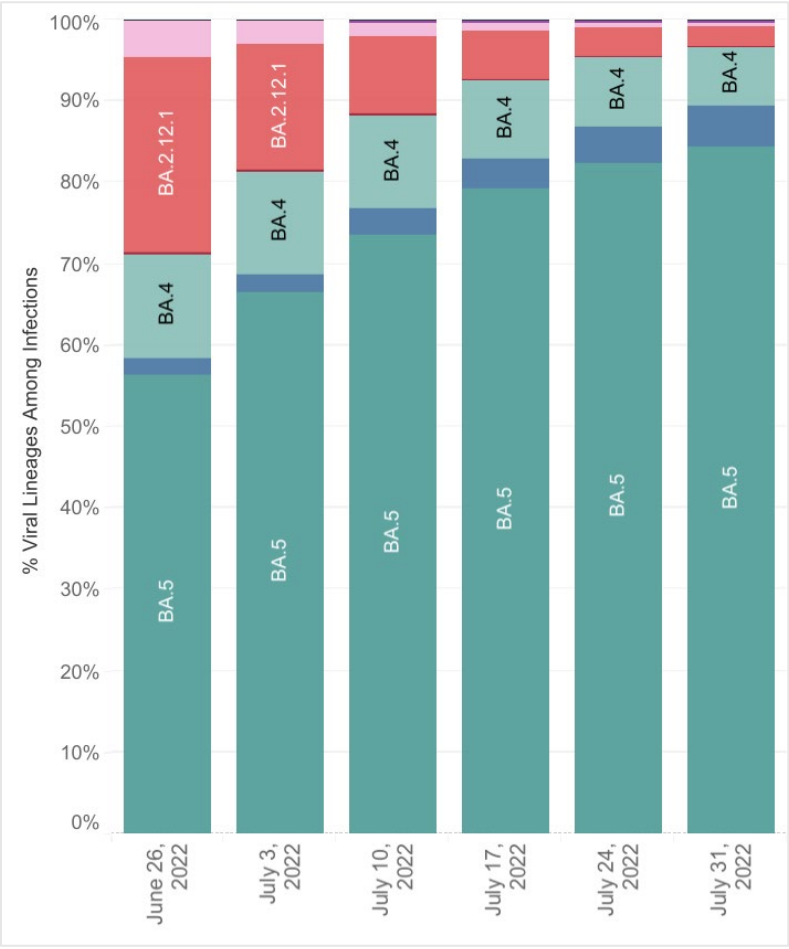
Source: CDC, "Trends in COVID-19 Cases and Deaths in the United States, by County-level Population Factors," accessed 11/8/2022, https://covid.cdc.gov/covid-data-tracker/#pop-factors_7daynewcases.

Omicron Subvariants

The evolution of SARS-CoV-2 (the virus that causes COVID-19) facilitated its continued spread over the last two years.[52]

Recent research found that the initial Omicron variant appeared earlier in the pandemic (as early as December 31, 2020, although it was not identified as a variant of concern until November 30, 2021), but Omicron's later mutations allowed it to spread more rapidly than previous variants and became predominant.[53] As of July 2022, five Omicron subvariants were circulating throughout the United States, as shown in **Figure 2.2**. Omicron BA.5 was by far the most common subvariant—81.9% of all cases at that time.[54] Cases increased in June and July 2022, in part because of the emergence of the more contagious BA.5.[55]

Figure 2.2: *Subvariants of COVID-19 Variant Omicron, 6/26/2022-7/31/2022*

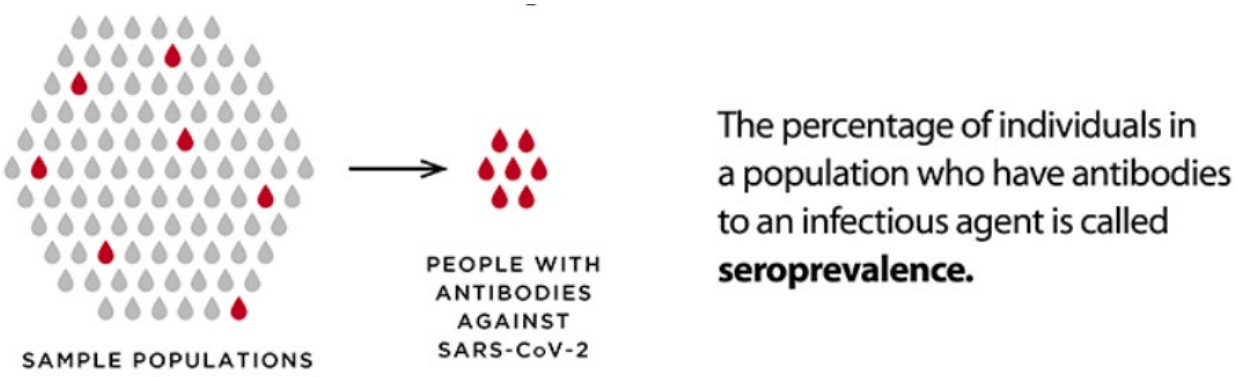


Source: CDC, "Variant Proportions," 7/31/2022, accessed 10/4/2022, https://covid.cdc.gov/covid-data-tracker/#variant-proportions. Ref. D87

Seroprevalence

The term *seroprevalence* refers to the percentage of people in a given population with antibodies in their blood for a specific infection, as shown in **Figure 2.3**.[56] Studying the seroprevalence of COVID-19 can help scientists estimate cumulative infection even for cases that are not reported.[57]

Figure 2.3: *CDC Seroprevalence Chart*

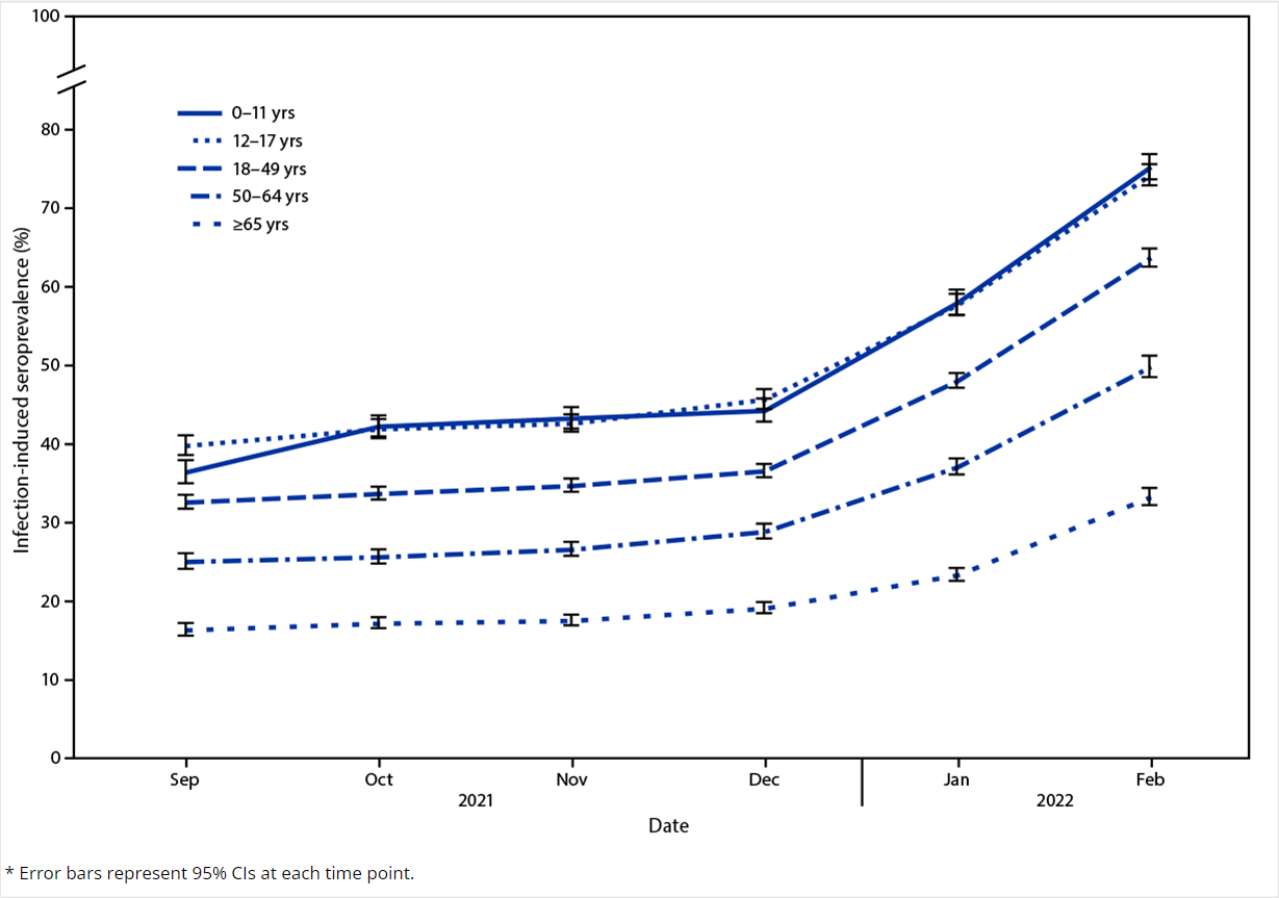


Source: CDC, "What COVID-19 Seroprevalence Surveys Can Tell Us," updated 7/8/2020, accessed 10/4/2022, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/seroprevalance-surveys-tell-us.html. Ref. D86

A CDC study conducted from September 2021 through February 2022 analyzed U.S. blood samples over four weeks, tracking increases in antibodies across the samples.[58] By February 2022, approximately 75% of the child and adolescent samples showed evidence of previous COVID-19 infection.[59] About one-third were newly positive for exposure as of December 2021.[60]

The CDC study also showed a large increase in the overall number of cases of COVID-19 from December 2021 through February 2022.[61] **Figure 2.4** provides insight into the CDC study's findings about seroprevalence over time, by age group.

Figure 2.4: *U.S. Seroprevalence of Infection-induced SARS-CoV-2 Antibodies,* by Age Group, September 1, 2021 – February 28, 2022*



Source: CDC, "Seroprevalence of Infection-Induced SARS-CoV-2 Antibodies—United States, September 2021–February 2022," 4/29/2022, accessed 9/30/2022, https://www.cdc.gov/mmwr/volumes/71/wr/mm7117e3.htm. Ref. D82

Note: CI stands for "confidence interval."

National Vaccination Campaign

As of July 31, 2022, four COVID-19 vaccines were available in the United States, as shown in **Table 2.1**. No new vaccines were authorized during the Interim Review Period.[62]

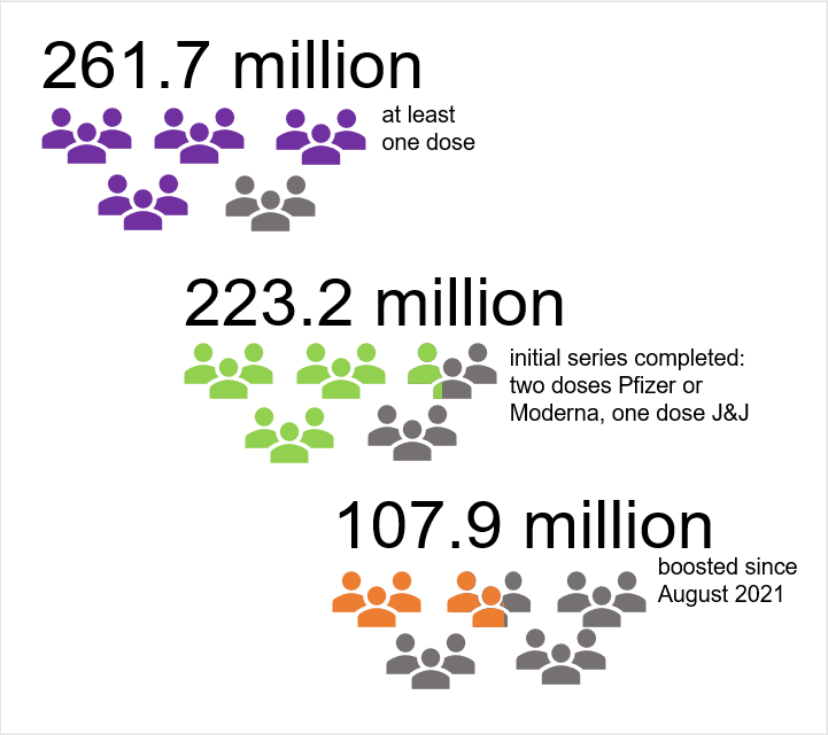
Table 2.1: *COVID-19 Vaccines Available in the United States, as of July 31, 2022*

Pharmaceutical Manufacturer	Vaccine Type	Approval Status	Number of Doses in Initial Series
Pfizer-BioNTech (also called Pfizer or Comirnaty)	mRNA	Fully approved	Two
Moderna (also called Spikevax)	mRNA	Fully approved	Two
Novavax	Protein subunit	EUA	Two
Johnson and Johnson (J&J)	Viral vector	EUA	One

Sources: CDC, "Overview of COVID-19 Vaccines," updated 8/24/2022, accessed 9/30/2022, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/overview-COVID-19-vaccines.html?s_cid=11758:different%20covid%20vaccines:sem.ga:p:RG:GM:gen:PTN:FY22; FDA, "EUA: Novavax COVID-19 Vaccine," updated 4/19/2022, accessed 9/30/2022, https://www.fda.gov/media/159898/download. Ref.s D84, D85

Approximately 78.8% of people in the United States have received at least 1 dose of vaccination against COVID-19 infection, as shown in **Figure 2.5**.[63] Booster shots for those 16 years or older have had full Food and Drug Administration (FDA) authorization since November 2021.[64]

Figure 2.5: *Vaccinations in the United States, as of July 29, 2022*



Source: CDC, "COVID Data Tracker Weekly Review: Protect Those Who Protect Us," 7/29/2022, accessed 9/23/2022, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/past-reports/07292022.html. Ref. D74

On June 18, 2022, FDA issued an Emergency Use Authorization (EUA) for COVID-19 vaccinations from Moderna and Pfizer-BioNTech for children over six months old.[65] This new expanded authorization added 20 million children to the eligible vaccination population.[66] For this age group, the Pfizer-BioNTech vaccine required 3 separate injections, and the Moderna vaccine initial series required 2 injections.[67]

On August 31, 2022—after the close of the Review Period for the Annex D Interim Report—FDA amended the Pfizer and Moderna vaccine EUAs.[68] The updated EUAs allowed Pfizer and Modern to release booster doses of their vaccines with 2

messenger ribonucleic acid (mRNA) components instead of 1 component.[69] The new booster, often called a bivalent booster, included mRNA to combat the original SARS-CoV-2 virus, as well as mRNA that targeted the new Omicron strains, BA.4 and BA.5.[70]

Because it was released after the Interim Review Period, doses of this booster were not included in the vaccination numbers for the Annex D Interim Report.

Reported vs. Actual Cases of COVID-19

Throughout the pandemic, but particularly from February 2020 through September 2021, the number of actual COVID-19 infections was likely much higher than the reported case count.[71] An August 2022 study found that during the period from February 2020 through September 2021, only 1 in 4 cases of U.S. COVID-19 was reported.[72] Using a collection of published statistical models, CDC estimated that in that time period alone, there were likely 146.6 million COVID-19 infections in the United States, including 124 million symptomatic illnesses.[73]

After the broad release of over-the-counter antigen testing, rates of reporting were reduced even further.[74] Self-tests allowed people to test for COVID-19 in their homes without results reaching government health agencies.[75] In a study conducted from October 31, 2021, to June 11, 2022, CDC reviewed the results of self-tests from four manufacturers.[76] Of the 393.4 million tests these 4 manufacturers produced (approximately 15.3% of the self-tests available in the United States at that time), 10.7 million test results were voluntarily reported through manufacturer websites or companion mobile apps.[77] For comparison, laboratory-based test results during that time period totaled approximately 276.3 million, and point-of-care antigen tests totaled 85.6 million.[78] CDC noted that self-testing was an important tool to combat COVID-19 infection and spread; however, the quality (and quantity) of self-test results reporting made it difficult to track the rates of infection.[79]

As of July 27, 2022, more than one million COVID-19 deaths had been reported in the United States.[80] However, CDC estimates indicated that only 1 in 1.32 COVID-19 deaths were reported from February 2020 through September 2021, which suggests that actual deaths due to COVID-19 were higher than reported.[81]

HEALTH EQUITY LITERATURE REVIEW

Since the start of the pandemic, VHA has prioritized research efforts related to the impact of COVID-19 on Veterans, with a particular emphasis on Veterans from high-risk communities.[82] High-risk communities faced increased risk of infection, hospitalization, severe complications and death from COVID-19.[83]

This section of the Annex D Interim Report is a review of published research that used VHA data to study COVID-19 impacts across Veterans of different racial/ethnic groups, rurality and sex/gender.

Some of the notable findings from this review include the following:

- From February 8, 2020, through March 30, 2020, Black Veterans aged 54-75 had disproportionately high rates of COVID-19 positivity, but among those who tested positive, race/ethnicity was not strongly correlated with hospitalization or ICU admission.[84]
- From March 1, 2020, through December 31, 2021, Hispanic Veterans were disproportionately impacted by COVID-19 infection and were more likely to require hospitalization for COVID-19 illness than White Veterans.[85]
- Some racial/ethnic groups experienced greater risk of testing positive or dying from COVID-19 during different time periods.[86] For example, Hispanic Veterans were at the greatest risk of testing positive in summer 2020 (June 1, 2020, through August 31, 2020), but American Indian or Alaska Native (AI/AN) Veterans were most likely to test positive in autumn 2020 (September 1, 2020, through November 25, 2020).[87]
- During the first three months of the pandemic, Veterans living in urban locations were more likely to test positive for COVID-19 than Veterans residing in rural locations.[88] However, by March 2021, Veterans residing in rural locations were just as susceptible to infection from COVID-19 as Veterans in urban areas.[89]
- The increased likelihood of comorbidities and underlying health conditions for certain racial/ethnic groups did not explain the disparity in COVID-19 confirmed cases and deaths from February through July 2020.[90]

Continued research focused on understanding the relationship between COVID-19 and health equity will aid in VHA's efforts to provide access to high-quality care for all Veteran populations.[91]

Research Question

Research Question: How did the impact of COVID-19 (specifically, rates of infection, hospitalization and mortality) vary among Veterans of different racial/ethnic groups, rurality and sex/gender?

The PICO framework helped structure the research question for this literature review. PICO is a mnemonic used in evidence-based practice (EBP) to develop research questions and frame search strategies.[92] PICO stands for Population/Patient, Intervention, Comparison/Control and Outcome.[93] **Table 3.1** outlines the components of the review's PICO question.

Table 3.1: *PICO Framework Guidelines for Literature Review*

PICO Subject Area	Core Element	Literature Review Component
Population/**P**atient	Who is being studied?	Veterans of different minority/ethnic groups, rurality and sex/gender living in the United States who have been impacted by/treated for COVID-19
Intervention	What exposure is being studied?	Infection with COVID-19
Comparison/**C**ontrol	What is the intervention being compared to?	Veterans of different racial/ethnic groups, rurality and sex/gender
Outcome	What are the results of the intervention?	Rates of infection, hospitalization and mortality
Source: UVAHealth, "Pico(T): Definitions and Examples," 3/18/2022, accessed 9/27/2022, https://guides.hsl.virginia.edu/c.php?g=921177&p=6638623. Ref. D66		

Methods and Standards

The population of research studies for this review were drawn from a bibliography created by the VHA Office of Health Equity (OHE). This bibliography, which is updated quarterly, catalogues published research using Veteran data related to health equities and COVID-19.[94] It features a range of studies examining the impact of COVID-19 on Veteran populations grouped by the following:[95]

- Age
- Sex/gender
- Race/ethnicity
- Urban/rural residency
- High-risk settings or shared housing
- Socio-economic status
- Specific mental health issue
- Specific physical health issue

As of September 2022, the VHA OHE bibliography contained 48 studies.[96]

To create this literature review, a systematic search of the bibliography was performed to identify studies relevant to the research question. Titles and abstracts contained in the bibliography were reviewed for key words and phrases such as "equity," "social determinants of health" (SDoH), "racial/ethnic/minority group" and "mortality."

The literature review only considered articles that met the following criteria:

- Published in the English language
- Studied Veteran populations located in the United States
- Included data collected from February 1, 2020, through July 31, 2022

From the 48 articles contained in the bibliography, 15 studies were identified for full-text review. The other 33 articles were excluded, primarily because they focused on a narrower sub-population of Veterans or a specific health-related issue; this review aimed to provide an examination of the broader Veteran population. Some of the excluded articles focused on topics that included:

- A specific health or mental health condition, such as cancer or substance use
- Shared housing in nursing homes or related settings
- One specific socioeconomic population, such as Veterans experiencing homelessness

Studies that did not contain original research or did not contain an analysis of previously included research were also excluded.

Based on a reading of the abstracts about each selected article, studies relevant to the research question were expected to discuss Veterans of different racial/ethnic groups and sex/gender in at least one of these categories:

- Rates of infection
- Hospitalization
- Population mortality

Particular attention was given to studies that discussed disparities between rural and urban environments and changes in infection, hospitalization and mortality rates over time.

After reviewing the 15 articles in full, 3 articles were removed from the literature review. They were removed because of their period of review, the fact that they did not contain original research or the presence of superseding research.

Results

The 12 selected studies (the Selected Studies) employed the following 3 design types:[97]

- **Cross-sectional observational analysis** examines data from a population at a specific point in time.[98]
- **Retrospective cohort analysis** examines a population that shares exposure to an outcome of interest (for instance, COVID-19) using preexisting data and records.[99]
- **Longitudinal cohort analysis** involves repeatedly collecting data from the same population over a specific period of time.[100]

Data analyzed by the Selected Studies included variables on demographics, comorbidities, lab test results and SDoH.[101]

The 12 studies pulled their data from multiple sources, including VA's electronic health record (EHR) system, the United States Veterans Eligibility Trends and Statistics (USVETS) dataset and the VA COVID-19 Shared Data Resource, which is a tool used to support and facilitate COVID-19 research.[102]

One study built a COVID-19 surveillance platform on a pre-existing tool—the Surveillance Platform for Enteric and Respiratory Infectious Organisms in the Veterans Affairs (SUPERNOVA)—that captures instances of respiratory and gastric illness across five VAMCs.[103]

All studies leveraged relatively large sample sizes, ranging from 88,747 to 9,127,673 Veterans, depending on the length of the study period and the geographical focus area.[104] Sample populations were diverse and included a wide range of ages, races/ethnicities and underlying health conditions.[105] Both males and females were represented within the Veteran population studied.[106]

To help answer the research question and ascertain the impact of COVID-19 across Veterans of different racial/ethnic groups, study results were categorized into three areas:

- Testing and infection
- Hospitalization
- Mortality

Each study used its own method to select the COVID-19-positive Veterans included in their research, but each of the Selected Studies used at least one of the following:

- Veterans who sought out testing or evaluation for COVID-19 at VA facilities[107]

- Veterans who were admitted to a VAMC who tested positive for COVID-19 within the 14-day period preceding their hospitalization or during their hospitalization[108]
- Veterans who had one or more clinical encounters at a VA facility within the timeframe specified by the study prior to testing positive for COVID-19[109]

Table 3.2 provides an overview of the studies in the literature review, including study design type, sample population, dates, key variables of interest and findings.

Table 3.2: *Literature Review Studies on Health Equity and COVID-19*

Authors & Titles	Methods and Sample	Key Findings	Includes COVID-19 test results from tests performed outside VA
Rentsch et al., COVID-19 Testing, Hospital Admission, and Intensive Care Among 2,026,227 United States Veterans Aged 54-75 Years	Retrospective Cohort Analysis (2/8/2020 – 3/3/2020) Key variables: COVID-19 positive, demographics, comorbidities, medication history substance use, vital signs, lab measures Study sample population = 2,026,227 Veterans born from 1945 through 1965 and engaged in care at VHA	Black Veterans experienced a higher rate of COVID-19 positive tests than non-Black Veterans, but not a greater rate of hospitalization or ICU admittance.	Yes
Cardemil et al., COVID-19-Related Hospitalization Rates and Severe Outcomes Among Veterans From 5 Veterans Affairs Medical Centers: Hospital-Based Surveillance Study	Cross-sectional Surveillance Analysis (2/27/2020 – 7/17/2020) Key variables: COVID-19 positive, demographics, underlying conditions, clinical outcomes Study sample population = 396,280 Veterans obtaining care in inpatient and outpatient facilities in FY 2019 in Atlanta, Bronx, Houston, Los Angeles and Palo Alto	Older Veterans experienced high hospitalization rates and a higher rate of severe outcomes to COVID-19 infection. Hispanic and non-Hispanic Black Veterans also experienced higher hospitalization rates than non-Hispanic White Veterans.	No
Upchurch et al., COVID-19 Infection in the Veterans Health Administration: Gender-specific Racial and Ethnic Differences	Retrospective Cohort Analysis (3/1/2020 – 8/5/2020) Key variables: COVID-19 positive, demographics, prior diagnoses and comorbidities Study sample population = 355,603 Veterans with a COVID-19 test result from any VHA facility	AI/AN, Hispanic and Black Veterans were disproportionately impacted by COVID-19 and more likely to experience a positive COVID-19 test than White Veterans.	No

Authors & Titles	Methods and Sample	Key Findings	Includes COVID-19 test results from tests performed outside VA
Wong et al., Time Trends in Racial/Ethnic Differences in COVID-19 Infection and Mortality	Retrospective Cohort Analysis (3/1/2020 – 11/25/2020) Key variables: Veteran race/ethnicity, COVID-19 positive, mortality, demographics and clinical conditions Study sample population = 705,715 Veterans who received polymerase chain reaction (PCR) tests	The racial and ethnic groups at highest risk of experiencing a positive COVID-19 test or dying from COVID-19 changed over time. AI/AN, Black, Hispanic, and Native Hawaiian/Other Pacific Islander (NHOPI) Veterans experienced higher rates of COVID-19 infection during summer compared to non-Hispanic White Veterans.	No
Ioannou et al., Changes in the associations of race and rurality with SARS-CoV-2 infection, mortality, and case fatality in the United States from February 2020 to March 2021: A population-based cohort study	Retrospective Cohort Analysis (2/1/2020 – 3/31/2021) Key variables: Veteran race/ethnicity, demographics, urban v. rural, comorbidities, COVID-19 positive Study sample population = 9,127,673 individuals aged 18 years or older who were alive and enrolled in care at VHA on 2/1/2020	Black and AI/AN Veterans and Veterans living in urban environments were less likely to test positive or die from COVID-19 over time.	No
Ferguson et al., Geographic and temporal variation in racial and ethnic disparities in SARS-CoV-2 positivity between February 2020 and August 2021 in the United States	Retrospective Cohort Analysis (2/12/2020 – 8/16/2021) Key variables: Race/ethnicity, age, sex, U.S. Census region, time and COVID-19 positive Study sample population = 1,313,402 Veterans tested for COVID-19 in VA medical facilities	Racial and ethnic disparities associated with testing positive for COVID-19 were most significant at the beginning of the pandemic and decreased over time.	Yes

Authors & Titles	Methods and Sample	Key Findings	Includes COVID-19 test results from tests performed outside VA
Rentsch et al., Patterns of COVID-19 testing and mortality by race and ethnicity among United States veterans: A nationwide cohort study	Retrospective Cohort Analysis (2/8/2020 – 7/22/2020) Key variables: Race/ethnicity, demographics, clinical conditions, pharmacy fills, region, time, outbreak pattern and COVID-19 positive Study sample population = 5,834,543 individuals receiving care in the VA health care system	Black and Hispanic Veterans were disproportionately impacted by COVID-19 infection despite controlling for demographics, geographic location and comorbidities.	Yes
Ioannou et al., Risk Factors for Hospitalization, Mechanical Ventilation, or Death Among 10,131 U.S. Veterans With SARS-CoV-2 Infection	Longitudinal Cohort Analysis (2/28/2020 – 5/14/2020) Key variables: COVID-19 positive, demographics, comorbidities, symptoms and lab rest results Study sample population = 88,747 individuals tested for COVID-19 by PCR in the VA health care system	Veterans who are male, older and have an increased comorbidity burden had a higher risk of dying from COVID-19.	Yes
Ferguson et al., Differences in COVID-19 Testing and Test Positivity Among Veterans, United States, 2020	Retrospective Cohort Analysis (2/8/2020 – 12/18/2020) Key variables: Demographics, COVID-19 positive, urban/rural status, geographic region and priority group (disability status) Study sample population = 6,292,800 Veterans in VHA care at 130 VHA medical facilities	Despite access to subsidized care, Black and Hispanic/Latino Veterans were more likely to test positive for COVID-19, which suggested other inequalities impacted COVID-19 prevalence.	No
Ferguson et al., Temporal Variation in Individual Social Risk Factors Associated with Testing Positive for SARS-CoV-2 Among Veterans in the Veterans Health Administration	Retrospective Cohort Analysis (2/27/2020 – 2/16/2021) Key variables: SDoH (household size, poverty levels, education), time and COVID-19 positive Study sample population = 946,358 Veterans who obtained testing or treatment for COVID-19 at VA medical facilities	Veterans with larger households had increased risk of testing positive for COVID-19. SDoH may have impacted the likelihood of a Veteran testing positive for COVID-19.	No

Authors & Titles	Methods and Sample	Key Findings	Includes COVID-19 test results from tests performed outside VA
Luo et al., Hospitalization, mechanical ventilation, and case-fatality outcomes in U.S. veterans with COVID-19 disease between years 2020-2021	Retrospective Cohort Analysis (3/1/2020 – 12/31/2021) Key variables: Demographics, COVID-19 positive, symptom severity outcomes and body mass index (BMI) Study sample population = 419,559 Veterans who tested positive for COVID-19 in the VA hospital system	Veterans aged 65 or older and Veterans who are underweight experienced a greater incidence of death from COVID-19. When adjusting for age, there was no increased incidence of death in Black Veterans compared to White Veterans.	No
Abdel Magid et al., Differences in COVID-19 Risk by Race and County-Level Social Determinants of Health among Veterans	Retrospective Cohort Analysis (2/8/2020 – 12/28/2020) Key variables: Demographics, COVID-19 positive, home location and county-level SDoH Study sample population = 778,599 Veterans enrolled in VA care who were tested for COVID-19 at VA	County-level SDoH factors influenced COVID-19 infection risk; with a greater likelihood of testing positive for COVID-19 with increased county-level SDoH.	No

Notes: Information highlighted in the table above is not inclusive of all variables and findings from the studies contained in this review.

Sources: Rentsch et al., “COVID-19 Testing, Hospital Admission, and Intensive Care Among 2,026,227 United States Veterans Aged 54-75 Years,” 4/14/2020; Cardemil et al., "COVID-19-Related Hospitalization Rates and Severe Outcomes Among Veterans From 5 Veterans Affairs Medical Centers: Hospital-Based Surveillance Study," 1/21/2022; Upchurch et al., "COVID-19 Infection in the Veterans Health Administration: Gender-specific Racial and Ethnic Differences," 10/2/2021; Wong et al., “Time Trends in Racial/Ethnic Differences in COVID-19 Infection and Mortality,” 5/1/2021; Ioannou et al., “Changes in the associations of race and rurality with SARS-CoV-2 infection, mortality, and case fatality in the United States from February 2020 to March 2021: A population-based cohort study,” 10/21/2021; Ferguson et al., "Geographic and temporal variation in racial and ethnic disparities in SARS-CoV-2 positivity between February 2020 and August 2021 in the United States," 1/7/2022; Rentsch et al., “Patterns of COVID-19 testing and mortality by race and ethnicity among United States veterans: A nationwide cohort study,” 9/22/2020; Ioannou et al., “Risk Factors for Hospitalization, Mechanical Ventilation, or Death Among 10 131 US Veterans With SARS-CoV-2 Infection,” 9/1/2020; Ferguson et al., "Differences in COVID-19 Testing and Test Positivity Among Veterans, "4/7/2021; Ferguson et al., “Temporal Variation in Individual Social Risk Factors Associated with Testing Positive for SARS-CoV-2 Among Veterans in the Veterans Health Administration,” 6/23/2022; Luo et al., “Hospitalization, mechanical ventilation, and case-fatality outcomes in US veterans with COVID-19 disease between years 2020-2021,” 4/21/2022; Abdel Magid et al., “Differences in COVID-19 Risk by Race and County-Level Social Determinants of Health among Veterans,” 12/13/2021.

Assessment of Testing and Infection

COVID-19 positivity was determined using data from polymerase chain reaction (PCR) testing, obtained primarily through nasopharyngeal swabs.[110] Antibody tests were excluded from some analyses as were VA employee COVID-19 test results.[111] COVID-19 test samples were analyzed in VA facility laboratories, state public health laboratories or commercial laboratories.[112]

VHA is committed to reducing financial barriers and increasing access to health care for eligible Veterans.[113] As part of that effort, VHA tested a greater number of marginalized community members compared to other health care systems.[114] This increased testing of traditionally disenfranchised populations enabled VHA researchers to identify unique findings in testing patterns across Veterans of different race/ethnicities and sex/genders.[115]

For example, the study on COVID-19 testing and test positivity by Ferguson et al. found that Veterans with service-connected disabilities and lower incomes were more likely to obtain COVID-19 testing than low-income individuals external to the VHA system.[116]

Similarly, studies conducted by Rentsch et al. from February 8, 2020, through March 30, 2020, and by Ferguson et al. from February 8, 2020, through December 28, 2020, found that Black and Hispanic/Latino Veterans were more likely to obtain COVID-19 testing compared to White Veterans.[117] Black (23%) and Hispanic/Latino (43%) Veterans, according to Ferguson et al., were also more likely to test positive compared to White and non-Hispanic/Latino Veterans tested for COVID-19.[118] In addition, even when controlling for the higher positivity rates in the locations where Black Veterans were tested, Rentsch et al. found that these Veterans were still more likely to test positive among study participants tested for COVID-19.[119]

Testing and positivity rates varied between male and female Veterans. From February 8, 2020, through March 30, 2020, Rentsch et al. found that female Veterans were more likely to obtain testing for COVID-19 than male Veterans.[120] Despite these increased rates of testing, Ferguson et al., found that among Veterans tested from February 8, 2020, through December 20, 2020, female Veterans were less likely than male Veterans to receive a positive COVID-19 test result.[121]

A study by Wong et al. conducted during 2020 found that for Veterans of different racial/ethnic groups, the risk of testing positive for COVID-19 changed over time.[122] For example, among Veterans evaluated for COVID-19 at VHA during the study period, non-Hispanic Black Veterans had the greatest risk of testing positive in spring 2020 (March 1, 2020, through May 31, 2020), Hispanic Veterans were more

likely to test positive in summer 2020 (June 1, 2020, through August 31, 2020), and AI/AN Veterans had increased rates of COVID-19 positivity in autumn 2020 (September 1, 2020, through November 25, 2020).[123] These variations, according to Wong et al., underscore the importance of examining disparities in the context of time.[124] Doing so will allow VHA and other health care organizations to tailor future pandemic and crisis response efforts to support the most impacted groups in a timely manner.[125]

Rates of testing and prevalence of COVID-19 positive cases also varied by geographical location.[126] Studies conducted from February 8, 2020, through December 28, 2020, found that urban-dwelling Veterans were more likely to seek testing and test positive for COVID-19 than Veterans living in rural locations.[127] Although there was an initial concentration of COVID-19 cases in metropolitan areas, as the pandemic became more widespread, the association between COVID-19 infection and urban residence decreased.[128] For instance, a study by Ioannou et al. found that Veterans living in urban locations from February 2020 through April 2020 had an increased risk of testing positive for COVID-19 compared to rural residents; however, by March 2021, Veterans living in rural areas were just as likely to test positive for COVID-19 as Veterans residing in urban locations.[129]

This shift from urban to rural risk did not negate the unique challenges faced by at-risk Veterans in both urban and rural environments.[130] For example, Ferguson et al. noted an association between testing positive for COVID-19 and living in counties with higher percentages of Medicaid-eligible individuals, non-White and non-U.S.-born residents.[131] Ioannou et al. found a similar association, noting that factors such as overcrowding, housing distress and a reliance on public transportation may increase urban-dwelling Veterans' exposure to and risk of contracting and dying from COVID-19.[132]

In rural locations, a different set of challenges may have contributed to increased rates of infection and mortality.[133] Ioannou et al. noted that inaccessibility to COVID-19 screening and care, higher rates of disability, a lack of social capital and the commonness of high-risk jobs (including meat processing) resulted in increased risk of testing positive for COVID-19.[134] These findings highlight that SDoH, including financial resources and the locations in which they are concentrated, may impact Veteran COVID-19 testing and infection rates.[135] Further research is needed to better understand the relationship between these factors, SDoH and COVID-19.[136]

Assessment of Hospitalizations

In severe cases of COVID-19, some Veterans were hospitalized, and a smaller subset required escalated care, including admittance to ICUs or mechanical

ventilation (MV).[137] Several of the Selected Studies found that a Veteran's sex/gender, rurality or race/ethnicity were associated with an increased risk of hospitalization and an escalation in the required level of care.[138]

Across multiple studies, male Veterans experienced higher rates of hospitalization and ICU admission and were more likely to require MV than female Veterans.[139] A study of Veterans aged 54-75 years conducted from February 8, 2020, through March 30, 2020, by Rentsch et al. found that 29.6% of the female Veterans who tested positive for COVID-19 were hospitalized.[140] Among the male Veterans who tested positive, 51.8% were hospitalized.[141] Of these groups, 11.1% of females and 21.3% of males were admitted to the ICU.[142] As the pandemic progressed, male Veterans continued to experience higher rates of hospitalization and escalated care.[143] In their multi-year study, Luo et al. found that from March 1, 2020, through December 31, 2021, a total of 85.7% (359,591 of 419,559) of the study sample population who tested positive for COVID-19 were male. In addition, 94.2% (55,316 of 58,728) of hospitalized Veterans were male, and 96.1% (6,522 of 6,789) of hospitalized Veterans requiring MV were male.[144]

An ICU nurse based at the West Palm Beach, Florida VAMC (Photo credit: VA)

Luo et al. further noted that among Veterans who tested positive for COVID-19 (419,559), age-adjusted rates indicated that 11.75% of male Veterans were hospitalized.[145] Among hospitalized Veterans (58,728), age-adjusted rates showed that 11.75% of male Veterans required MV.[146]

Hospitalization rates and the need for MV also varied by race and ethnicity across different time periods.[147] Rentsch et al. found that from February 8, 2020, through March 30, 2020, Black Veterans did not experience increased rates of hospitalization or escalated care compared to non-Black Veterans.[148]

However, studies following outcomes across a longer period of time found that Veterans of different races and ethnicities experienced increased rates of hospitalization and MV, and Hispanic or Latino and non-Hispanic Black Veterans were disproportionately impacted.[149] For example, Cardemil et al. found that from February 27, 2020, through July 17, 2020, Black and Hispanic/Latino Veterans experienced 4.6- and 4.2-times higher rates of hospitalization, respectively, compared to non-Hispanic White Veterans.[150] Similarly, Luo et al. found that among Veterans hospitalized from March 1, 2020, through December 31, 2021, Hispanic and Latino, Black and AI/AN Veterans had higher incidences of hospitalization compared to White Veterans.[151] Black, Hispanic and Latino, AI/AN and Native Hawaiian or Other Pacific Islander (NHOPI) Veterans also experienced increased incidence of MV; the highest rates of MV were found among AI/AN and NHOPI Veterans.[152]

As reported in Luo et al., certain factors may have impacted the increased use of MV in certain racial/ethnic groups.[153] For instance, Ioannou et al. noted that prior studies found that Black Veterans were less likely to have advanced health care directives in place—such as living wills or do-not-resuscitate orders—which may have resulted in an increased rate of MV usage.[154] For AI/AN Veterans residing in rural locations, financial and transportation barriers may have limited or prevented Veterans from accessing health care services in a timely manner.[155] This delayed intervention may be partly responsible for the increased incidence of MV in these populations and more severe illness could require escalated treatment, as noted in other studies.[156]

Risk factors, including prevalence of comorbidities, have been associated with an increase in severe COVID-19 outcomes, such as hospitalization and MV.[157] The prevalence of these comorbidities vary by race and ethnicity across Veteran populations.[158] The following list shows the comorbidities that disproportionately affect each listed race and ethnicity:

- Non-Hispanic Black Veterans: chronic kidney disease, type two diabetes, compromised immune system[159]
- Hispanic Veterans: liver disease[160]
- Non-Hispanic White Veterans: chronic obstructive pulmonary disease (COPD), heart disease, obesity[161]
- AI/AN: obesity[162]

- NHOPI: obesity[163]

Identifying risk factors (including prevalence of comorbidities that are known to increase severe outcomes in Veterans with COVID-19) may enable VHA and other health care organizations to intervene earlier, using targeted prevention, control and treatment mechanisms for at-risk Veteran populations receiving care at VHA facilities.[164]

Although Rentsch et al. included only a limited discussion of hospitalization, ICU admission and MV relative to rural residency, the study found that from February 8, 2020, through March 30, 2020, a total of 27 of 56 Veterans residing in rural locations (48.2%) were hospitalized due to COVID-19, compared to 270 of 529 (51.0%) urban-dwelling Veterans.[165] Of those hospitalized, 9 of 27 (33.3%) rural Veterans and 113 of 270 (41.9%) urban Veterans were admitted to the ICU.[166]

Assessment of Mortality

Across the Selected Studies, the number of COVID-19-associated deaths varied by sex/gender, race/ethnicity and residential location and were measured in population mortality or case fatality.[167] Through January 2021, studies found that male, NHOPI, AI/AN and urban-dwelling Veterans faced higher rates of population mortality and case fatality, and increased risk of death from COVID-19.[168]

Across multiple studies, male Veterans were more likely to die from COVID-19 than female Veterans.[169] In a study of 88,747 Veterans tested for COVID-19 from February 28, 2020, through May 14, 2020, Ioannou et al. found that there was a significant portion of 30-day mortality risk attributable to the male sex (compared with the female sex).[170] In a subsequent study examining COVID-19-related mortality from February 1, 2020, through March 31, 2021, Ioannou et al. found that male Veterans continued to experience increased mortality compared to female Veterans.[171] Ioannou et al.'s findings are outlined in Table 3.3 below.

***Table 3.3**: Veteran COVID-19-related deaths, February 2020 – February 2021*

Time Period	Female (Mortality (95% CI))	Male (Mortality (95% CI))
February 2020 – April 2020 Sample Size: 9,127,673	1	2.14 (1.28-3.59)
May 2020 – June 2020 Sample Size: 9,059,880	1	1.21 (0.81-1.81)
July 2020 – August 2020 Sample Size: 8,998,307	1	1.52 (1.05-2.21)
September 2020 – October 2020 Sample Size: 8,922,764	1	1.96 (1.15-3.35)

Time Period	Female (Mortality (95% CI))	Male (Mortality (95% CI))
November 2020 – December 2020 Sample Size: 8,857,881	1	1.50 (1.17-1.94)
January 2020 – February 2021 Sample Size: 8,790,422	1	1.68 (1.30-2.16)
Entire Period: February 2020 – February 2021 Sample Size: 9,127,673	1	1.59 (1.38-1.82)
Note: Adjusted for sex, age, race, ethnicity, geographical region, urban/rural location, BMI and comorbidity burden. Source: Ioannou et al., "Changes in the associations of race and rurality with SARS-CoV-2 infection, mortality, and case fatality in the United States from February 2020 to March 2021: A population-based cohort study," pg. 18, 10/21/2021, https://pubmed.ncbi.nlm.nih.gov/34673772/. Ref. D57		

This trend continued through the end of 2021, as noted by Luo et al.[172] Luo et al.'s study found that among Veterans infected from March 1, 2020, through December 31, 2021, 201 of 59,965 (0.34%) COVID-19-positive female Veterans died, and 8,441 of 359,591 (2.3%) COVID-19-positive male Veterans died.[173] Age-adjusted case fatality rates were 8.06% for female Veterans and 12.10% for male Veterans included in the study sample population.[174] Table 3.4 outlines Luo et al.'s findings in greater detail.

Table 3.4: *60-day outcomes for Veterans who tested positive for COVID-19, 2020 and 2021*

Outcome of Interest	All Persons Total #	Female Total # (%)	Male Total # (%)
COVID-19-Positive	419,559	59,965 (14.3%)	359,591 (85.7%)
Fatality (Hospitalized Cohort)	8,642	201 (2.3%)	8441 (97.7%)
Source: Luo et al., "Hospitalization, mechanical ventilation, and case-fatality outcomes in US veterans with COVID-19 disease between years 2020-2021," pg. 39, 4/21/2022, https://pubmed.ncbi.nlm.nih.gov/35462045/. Ref. D55			

Mortality proportion compares deaths in a population over time, considering the relationship between certain sub-groups (for instance, different races or ethnicities) and the whole population.[175] During the pandemic, mortality proportion varied by race and ethnicity, changing over time.[176] For example, a study by Wong et al. found that some Veteran races/ethnicities experienced increased mortality in summer 2020 (June 1, 2020, through August 31, 2020), particularly AI/AN Veterans.[177] When compared to the age-adjusted mortality proportion of Asian (2.09), non-Hispanic Black (0.98), Hispanic (1.32) and NHOPI (1.07) Veterans, AI/AN (2.16) Veterans were more likely to experience mortality and were twice as likely to die than Non-Hispanic White (1.00) Veterans.[178]

Disparities were also found in spring 2020 (March 1, 2020, through May 31, 2020) with increased mortality among AI/AN Veterans (17%).[179] In autumn 2020 (September 1, 2020, through November 25, 2020), NHOPI (2.8%) and AI/AN (2.7%) Veterans experienced increased mortality compared to Veterans of other racial/ethnic groups.[180]

Numbers in models adjusted for age, sex and diagnoses of CDC-identified risk factors indicate mortality proportions for AI/AN Veterans of 1.41 (spring 2020) and 1.40 (autumn 2020), and in NHOPI Veterans of 1.00 (autumn 2020).[181] Across all time periods examined in 2020—spring, summer and autumn—in unadjusted analyses, mortality proportions among non-Hispanic Black and Hispanic Veterans were lower than those experienced by non-Hispanic White Veterans.[182] In adjusted analyses, mortality proportions among non-Hispanic Black Veterans (compared to non-Hispanic White Veterans) were lower in summer 2020 (0.98) and autumn 2020 (0.77).[183] Among Hispanic Veterans, mortality proportions were lower in autumn 2020 (0.97) than for non-Hispanic White Veterans.[184]

Although Black Veterans experienced higher rates of hospitalization and MV (compared to White Veterans) from February 28, 2020, through May 14, 2020, Ioannou et al. found that Black Veterans were not more likely to die from COVID-19.[185] Rentsch et al. found similar results, noting that among Veterans who tested positive for COVID-19 from February 8, 2020, through July 22, 2020, there were no differences in 30-day mortality by race or ethnicity.[186] Similarly, Luo et al. found that Black race and Hispanic ethnicity were not associated with increased rates of death (compared to White Veterans) from March 1, 2020, through February 28, 2022.[187]

From February 1, 2020, through March 31, 2020, Ioannou et al. noted an increased risk of mortality (4 times higher) and an increased risk of case fatality (2.2 times higher) among Black Veterans; however, this risk decreased over time and was not significant by November 2020.[188] Some studies (including those by Luo et al. and Ferguson et al.) speculated that access to subsidized or free quality care at VHA facilities may have contributed to a reduction in mortality and case fatality in Veterans of different races/ethnicities, compared to minority groups receiving care at non-VHA facilities.[189]

Rentsch et al. included only a limited review of data related to rurality and death from COVID-19, based on a population of Veterans tested for COVID-19 from February 8, 2020, through July 22, 2020.[190] The study noted that of the sample population in VHA care, 34.3% (2,002,299) of Veterans resided in rural locations, and 65.7% (3,832,244) lived in urban settings.[191] From these groups, 1,057 Veterans died from COVID-19, with 11.4% (121) of Veterans located in rural areas, compared to 88.6% (936) of Veterans in urban locations.[192] Similar results were noted by Ioannou et al., which found that from February through April 2020, urban-dwelling Veterans experienced an increased risk of mortality (2.5 times higher) and an increased risk of case fatality (2.2 times higher) compared to Veterans living in rural areas.[193] Generally speaking, this risk decreased over time, but Ioannou et al. found that after September 2020, COVID-19-related mortality and case fatality in rural and urban locations reversed, and rural death rates were higher through January 2021.[194]

Limitations and Areas for Future Research

Limitations, which are expected and explained in research studies, are potential constraints that can impact the study's findings or the ways the findings are used.[195] These constraints may be the result of the research study's design or methods or may be related to the researcher's ability to obtain information.[196] The Selected Studies had several limitations identified and documented by the study authors, including the following:

- Underrepresentation of female Veterans in study sample populations compared to the general population[197]
- Variations in testing access, testing protocols, social distancing policies or treatment mechanisms across facilities, time or geographic location[198]
- Underestimation of rates of infection, hospitalization, MV or mortality among Veterans studied due to incomplete capture of COVID-19 tests and hospital admissions that occurred outside the VHA system[199]
- Limited generalizability to populations that do not have access to VHA services or rely on other institutions for health care.[200]

Table 3.5 outlines these limitations in greater detail.

Table 3.5: *Limitations in the Selected Studies, as Identified by Study Authors*

Authors & Titles	Under-representation of Female Veterans	Variations in Testing Access, Protocols or Policies and Treatment Mechanisms	Underestimation of Rates of Infection, Hospitalization, MV or Mortality	Limited Generalizability to Populations External to VHA
Rentsch et al., COVID-19 Testing, Hospital Admission, and Intensive Care Among 2,026,227 United States Veterans Aged 54-75 Years	X	X		
Cardemil et al., COVID-19-Related Hospitalization Rates and Severe Outcomes Among Veterans From 5 Veterans Affairs Medical Centers: Hospital-Based Surveillance Study	X	X	X	
Upchurch et al., COVID-19 Infection in the Veterans Health Administration: Gender-specific Racial and Ethnic Differences				X

Authors & Titles	Under-representation of Female Veterans	Variations in Testing Access, Protocols or Policies and Treatment Mechanisms	Underestimation of Rates of Infection, Hospitalization, MV or Mortality	Limited Generalizability to Populations External to VHA
Wong et al., Time Trends in Racial/Ethnic Differences in COVID-19 Infection and Mortality		X		X
Ioannou et al., Changes in the associations of race and rurality with SARS-CoV-2 infection, mortality, and case fatality in the United States from February 2020 to March 2021: A population-based cohort study	X		X	X
Ferguson et al., Geographic and temporal variation in racial and ethnic disparities in SARS-CoV-2 positivity between February 2020 and August 2021 in the United States		X	X	X
Rentsch et al., Patterns of COVID-19 testing and mortality by race and ethnicity among United States veterans: A nationwide cohort study	X		X	
Ioannou et al., Risk Factors for Hospitalization, Mechanical Ventilation, or Death Among 10,131 US Veterans With SARS-CoV-2 Infection	X	X	X	
Ferguson et al., Differences in COVID-19 Testing and Test Positivity Among Veterans, United States, 2020	X	X	X	X
Ferguson et al., Temporal Variation in Individual Social Risk Factors Associated with Testing Positive for SARS-CoV-2 Among Veterans in the Veterans Health Administration	X		X	X
Luo et al., Hospitalization, mechanical ventilation, and case-fatality outcomes in U.S. veterans with COVID-19 disease between years 2020-2021			X	

Authors & Titles	Under-representation of Female Veterans	Variations in Testing Access, Protocols or Policies and Treatment Mechanisms	Underestimation of Rates of Infection, Hospitalization, MV or Mortality	Limited Generalizability to Populations External to VHA
Abdel Magid et al., Differences in COVID-19 Risk by Race and County-Level Social Determinants of Health among Veterans	X			

Notes: Information highlighted in the table above is not inclusive of all limitations identified in the studies contained in this review.
Sources: Rentsch et al., "COVID-19 Testing, Hospital Admission, and Intensive Care Among 2,026,227 United States Veterans Aged 54-75 Years," 4/14/2020; Cardemil et al., "COVID-19-Related Hospitalization Rates and Severe Outcomes Among Veterans From 5 Veterans Affairs Medical Centers: Hospital-Based Surveillance Study," 1/21/2022; Upchurch et al., "COVID-19 Infection in the Veterans Health Administration: Gender-specific Racial and Ethnic Differences," 10/2/2021; Wong et al., "Time Trends in Racial/Ethnic Differences in COVID-19 Infection and Mortality," 5/1/2021; Ioannou et al., "Changes in the associations of race and rurality with SARS-CoV-2 infection, mortality, and case fatality in the United States from February 2020 to March 2021: A population-based cohort study," 10/21/2021; Ferguson et al., "Geographic and temporal variation in racial and ethnic disparities in SARS-CoV-2 positivity between February 2020 and August 2021 in the United States," 1/7/2022; Rentsch et al., "Patterns of COVID-19 testing and mortality by race and ethnicity among United States veterans: A nationwide cohort study," 9/22/2020; Ioannou et al., "Risk Factors for Hospitalization, Mechanical Ventilation, or Death Among 10 131 US Veterans With SARS-CoV-2 Infection," 9/1/2020; Ferguson et al., "Differences in COVID-19 Testing and Test Positivity Among Veterans,"4/7/2021; Ferguson et al., "Temporal Variation in Individual Social Risk Factors Associated with Testing Positive for SARS-CoV-2 Among Veterans in the Veterans Health Administration," 6/23/2022; Luo et al., "Hospitalization, mechanical ventilation, and case-fatality outcomes in US veterans with COVID-19 disease between years 2020-2021," 4/21/2022; Abdel Magid et al., "Differences in COVID-19 Risk by Race and County-Level Social Determinants of Health among Veterans," 12/13/2021.

Acknowledgement of these limitations can facilitate a clearer understanding of the study findings and help identify areas for future research and outreach, including the following:

- Continued data collection and analysis to increase knowledge of COVID-19 risk factors, clinical care methodologies and long-term patient outcomes[201]
- Development and deployment of targeted COVID-19 outreach and education programs that consider culture, race and ethnicity, tailored to the unique needs of male and female Veterans and Veterans of different racial/ethnic groups at high risk for COVID-19 infection[202]
- Examination of disparities in access to COVID-19 treatments across Veterans of different races/ethnicities[203]
- Identification of trends in racial/ethnic disparities relative to changes in policies and protocols that impact social distancing and other national, state and local COVID-19 government mandates[204]

- Focused analysis of the impact of SDoH on COVID-19 testing, hospitalizations and mortality across Veteran populations of different races/ethnicities[205]

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RESEARCH & INNOVATION

Throughout the Annex D Interim Review Period, the VHA Office of Research and Development (ORD) advanced COVID-19 scholarship and research by publishing studies, initiating new clinical trials, completing therapeutic studies and advancing ongoing vaccine trials and other studies aimed at understanding COVID-19 and its impact.[206] Additionally, VA Office of Healthcare Innovation and Learning (OHIL) continued its efforts to protect against future supply chain issues like the ones faced during COVID-19 by validating 3D devices and enhancing digital stockpiles.[207]

This section outlines the continued advancement of VHA's research and innovative practices to support the medical response to the COVID-19 pandemic from April 1, 2022, through July 31, 2022.

Research Advances

During the Interim Review Period, VHA conducted the following research activities:[208]

- Collaborated on 316 published articles related to COVID-19
- Initiated two new clinical trials
- Continued participation in ongoing clinical trials, including vaccine trials
- Initiated a new research study on COVID-19 diagnostics
- Initiated a new real-world evidence (RWE), non-interventional study on COVID-19 that received a favorable scientific peer review

For the past year, VHA has worked in partnership with the Biomedical Advanced Research and Development Authority (BARDA) to develop a plan for retrieving, processing and analyzing VHA medical data to obtain insights on treatments used in VA.[209] The partnership aims to improve the delivery of health care throughout the United States.[210] Through RWE analysis of VHA data, VHA and BARDA sought to answer specific questions about treatments and medications related to COVID-19.[211]

Real-world Evidence

RWE is clinical evidence about the potential risks and benefits of medical products (drugs, devices). This evidence comes from real-world data that are routinely collected during clinical practice relating to patient health status or the delivery of health care.

Source: FDA, Real-World Evidence, https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence, 9/08/2022, accessed 10/07/2022. D118

During the Interim Review Period, FDA joined this partnership to assist in conducting research focused on RWE analysis on COVID-19.[212]

This partnership also involved VA Health Services Research and Development (HSR&D) investigators through the COVID-19 Observational Research Collaboratory (CORC).[213]

Active Research Studies

During this review period, VHA initiated 2 new therapeutic trials, and continued progress on 8 previously initiated trials, 1 of which was then finalized and posted to clinicaltrials.gov.[214] These trials, their phases and their estimated primary completion dates are detailed below. **Table 4.1** shows newly initiated therapeutic trials, and **Table 4.2** shows selected therapeutic trials focused on COVID-19 that were active during the Interim Review Period.

Table 4.1: *Newly Initiated COVID-19 Therapeutic Trials (4/1/2022 – 7/31/2022)*

Title	Intervention	Trial Phase	Partner Organization	Description
ACTIV-4a: A Multicenter, Adaptive, Randomized Controlled Platform Trial of the Safety and Efficacy of Antithrombotic and Additional Strategies in Hospitalized Adults With COVID-19	Pharmacologic Anticoagulation	IV	National Heart, Lung, and Blood Institute (NHLBI)	This study aimed to determine the safety and efficacy of using different doses of blood thinners (antithrombotic agents) for patients hospitalized with COVID-19. Blood thinners are commonly used on COVID-19 patients to mitigate blood clotting. VHA Sites: New York Harbor, New York; San Juan, Puerto Rico
ACTIV-4c: COVID-19 Post-hospital Thrombosis Prevention Trial: An Adaptive, Multicenter, Prospective, Randomized Platform Trial Evaluating the Efficacy and Safety of Antithrombotic Strategies in Patients With COVID-19 Following Hospital Discharge	Pharmacologic Anticoagulation	III	NHLBI	This study examined the safety and effectiveness of using blood-thinning drugs (antithrombotic therapy) compared with using no blood-thinning drugs after hospitalization in patients who were hospitalized for 48 hours or longer with COVID-19. VHA Sites: Little Rock, Arkansas; Minneapolis, Minnesota; and Tampa, Florida

Source: VHA, ORD, response to research questionnaire, 9/27/2022; NYU Clinical Research Studies, "A Multicenter, Adaptive, Randomized Controlled Platform Trial of the Safety and Efficacy of Antithrombotic and Additional Strategies in Hospitalized Adults With COVID-19," https://clinicaltrials.med.nyu.edu/clinicaltrial/1298/multicenter-adaptive-randomized-controlled/, accessed 10/6/2022; NHLBI-CONNECTS, COVID-19 Post-Hospital Thrombosis Prevention Study, https://nhlbi-connects.org/secure/study/8, accessed 10/6/2022. Ref.s D68, D116, D117.

Table 4.2: *Summary of Selected Previously Initiated COVID-19 Therapeutic Trials (April 1, 2022 - July 31, 2022)*

Intervention	Trial Phase	Sponsor/Funding Type	Title and Trial Status
Nitazoxanide (NTZ)	III	Romark Medical Institute/Private	Post-exposure prophylaxis in patients with COVID-19 and other respiratory illnesses in elderly residents of long-term-care facilities. **Status**: Study completed; analyzing data
Nitazoxanide (NTZ) 2	III	Romark Medical Institute/Private	Post-exposure prophylaxis in patients with COVID-19 and other respiratory illnesses in health care workers. **Status**: Study completed; analyzing data
Ramipril	III	UC San Diego/ Academic	Prevention of ICU admission, mechanical ventilation or death in persons with COVID-19 **Status**: Study completed; analyzing data.
hIVIG	III	NIH/Agency Collaboration	Inpatient Treatment of COVID-19 With Anti-Coronavirus Immunoglobulin (ITAC). **Status**: Study completed and posted to clinicaltrials.gov, 4/4/2022
Baricitinib Tocilizumab (TCZ)	III	Genentech/Private	Treatment of hospitalized patients with COVID-19 pneumonia. **Status**: Complete
Leronlimab (PRO 140)	Lib/III	CytoDyn/Private	Treatment of patients with severe or critical COVID-19. **Status**: Active - Enrollment Complete

Source: VHA ORD, response to research questionnaire, 9/27/2022; Clinicaltrials.gov, "Inpatient Treatment of COVID-19 With Anti-Coronavirus Immunoglobulin (ITAC)" https://clinicaltrials.gov/ct2/show/results/NCT04546581?term=NIH%2C+hIVIG&draw=2&rank=2, accessed 10/5/2022.; VHA, "Coronavirus Disease 2019 (COVID-19) Response Report- Annex C," pp.70-71, 7/25/2022. Ref.s D68, D150

VHA continued to participate in three previously initiated COVID-19 vaccine trials, as listed in **Table 4.3**.

Table 4.3: *Previously Initiated COVID-19 Vaccine Trials (4/1/2022 – 7/31/2022)*

Intervention	Trial Phase	Partner Organization	Trial Status
mRNA-1273 (Moderna)	III	Moderna	Enrollment is complete, and the study is ongoing with an estimated completion date of December 29, 2022. VHA Sites: Greater Los Angeles, California
SARS-CoV-2 rS/Matrix-M1 Adjuvant	III	Novavax	The study closed to enrollment with an estimated primary completion date of June 30, 2023. VHA Sites: Ann Arbor, Michigan; Miami, Florida
Ad26.COV2.S	III	Janssen	Enrollment is complete, and the study is ongoing with an estimated study completion date of March 31, 2023. VHA Sites: Albuquerque, New Mexico; Atlanta, Georgia; Aurora/Denver, Colorado; Baltimore, Maryland; Birmingham, Alabama; Bronx, New York; Chicago, Illinois; Columbia, South Carolina; Dallas, Texas; Durham, North Carolina; Gainesville, Florida; Little Rock, Arkansas; New Orleans, Louisiana; Phoenix, Arizona; Reno, Nevada; San Francisco, California; Tampa, Florida
Note: No new vaccine trials were initiated during this review period. Source: VHA ORD, response to research questionnaire, 9/27/2022. D68.			

VHA also initiated a new research study on COVID-19 diagnostics during the Interim Review Period.[215] The title of the study was "Evaluation of Point-of-Care (EPOC) for COVID-19."[216] This study compared two point-of-care tests—the LumiraDx SARS-CoV-2 Antibody Test and the RightSign COVID-19 IgG/IgM Rapid Test for SARS-CoV-2 antibodies.[217] The purpose of this study was to examine the rate of convenience and ease of reproducibility of conducting two point-of-care tests (an antibody test and a rapid antibody test) in comparison to tests conducted at a central laboratory.[218] These tests were run on specimens that were obtained from the same study participants at the same time.[219] This study was funded by the University of Minnesota, Insight Group and the first VA site registered on June 16, 2022.[220] The results of this study were in progress as of the publication of this report. As of July 31, 2022, the estimated completion date was April 1, 2023.[221]

Non-Interventional COVID-19 Studies

VHA initiated two new non-interventional studies of COVID-19 during the Interim Review Period.[222] The project titles and summaries for these studies are detailed in **Table 4.4**.

Table 4.4: *Newly Initiated Non-Interventional COVID-19 Studies (April 1, 2022 - July 31, 2022)*

Project Title	Project Summary
CSP #2038: COVID-19 Pharmacotherapy Effectiveness in the VA Healthcare System (COPE-VA)	This study was designed as an RWE analysis to inform VHA research partners and to provide clinical and operational strategies to make the best and most effective use of COVID-19 medications. One of the comprehensive goals for this study was to build a rapid-response platform (a system that uses the same basic components and structures and can be adapted for use on different pathogens) to use with future studies that compare the effectiveness of current and novel COVID-19 therapies.
Effectiveness of mRNA COVID-19 vaccines against Omicron and Delta variants in a matched test-negative case-control study among US veterans	This data analysis studied the efficacy of mRNA booster doses during the prominence of COVID-19 variants Delta and Omicron. The analysis found that among a mostly male, older population of U.S. Veterans (many with multiple medical conditions), an mRNA vaccine booster was significantly effective against hospitalization, infection and death. Booster vaccination effectiveness against infection was slightly higher against Delta than against the Omicron variant, and effectiveness against severe disease and death was similarly high against both variants.
Source: VHA ORD, response to research questionnaire, 9/27/2022; Coalition for Epidemic Preparedness Innovations (CEPI), Platform Technologies, accessed 10/09/2022, https://cepi.net/research_dev/technology/#:~:text=Rapid%20response%20platforms%20broadly%20refer%20to%20systems%20that,set%20up%20for%20rapid%20use%20against%20novel%20pathogens. Ref.s D68, D122	

VHA leadership reported that ORD worked in collaboration with a VHA interdisciplinary team to make notable research contributions to the medical field with the advancement of knowledge about Long COVID and its treatment.[223] For more information, see the Long COVID section of this Report.

A Culture Shift in VHA Research

In the beginning of the pandemic, ORD engaged in urgent emergency responses with focused research priorities, including COVID-19 treatment and vaccination.[224] As a result of its experience with this emergency response, ORD worked to develop new and better communication channels and collaboration between VHA offices.[225]

ORD focused on establishing a research infrastructure that could address future emerging infectious diseases with efficiency.[226] In this way, ORD advanced forward thinking and planning for the future.[227]

VHA leadership reported that VHA research also experienced a culture shift as a result of the pandemic.[228] Brought on by the demands of COVID-19 treatment, this

culture shift encouraged VHA to improve its integration with clinical and operational partners, which allowed the organization to move more swiftly from research and knowledge collection to clinical action.[229] Supported in part by the improved use of technology platforms that allowed greater and easier access to interagency connection and communication, VHA pushed hard throughout the pandemic to apply research to clinical practice at a rapid pace.[230]

Another positive outcome of the culture shift was action to dedicate focused time and resources to nationwide VHA projects, rather than dispersing resources across various smaller, individual projects.[231]

As COVID-19 treatment and operations at VHA became more stable, ORD refocused on projects previously delayed by the pandemic.[232]

Research Interests

Genomic Sequencing

ORD continued to focus efforts on studying genomic sequencing.[233] Working with public health agencies in various states around the country, the VA Sequencing Collaborations United for Research and Epidemiology (VA SeqCURE) researched SARS-CoV-2 genomes to identify COVID-19 variants and variant trends.[234] Through this research, ORD conducted analyses of COVID-19 variants and comparisons of what was known with the wide variety of variants that were still emerging.[235] Additionally, VHA researchers engaged in a study that used genomic sequencing to better understand COVID-19 rebound.[236] VHA leadership shared that this study was still in progress.[237] For more information about COVID-19 rebound, see the Therapeutics section of this report.

Vaccine Effectiveness

VHA leadership reported that RWE was gathered and used to study vaccine effectiveness for different COVID-19 variants within the Veteran population.[238] During this review period, a VHA research team that specialized in vaccine and booster effectiveness conducted a study of this analysis across the Delta and Omicron COVID-19 variants.[239] Using EHR data from 114,640 Veterans who took a COVID-19 test from November 2021 through January 2022, the research team examined the efficacy of messenger RNA (mRNA) booster doses when Delta and Omicron variants were dominant.[240]

The team found that the mRNA booster was highly effective against COVID-19 infection, hospitalization and death.[241] They also found that although the booster vaccination was moderately more effective against contracting the Delta variant than

the Omicron variant, its effectiveness against death and severe disease was similar for both.[242]

Innovation

As part of its ongoing effort to address supply chain issues relevant to COVID-19 response, OHIL reported on several initiatives that started or continued during the Interim Review Period.[243]

Digital Stockpiling

During the Interim Review Period, digital stockpiling received increased attention from VHA, in part because digital supply creation allowed VHA to produce supplies that were difficult to obtain during the pandemic (and that may be hard to obtain in future emergencies).[244] As discussed in Annex C, innovative techniques like 3D printing have helped VHA provide points of care with much-needed supplies throughout the COVID-19 crisis.[245]

VHA leadership reported that the organization collaborated with industry manufacturers, the National Institutes of Health (NIH) and FDA to create blueprints for products that could be 3D-printed using a shelf-stable powder.[246] VHA has used this powder, which can be stored for two years or more, to manufacture nasal swabs used for PCR and genetic testing in VA facilities throughout the Nation, as reported in Annex C.[247] Expanding on its previous success, VHA worked to create blueprints for other printable products, including face masks and shields.[248] In future emergencies, VHA could access these blueprints and print supplies using the versatile powder.[249]

Creating goods with this innovative printing technique would provide several positive outcomes:[250]

- Reduction in the space required to store supplies needed for VHA facilities
- Limited waste of goods due to expiration
- Minimized cost in creation and transport of goods

VHA leadership noted that VHA's digital stockpiling efforts will remain ongoing and active after the Interim Review Period.[251]

Validating VHA Nasal Swabs

During the Interim Review Period, a randomized study determined that the VHA nasal swabs were not inferior to the traditionally manufactured nasal swabs that had been identified as the standard-of-care for COVID-19 testing.[252]

To test the accuracy of the 3D swabs, researchers swabbed Veterans first with an FDA-listed swab that was commercially available and considered the standard of care for COVID-19 testing. Next, researchers used the 3D-printed swab to see if there was any difference in the outcome of detecting SARS-CoV-2 by a rapid PCR test.[253] The tests were conducted at four VAMCs: Long Beach, California; Charleston, South Carolina; Orlando, Florida; and Cleveland, Ohio.[254] VA Puget Sound—located outside Seattle, Washington—was the coordinating site.[255]

In a traditional study, the swab order would be randomized so half the time the 3D swab came first.[256] However, because these Veterans came to VA for routine care, and double-swabbing might not produce as accurate a result, researchers did not want to take the chance that a Veteran volunteer could receive a false negative on their test.[257] To make sure that Veterans were still getting the most accurate test results, the clinical swab was administered first, and the second swab was randomized (sometimes it was a 3D swab, sometimes not).[258] The result of the 3D swabs was compared to the traditional swab result to confirm that both were testing at the same level of accuracy.[259]

The 3D-printed nasal swabs were designed in response to the shortage of swabs to test for COVID-19; however, they can also be used to test for five other viruses, including Influenza A, Influenza B and respiratory syncytial virus (RSV).[260]

Recycling Pathways

Aware of the ongoing waste related to expired and used PPE, VHA has worked to develop more supplies that can be recycled or reused after their initial job is complete.[261]

At the conclusion of the Interim Review Period, the initiative was still in its early stages.[262] VHA leadership reported that OHIL was researching the broader market, looking at recycling and reusable products with hopes of bringing new ideas and innovations to VHA products.[263]

NATIONAL PUBLIC POLICY

During the Annex D Interim Review Period, COVID-19 policies across the country shifted. Although the Federal public health emergency (PHE) was renewed, some state governments ended their public health emergencies.[264] Some states closed their publicly run testing facilities.[265] Others reduced restrictions; for instance, on April 1, 2022, California lifted its requirement for proof of vaccination or a negative COVID-19 test for those attending events of more than 1,000 people.[266] Massachusetts ended a program that provided self-test kits to schools.[267]

Reasons cited for these new policies included the following:

- Decreased need for testing facilities due to increased self-testing[268]
- Shifting strategies to address COVID-19 as an endemic disease[269]

COVID-19 Case Reports

State and organizational reporting policies also changed during the Interim Review Period.[270] According to Johns Hopkins University, more than half of U.S. states reduced their COVID-19 reporting to once per week.[271] Reported data included case counts, deaths, vaccinations and tests conducted by the state.[272] As a result of state policy shifts, Johns Hopkins reported that its Coronavirus Resource Center would reduce its updates on COVID-19 cases, deaths, vaccinations and testing.[273]

Johns Hopkins also noted that self-testing had reduced the effectiveness of state testing reports because many people did not report the results of self-tests to the state.[274]

Changing Public Health Policies

Over the course of the pandemic, CDC altered the metrics it used to determine recommended precautions, including masking and social distancing.[275] The early metrics, introduced in September 2020, measured COVID-19 prevalence using the following:[276]

- New cases of COVID-19 (in the last 7 days) per 100,000 people
- Percentage of positive nucleic acid amplification tests (NAATs) in the last 7 days

But these metrics did not consider the potential pressures on the health care system or the severity of COVID-19 symptoms.[277] As a result, the metrics could appear elevated even when cases were mild or asymptomatic.[278] Alternatively, overall COVID-19 case counts could be lower, but the rate of hospitalizations could be higher.[279]

With this in mind, CDC updated the process it used to inform its recommendations.[280] As of July 31, 2022, COVID-19 community levels were the primary metric used to determine public health precautions.[281] COVID-19 community levels were determined not only by case count, but also by the potential strain on hospitals and health care facilities caused by severe illness.[282] In addition to consideration for case counts, COVID-19 community levels were measured using the following indicators:[283]

- New hospital admissions with confirmed COVID-19 cases per 100,000 people in the past 7 days
- Percentage of staffed inpatient beds occupied by patients with confirmed cases of COVID-19

VHA used CDC's system to determine its own guidelines for VHA facilities, based on COVID-19 community levels.[284] The system included protocols related to personal protective equipment (PPE), testing, visitor access and other preventive guidance.[285] **Figure 5.1** provides details by community prevalence level.

Figure 5.1: *VHA Health Facility COVID-19 Health Protection Levels*

Low COVID-19 Prevalence	Medium COVID-19 Prevalence	High COVID-19 Prevalence
 Masks required	 Masks required	 Masks required
 Self-screen for symptoms	 Self-screen for symptoms	 Medical team may perform entry screening
 Visitors welcome	 Partners can visit	 Limited visitors, physical distancing required
 In-person appointments encouraged	 In-person appointments encouraged, telecare possible	 Telehealth options may be preferable

Source: VHA, "Coronavirus Veteran Frequently Asked Questions," accessed 9/26/2022, https://www.va.gov/coronavirus-veteran-frequently-asked-questions/#health-care-appointments-and-m. Ref. D95

Public Health Precautions

Many organizations lifted their more restrictive public health policies during the Interim Review Period.[286] Restrictions for childcare organizations were adjusted—including schools, daycares and camps.[287] Precautions were removed, with the understanding that they may be re-introduced when COVID-19 community levels were high.[288]

In a White House briefing in July 2022, the COVID-19 Response Coordinator highlighted the current themes of COVID-19 prevention.[289] These included the following:[290]

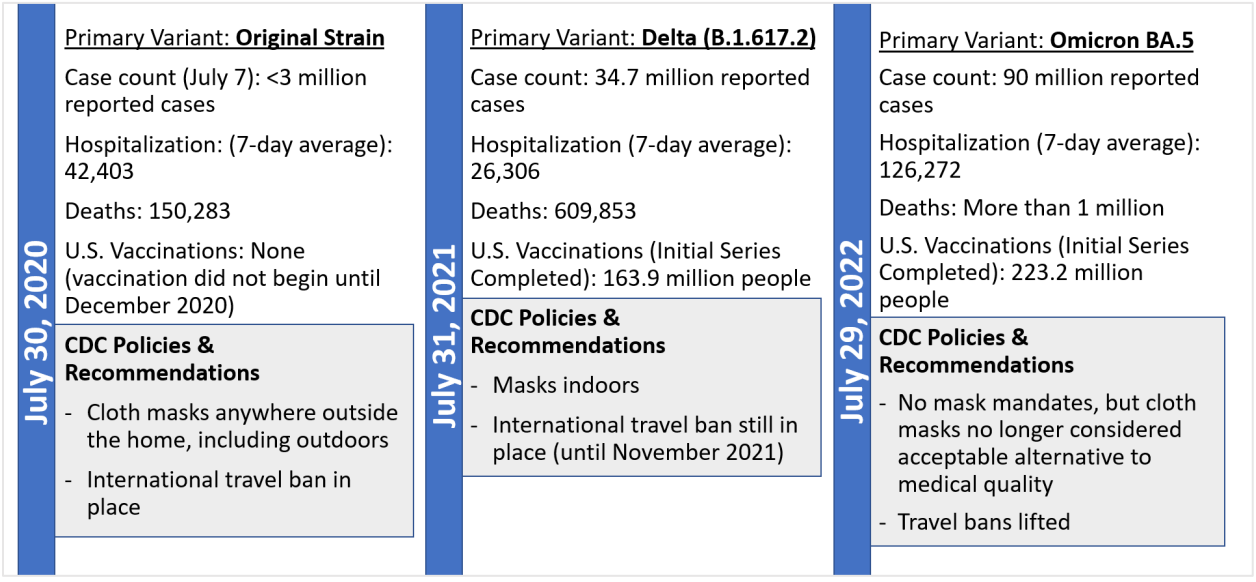
- Taking an antigen test before attending a large gathering
- Vaccinating and boosting in a timely fashion
- Using Test to Treat facilities to obtain swift treatment if a test comes back positive for COVID-19
- Masking when community prevalence is high

These themes differ greatly from the policies of July 2021, which included the following:[291]

- Wearing a mask in all indoor public places for those who were under-vaccinated or un-vaccinated (and two years of age or older)
- Wearing a mask in crowded outdoor spaces or at events that required close contact with unvaccinated people
- Wearing a mask on all modes of public transportation, regardless of vaccination status
- Staying six feet apart from people who did not live in the same household

Figure 5.2 provides a glimpse of the changing nature of the pandemic from July 2020 through July 2022, including high-level statistics for the United States, and a sampling of policies and recommendations associated with that time.

Figure 5.2: *Changing COVID-19 Statistics & Policies, 2020, 2021 and 2022*



Sources, July 2020: CDC, "COVIDView Summary ending on July 25, 2020," updated 7/31/2020, accessed 10/12/2022, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/past-reports/07312020.html; CDC, CDC Museum Timeline: Late 2020, accessed 10/12/2022,

https://www.cdc.gov/museum/timeline/covid19.html#Late-2020; CDC, "Coronavirus Disease 2019 (COVID-19): Cases in the U.S.," 7/30/2020, accessed 10/13/2022, https://stacks.cdc.gov/view/cdc/91270; CDC, "CDC Calls on Americans to Wear Masks to Prevent COVID-19 Spread," 7/14/2020; Center for Infectious Disease Research and Policy, "US lifts COVID-19 travel ban 20 months after it began," 11/8/2021, accessed 10/12/2022, https://www.cidrap.umn.edu/news-perspective/2021/11/us-lifts-covid-19-travel-ban-20-months-after-it-began; NIH, "Benefits and Risks of Visitor Restrictions for Hospitalized Children During the COVID Pandemic," 5/19/2020, accessed 10/12/2022, https://pubmed.ncbi.nlm.nih.gov/32430441/. Ref.s D141, D142, D125, D144, D143, D157

Sources, July 2021: CDC, "Weekly Report: Don't Run Out the Shot Clock," 7/30/2021, accessed 10/12/2022, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/past-reports/07302021.html; CDC, "Guidance for Implementing COVID-19 Prevention Strategies in the Context of Varying Community Transmission Levels and Vaccination Coverage," 7/30/2021, accessed 10/12/2022, https://www.cdc.gov/mmwr/volumes/70/wr/mm7030e2.htm. Ref.s D145, D146

Sources, July 2022: CDC, "Weekly Report: Protect Those Who Protect Us," 7/29/2022, accessed 10/12/2022, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/past-reports/07292022.html; CDC, "Types of Masks and Respirators," updated 9/8/2022, accessed 10/12/2022, https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html. Ref.s D74, D147

Personal Respiratory Precautions

Masking precautions changed over the course of the pandemic as new information about the transmission of the virus became available.[292] These changes followed new evidence related to the following:[293]

- SARS-Cov-2 and its ability to travel through the air
- The contagious nature of COVID-19 even when the host was asymptomatic

In 2020, cloth masks were considered acceptable alternatives to medical-grade masks (for non-clinicians).[294] VHA health care policies at the time encouraged people to wear a face covering, which could include a bandana, scarf or cloth mask.[295] Although it was known that cloth masks were less effective than surgical masks, some evidence suggested that cloth masks could prevent transmission of the virus.[296] This belief was based on the understanding that SARS-CoV-2 could travel only short distances through droplets produced by coughing, sneezing or close contact speech.[297]

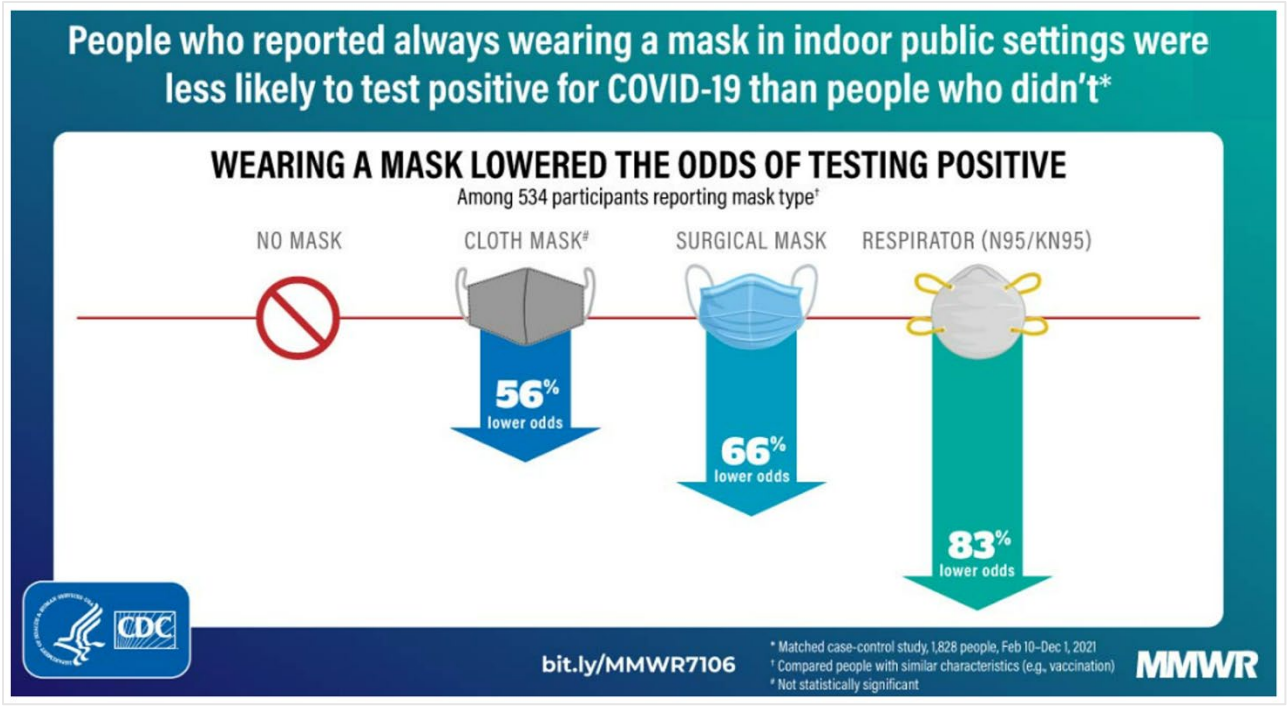
Over time, studies began to show that the SARS-CoV-2 virus could travel farther and live longer in the air than previously believed.[298] Research also showed that 40% to 45% of people infected with SARS-CoV-2 were asymptomatic, which meant they were not coughing or sneezing but were still able to infect others.[299]

A CDC study released in early 2022 found that wearing surgical or medical-grade masks (such as KN95 and N95) resulted in lower instances of infection by the Omicron variant when compared with cloth masks, as shown in **Figure 5.3**.[300]

As a result of this new evidence, health care organizations (including VHA) adjusted their policies, stating that only surgical and medical-grade masks should be worn in

medical facilities throughout the country.[301] VHA has also instituted a policy of providing these masks to Veterans and their households.[302]

Figure 5.3: *CDC Findings Related to Mask Types and COVID-19 Infection*



Source: CDC, "Effectiveness of Face Mask or Respirator Use in Indoor Public Settings for Prevention of SARS-CoV-2 Infection—California, February-December 2021," 2/11/2022, accessed 9/27/2022, https://www.cdc.gov/mmwr/volumes/71/wr/mm7106e1.htm. Ref. D98

Note: *Matched case-control study, 1,828 people, Feb 10-Dec 1, 2021; †Compared people with similar characteristics (for example, vaccination); #Not statistically significant

Deferred Care

In 2020, many health care organizations (including VHA) deferred care, including surgeries and preventive exams.[303] Although these policies may have been prudent as a means of preventing the spread of COVID-19, there were negative consequences on the broader care provided to patients.[304]

Deferring non-urgent care early in the pandemic was intended to do the following:[305]

- Budget the use of PPE
- Reserve beds and other physical spaces in health care facilities
- Allow clinicians to care for COVID-19 patients

One study found a 48% decrease in U.S. surgeries immediately following the start of the pandemic.[306] At their lowest point (March to April 2020), average outpatient visits declined by nearly 40%.[307] Emergency Department (ED) visits declined by 42%—

there were 2.1 million ED visits in the United States from March 31, 2019, through April 27, 2019, and only 1.2 million ED visits from March 29, 2020, through April 25, 2020.[308]

Like many health care systems, VHA delayed elective and non-urgent surgeries in early 2020.[309] The organization did not lose sight of the importance of these surgeries and spent time rescheduling appointments throughout 2021.[310] Despite these efforts, VHA leadership reported that, as of the Interim Review Period, the overall impact of deferred care was still unknown.[311]

Visitation in hospitals saw a similar policy shift across the pandemic.[312] Restrictions were severe at the start of the pandemic to protect those who were immuno-compromised, but more recent studies showed that visitation from loved ones was an important part of treatment and care, particularly for those who were very ill.[313] As a result, visitation restrictions shifted over time to allow for more visitors.[314]

In addition to care deferred by providers, individuals delayed their own care as a result of the pandemic.[315] As early as June 30, 2020, CDC had already identified concerns about individuals who had delayed or avoided care due to fears related to COVID-19.[316] A study released by the National Bureau of Economic Research stated that some individuals who chose to defer care might not return to catch up on the care they missed.[317] Both deferred and missed care (also known as foregone care) could have implications for the health of the individual.[318]

In June 2020, CDC estimated that approximately 41% of U.S. adults had delayed or avoided health care as a result of the pandemic.[319] More than two years later, VHA leadership reported concerns that the full picture of delay and avoidance was still unknown.[320] As of July 31, 2022, VHA was continuing the process of identifying groups of Veterans who delayed or avoided care during the pandemic.[321]

TEST TO TREAT

In March 2022, the President of the United States issued a call to action, encouraging all U.S. health care organizations to provide timely treatment of COVID-19 infection.[322] Prior to the White House messaging, VHA had already developed its Test to Treat protocol.[323] The term "Test to Treat" refers to a program that provides same-day COVID-19 testing, prescription and treatment all in one location.[324]

Before COVID-19, VHA used Test to Treat to combat influenza and other infections in a clinical setting.[325] Following the President's call to action, VHA worked to expand its Test to Treat capabilities, including enhancing virtual support for Veterans throughout the country.[326] Over time, VHA became an industry leader in Test to Treat implementation.[327]

The Test to Treat initiative became particularly important because of its aim to accelerate the treatment of COVID-19.[328] COVID-19 oral antiviral medications needed to be taken within five days of a person's first COVID-19 symptoms to be effective in treating the severity of the virus and limiting the risk of hospitalization.[329]

In April 2022, VHA piloted a dedicated Virtual Test to Treat clinic in VISN 1.[330] VISN 1 partnered with VA Health Connect (a new, 24/7 virtual suite of care services) and the Office of Healthcare Transformation to provide the fastest way for Veterans to receive care from home when they tested positive for COVID-19.[331]

VHA leadership reported that a part of the CCC modernization that occurred during the Interim Review Period was the inclusion of a VISN-level, CCC-branded VA Health Connect in each VISN.[332] This modernization played a significant role in the success of the original Virtual Test to Treat clinic.[333] The clinic maximized the ease of access to treatments by using VA Health Connect to facilitate treatment processes that included evaluation for further treatment to Test to Treat counseling.[334]

Throughout the Interim Report Review Period, VA Health Connect worked to link Veterans to clinical providers.[335] Providers used VA Health Connect to review medical records, to share treatment options and to follow up with Veterans' health care teams.[336] As of July 31, 2022, the piloted Test to Treat clinic was operating virtually, using resources such as VA Health Connect, telemedicine, self-test kits and COVID-19 oral antiviral medications delivered through the mail.[337]

As Virtual Test to Treat gained success, the piloted clinic built the foundation for an organized, efficient program.[338] During the Interim Review Period, the piloted Virtual Test to Treat clinic expanded toward a nationwide VHA Virtual Test to Treat program.[339]

VHA Virtual Test to Treat Program

From April 1, 2022, through July 31, 2022, VHA worked to implement the Virtual Test to Treat program nationally across VISNs.[340] As of July 31, 2022, a total of 9 of the 18 VISNs had functioning Virtual Test to Treat programs running, and the other VISNs were working to gain the appropriate staff needed to stand up a program.[341]

To support the program's rapid expansion, the Virtual Test to Treat program team produced training resources and guidance materials such as a Test to Treat toolkit, asynchronous education and a Test to Treat implementation plan.[342]

The process for VISNs to stand up a Virtual Test to Treat program was described in the Test to Treat Implementation Plan supported by the Test to Treat Toolkit.[343] These resources were housed in the VA Health Connect SharePoint: Virtual Test to Treat MS and were available to all VISNs.[344]

The Toolkit included guidance for each step of program implementation and identified the following steps for program implementation:[345]

1. Assemble a VISN Interdisciplinary Workgroup.
2. Review, modify and execute an implementation plan.
3. Communicate coordination strategies among VHA teams across the country.
4. Launch program.
5. Provide asynchronous education.

To start a Virtual Test to Treat program, VISNs were required to identify co-leads to drive the Test to Treat VISN planning, information sharing and overall implementation.[346] In the Virtual Test to Treat program toolkit, each step for implementation was linked to tools and guidance plans designed to support each step of program development and guide VISNs to follow a standard process.[347]

Virtual Test to Treat Program Workforce

In keeping with step one of the implementation plan, all programs were required to assemble a VISN Interdisciplinary Workgroup, including the following positions:[348]

- Network Director
- VISN Chief Medical Officer
- VISN CCC Nurse Leader (Chief Nursing Officer)
- VA Health Connect CCC Leaders
- VISN Pharmacy Leader

In addition to the required workgroup positions listed above, VHA leadership identified a range of other health care staff necessary to maintain an operational Virtual Test to Treat program.[349] This workforce included physicians, physician assistants, nurse practitioners and other nursing staff.[350] VISNs used emergency medicine clinicians for critical cases, and primary care clinicians assessed non-critical cases.[351] Pharmacy services were also a large part of the Test to Treat operational success.[352]

Pharmacy Collaboration

Tracking COVID-19 Medication Interactions

Before the Virtual Test to Treat programs could go live, each VISN's program was connected to Pharmacy Benefits Management (PBM) so its pharmacy templates could be integrated into VHA's Computerized Patient Record System (CPRS).[353] Training was required for providers to feel comfortable with FDA's EUA requirements for each COVID-19 medication, including potential drug interactions.[354]

VHA leadership reported that it was challenging to track the EUA list of drug interactions (drugs that interact with COVID-19 oral antiviral medications).[355] The interactions were updated often as new information became available, and VHA leadership were concerned that the EUA list of drug interactions was not comprehensive enough for the unique needs of the Veteran population.[356]

In response to these concerns, VHA collaborated with the national PBM team that managed VHA's national drug file.[357] VHA coordinated with this team to customize a comprehensive list of drug interactions, consistent with Veteran needs, to publish in VHA's CPRS.[358] To develop this customized drug interaction list, the team examined the EUA list and cross-referenced additional resources such as the Liverpool data base with drug interactions.[359]

PBM sustained consistent communication with facilities regarding COVID-19 medications and any changes in information about therapeutics by issuing memorandums and producing protocols for both inpatient and outpatient care.[360] These communications included different options for treatment and EUA requirements and regulations for different treatment criteria, such as avoiding harm by confirming that a COVID-19 medication would not interact negatively with a Veteran's current medications or health status.[361]

VHA leadership reported that collaboration with pharmacy staff was crucial for program success.[362] An essential component of the Virtual Test to Treat program's business process with pharmacies was the ability to communicate effectively and to

ensure overnight shipment of COVID-19 oral antiviral medications to Veterans.[363] VHA leadership reported that all VAMCs could provide expedited, overnight shipping to reach the needs of Veterans at home.[364] Additionally, VAMCs could dispense medications through commercial pharmacies if they were out of stock within the VAMC or if home delivery was not possible.[365]

COVID-19 Oral Antiviral Medication

During the Interim Review Period, VHA used Paxlovid more often than any other COVID-19 oral antiviral medication.[366] The VISN 1 Virtual Test to Treat pilot occurred in White River Junction, Vermont, and Boston, Massachusetts, from April through July 2022.[367] A total of 207 Veterans participated in the pilot during that time; 183 of those Veterans were prescribed Paxlovid, while 11 were prescribed Lagevrio.[368]

Since the implementation of the Virtual Test to Treat pilot clinic in April 2022, and its further expansion into a national program, VHA reported a steady rise in the prescriptions of Paxlovid.[369] VHA distribution of Paxlovid peaked with the rise of COVID-19 diagnoses in mid-to-late July 2022, during the same period that the Virtual Test to Treat program expanded nationally.[370] For more on this rise, see the Therapeutics section of this report.[371]

Since January 2022, VHA has tracked the distribution volumes and initiation timeframes for all COVID-19 oral antiviral medications.[372] According to VHA's data, from January 1, 2022, through August 27, 2022, up to 23,600 Veterans received Paxlovid within the EUA-recommended timeframe (within 5 days of the first symptom of COVID-19).[373] Some of these treatment recipients self-reported their COVID-19 symptoms, and some had positive tests and diagnoses.[374]

Among the group of total recipients who received Paxlovid treatment within the recommended EUA timeframe, the people with the most treatments received were 65 through 74 years of age—29.1% of total recipients.[375] This is in keeping with CDC guidance, which recommended seeking medication for COVID-19 for patients with higher risk of severe illness, including those over 50 years of age.[376]

White Veterans comprised the racial group that received the most treatment within the EUA recommended timeframe (63.4% of total recipients).[377] VHA began gathering data to learn how this cohort of Paxlovid recipients compared to the expected population for Paxlovid treatment.[378] As of the publication of this report, the analysis was not yet complete.[379] Table 6.1 and Table 6.2 provide more detailed information on demographics related to Veterans who received Paxlovid treatment within the EUA-recommended timeframe.

Table 6.1: *Veteran Paxlovid Treatment Within the EUA Recommended Timeframe: Veteran Recipient Age, January 1, 2022 – August 27, 2022*

Age Range	Percent
0-34	3.7%
35-44	10.1%
45-54	14.7%
55-64	22.4%
65-74	29.1%
75-84	16.2%
85 (and older)	3.4%
Missing Data	0.5%

Source: VHA leadership, response to email, 9/22/2022. Ref. D148
Note: Totals may not add due to rounding

Table 6.2: *Veteran Paxlovid Treatment Within the EUA Recommended Timeframe: Veteran Recipient Race, January 1, 2022 – August 27, 2022*

Race	Percent
White	63.4%
Black	19.8%
Hispanic	8.8%
Asian	2.9%
Native American	0.9%
Unknown	4.1%

Source: VHA leadership, response to email, 9/22/2022. Ref. D148
Note: Totals may not add due to rounding

Virtual Test to Treat Value

VHA leadership reported that one advantage of the Virtual Test to Treat program was that it allowed Veterans to stay home and use self-testing kits.[380] In addition to providing convenience and ease of care from home, the Virtual Test to Treat program also provided potential protection for at-risk Veterans who otherwise would be required to attend in-person treatment.[381]

VHA leadership reported that some higher-risk Veterans still had to come into facilities for in-person treatments, such as Veterans who received dialysis treatment or organ transplants.[382] Even so, VHA's policies kept infected Veterans at home, which lessened the risk to others.[383]

Additionally, the Virtual Test to Treat program connected Veterans who lived in areas without easy access to VAMCs with faster care.[384]

The Virtual Test to Treat program also reduced the demand in emergency facilities.[385] During times of increased COVID-19 infections—like the initial Omicron wave, beginning in winter 2021—VHA EDs became full, and wait times to receive care rose.[386] Virtual Test to Treat programs were designed to help offload urgent care and ED call-ins to Patient Aligned Care Teams (PACT).[387]

Challenges and Solutions

Virtual Test to Treat programs faced certain staffing challenges.[388] Some VHA call centers were decentralized and did not have the appropriate staff—such as pharmacists or providers—to provide fast, in-the-moment care.[389] With the modernization of the CCC, call centers worked to be able to operate with core and off-core (24-hour) services and virtually connected Veterans with nurses and medical support assistants to address Veteran needs in the moment.[390] Additionally, VHA leadership reported that with the CCC's new Customer Relationship Management (CRM) system, the call centers were able to gather and store standardized, real-time data to support clinical decision-making and resource sharing.[391]

Preparedness for Future Responses

Through the modernization of the CCC and implementation of VA Health Connect, VHA began to build surge capacity in Virtual Test to Treat programs.[392] This surge capacity supported contingency planning and disaster management by connecting Veterans to virtual care anywhere it was available.[393] Unlike in-person medical facilities, when Virtual Test to Treat programs reached capacity in a surge, they were able to quickly shift Veteran care to another available VISN's Virtual program.[394]

VHA's strategy to increase the accessibility of Virtual Test to Treat programs included designing a virtual structure that allowed easy resource sharing through its CRM and fast connection to care anywhere.[395]

THERAPEUTICS

This section focuses on VHA's use of therapeutic and prophylaxis agents to combat the SARS-CoV-2 virus that causes COVID-19.[396] This section also presents effectiveness recommendations from FDA and CDC and describes how VHA overcame challenges in the area of therapeutics.

VHA Therapeutics Updates

During the Interim Review Period, clinicians became aware of a phenomenon known as COVID-19 rebound—a condition in which a patient experienced a recurrence of COVID-19 symptoms after completing a 5-day course of Paxlovid.[397] The rebound usually began 2 to 8 days after the patient's recovery from initial illness.[398]

The Boston VAMC was one of the first facilities to identify COVID-19 rebound.[399] In a letter to the New England Journal of Medicine, the Boston VAMC chronicled its observations and described rebound viral replication in 13 observed cases.[400] The letter included concerns that patients might have a higher viral load during rebound, which could mean that patients were still contagious during the rebound period.[401] VA used its clinical genomic sequencing capability to study these cases.[402]

On May 24, 2022, CDC issued a Health Alert Network Health Advisory on COVID-19 rebound.[403] The alert noted that Paxlovid was still recommended for treatment for mild-to-moderate illness; however, clinicians were asked to report cases of rebound to Pfizer and FDA MedWatch.[404] NIH updated its guidelines, acknowledging COVID-19 viral rebound; however, the organization also noted that they could not yet reach conclusions about the frequency of rebound or the implications in a clinical setting.[405]

During the Interim Review Period, VHA ORD launched efforts to study the COVID-19 rebound effect.[406] VHA leadership reported that research will allow them to develop a better understanding of the rebound phenomenon.[407]

Therapeutics and Prophylaxis Approved for and in Clinical Use

From April 1, 2022, through July 31, 2022, 6 medications were available to counter the effects of COVID-19—5 of which were therapeutics (the additional medication was a prophylaxis drug).[408] All six medications had EUAs from FDA.[409] VHA providers prescribed these medications to treat Veterans and their families for COVID-19.[410]

The types of medications available for combating COVID-19 included:[411]

- **Antiviral drugs**, both oral and intravenous (IV), were prescribed to assist in combating severe COVID-19 illness by stopping the SARS-CoV-2 virus from multiplying.[412]
- **Monoclonal antibodies** were administered in an infusion and manufactured specifically to recognize the SARS-CoV-2 virus. These medications were used to promote the body's immunity against the virus and fight it directly.[413]
- **A corticosteroid** was administered by IV infusion as an alternative to Veklury for severe COVID-19 infection.[414]

Table 7.1 provides details on COVID-19 therapeutics and prophylaxis agents available as of July 31, 2022.

Table 7.1: *COVID-19 Therapeutics and Prophylaxis Agents, as of July 31, 2022*

Name	Type of Medication	Details
Paxlovid (Nirmatrelvir and Ritonavir)	Oral Antiviral	Authorized for short-term (no longer than 5 days) use as an oral antiviral treatment for mild-to-moderate COVID-19 infection. Available to patients 12 years and older at high risk for severe COVID-19 infection, hospitalization or death. Contraindicated for individuals hospitalized for severe COVID-19.
Lagevrio (Molnupiravir)	Oral Antiviral	Authorized for use as an oral antiviral treatment for mild-to-moderate COVID-19 infection among individuals 18 years and older at high risk for severe COVID-19 infection, hospitalization or death when alternative FDA-approved drugs for COVID-19 were not accessible or clinically indicated.
Veklury (Remdesivir)	Intravenous Antiviral	Authorized for use as an IV antiviral treatment for mild-to-moderate COVID-19 infection among individuals 28 days old and older at high risk for severe COVID-19 infection, hospitalization or death. Contraindicated if signs or symptoms of liver inflammation were present.
Evusheld (Tixagevimab and Cilgavimab)	Monoclonal Antibodies (Intramuscular Injection)	Authorized for use as a pre-exposure prophylaxis (PrEP) or preventive measure for COVID-19, designed to prevent infection with COVID-19 among individuals 12 years and older at risk for exposure or after exposure to the SAR-CoV-2 virus. EUA for this medication was for individuals not expected to mount an adequate immune response due to hematological concerns or immunosuppressive therapy.
Bebtelovimab	Monoclonal Antibodies (intravenous Injection)	Authorized for use as a treatment for mild-to-moderate COVID-19 infection among individuals 12 years and older at high risk for severe COVID-19 infection, hospitalization or death when alternative FDA-approved drugs for COVID-19 were not accessible or clinically indicated. Contraindicated for patients who required oxygen therapy due to COVID-19 infection.

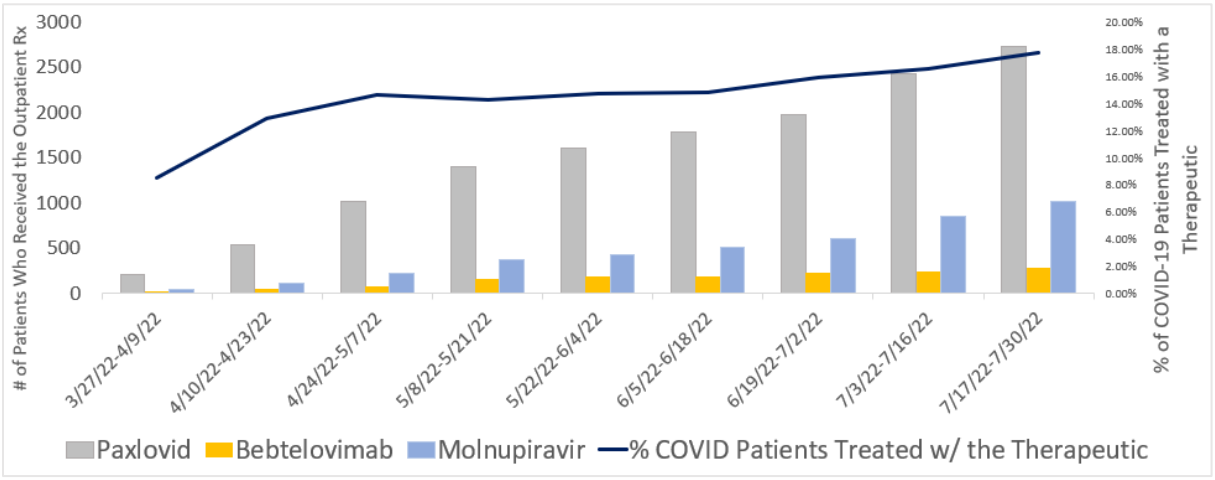
Name	Type of Medication	Details
Dexamethasone Sodium Phosphate	Injectable Corticosteroid	Authorized for use as a treatment or supportive therapy for individuals hospitalized for severe COVID-19 infection that required respiratory support. Available after hospitalization for individuals in outpatient care for underlying medical conditions that may impact recovery from COVID-19. Not recommended for patients with mild-to-moderate COVID-19 who did not require inpatient care or supplemental oxygen.
Sources: CDC, "Side-by-Side Overview of Therapeutics Authorized or Approved for the Prevention of COVID-19 Infection or Treatment of Mild-Moderate COVID-19," updated 7/20/2022, accessed 9/22/2022, https://aspr.hhs.gov/COVID-19/Therapeutics/Documents/side-by-side-overview.pdf; VHA Leadership, Interview #9, timestamp: 20:40, 9/13/2022; NIH, "Coronavirus Disease 2019 (COVID-19) Treatment Guidelines," updated 4/1/2022, accessed 9/26/2022, https://files.covid19treatmentguidelines.nih.gov/guidelines/archive/covid19treatmentguidelines-04-01-2022.pdf; FDA, "Coronavirus (COVID-19) Update: August 6, 2021," updated 8/6/2021, accessed 10/25/2022, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-august-6-2021; NIH, "Corticosteroids for Treatment of COVID-19: Effect, Evidence, Expectation and Extent," updated 11/4/2021, accessed 10/25/2022, https://pubmed.ncbi.nlm.nih.gov/34751250/. Ref.s D5, D45, D189, D190		

On March 25, 2022, FDA rescinded the EUA for an oral monoclonal antibody called Xevudy, commonly known by its generic name, Sotrovimab.[415] Sotrovimab was found to be significantly less effective against Omicron BA.2, which had become the dominant variant in the United States.[416] The efficacy of the drug changed because the Omicron BA.2 variant had a new mutation in its protein structure in the spot where the drug was designed to adhere to the virus.[417] As a result, Sotrovimab was no longer able to bind to (and neutralize) the SARS-CoV-2 virus.[418]

In response to this new information, VHA clinicians stopped prescribing Sotrovimab immediately.[419] Patient request forms for the drug were closed, and the ordering system for receiving more of the product was shut down.[420] Because of VA's quick action, no doses of Sotrovimab were given to VHA patients after the EUA was rescinded.[421]

Figure 7.1 shows the number of Veterans enrolled in outpatient services who received COVID-19 therapeutics during the Interim Review Period.[422]

Figure 7.1: *Veteran Outpatient Treatment for COVID-19, by Therapeutic Type*



Source: VHA leadership, response to email, 9/22/2022. Ref. D9

During the early part of the Interim Review Period, VHA researchers noted that frontline clinicians hesitated to prescribe Paxlovid in some cases, partly due to concerns related to potential drug interactions between Paxlovid and medications commonly used by Veterans.[423] Over time, clinicians became more proficient in managing drug interactions by adjusting dosages of Paxlovid and other medications that might interact with it.[424]

Also during this period, VHA continued to collaborate with FDA and CDC about COVID-19 medications.[425] The collaboration aimed to evaluate utilization and appropriateness of use and to identify and evaluate adverse drug effects associated with the use of Paxlovid and other medications.[426]

At the start of the Interim Review Period, oral therapeutic prescriptions were harder to obtain because of administrative delays.[427] (VHA needed time to develop new processes for integrating these medications into care.)[428] However, once rapid testing and treatment programs like Test to Treat were established, clinicians began to prescribe oral therapeutics more frequently.[429] The use of oral medications also increased because they were relatively simpler to use, compared to IV medication.[430]

Paxlovid was the most frequently used medication among outpatients with COVID-19, followed by Lagevrio (generic name Molnupiravir).[431] (Lagevrio is an oral medication that FDA has authorized for use if other treatments were not available.[432]) VHA leadership attributed the higher usage of Paxlovid to its effectiveness.[433]

Bebtelovimab was third in popularity and usage, in part because it is administered by IV injection, and FDA's authorization recommended it only if other treatments were not available.[434]

Evusheld was used as a preventive agent for the Veteran population; however, VHA leadership noted that the drug may have been under-used because it was released at the same time as other popular antiviral drugs.[435]

Dosage changes may also have impacted the use of Evusheld.[436] VHA worked with providers to combat this issue by distributing information about the medication through email, SharePoint, office hours and newsletters.[437] Examples of dosage shifts include the following:

- The initial EUA for Evusheld was issued by FDA on December 8, 2021. The recommendation was for a dose of Tixagevimab (150 mg) plus Cilgavimab (150 mg) to reduce risk of contracting COVID-19.[438]
- FDA issued an update to the EUA on February 24, 2022, recommending that patients receive a total of Tixagevimab (300 mg) plus Cilgavimab (300 mg) to reduce risk of contracting Omicron.[439]
- On April 29, 2022, FDA recommended that clinicians administer a second dose as soon as possible for individuals who received an initial dose of Tixagevimab (150 mg) plus Cilgavimab (150 mg) based on the administration date of the first dose.[440]
- On June 29, 2022, FDA made a final update to administer a second dosage of Tixagevimab (300 mg) plus Cilgavimab (300 mg) 6 months after the initial dose.[441]

Administration Guidance and Recommendations

VHA administration guidance for therapeutics aligned with general effectiveness recommendations from FDA and CDC, as well as NIH drug use recommendations.[442]

In keeping with FDA and CDC guidelines, VHA did not administer prophylactic antibodies within two weeks of COVID-19 vaccination.[443] The NIH guidelines for COVID-19 treatment were updated five times during the review period, as shown in **Table 7.2**. As the NIH guidelines were released, VHA worked to quickly incorporate them into clinical guidance and practice.[444]

Table 7.2: *Key Updates to NIH Guidelines for Therapeutic Use in Adults*

Date	Key Updates to NIH Guidelines for Therapeutic Use in Adults
April 1, 2022	NIH guidelines identified the following preferred therapeutic treatments to be used to combat the SAR-CoV-2 virus: • Paxlovid • Veklury (for severe COVID-19 infection and more serious illness) NIH guidelines also stated that the following therapeutics may be used as appropriate alternative therapies if preferred therapeutics are not available or clinically indicated: • Bebtelovimab • Lagevrio Patients who require hospitalization for SAR-CoV-2 infection may be prescribed one or both of the following if supplemental oxygen is required: • Veklury • Dexamethasone (not recommended for patients with mild to moderate COVID-19 that do not require inpatient care or supplemental oxygen) Adults may continue use of medications if recommended by health care provider after discharge for underlying conditions. Pediatric patients should discontinue use of Veklury and Dexamethasone following discharge from inpatient care or emergency department. In accordance with FDA, the NIH guidelines recommended use of Sotrovimab in communities in which Omicron BA.2 is not the dominant subvariant and where other COVID-19 therapeutic options are not clinically appropriate or available.
April 8, 2022	NIH guidelines noted that FDA paused the EUA on use of Sotrovimab to treat COVID-19 infection. • Sotrovimab was recognized as being active against the Omicron BA.1 and BA.1.1 subvariants but significantly less effective against the Omicron BA.2 subvariant, which became the primary subvariant among citizens in the United States. NIH guidelines outlined new dosing information for a PrEP or preventive measure for COVID-19 infection. The recommendation was to administer two consecutive IV injections (3 mL each) of Tixagevimab 300 mg plus Cilgavimab 300 mg (Evusheld) to individuals who met the following eligibility criteria: • Patients who were aged 12 years and older • Patients who were moderately to severely immunocompromised • Patients who were not eligible for vaccination with other therapeutic agents

Date	Key Updates to NIH Guidelines for Therapeutic Use in Adults
April 29, 2022	In accordance with FDA, the NIH guidelines stated that Sotrovimab was no longer recommended as a treatment option for COVID-19 infection. NIH guidelines reflected the FDA EUA modification for Tixagevimab plus Cilgavimab (Evusheld). FDA recommended that clinicians administer a second dose as soon as possible for individuals who received an initial dose of Tixagevimab (150 mg) plus Cilgavimab (150 mg), based on the administration date of the first dose. • If the initial dose was administered less than or at 3 months ago, the second dose should be Tixagevimab (150 mg) plus Cilgavimab (150 mg). • If the initial dose was administered more than 3 months ago, the second dose should be Tixagevimab (300 mg) plus Cilgavimab (300 mg). NIH recommended that Bebtelovimab be used as a treatment for non-hospitalized patients at high risk for death and hospitalized patients with mild-to-moderate COVID-19. NIH guidelines state that Bebtelovimab should be used only when preferred therapeutics were not available.
May 13, 2022	The NIH guidelines added a drug-drug interaction section to outline the interactions between Paxlovid and other commonly used medications, as well as a section about SARS-CoV-2 viral rebound and the COVID-19 rebound effect.
May 31, 2022	NIH guidelines made the following recommendations for cancer patients at risk for COVID-19 infection or diagnosed with mild-to-moderate COVID-19 infection: • Evusheld was recommended as a PrEP preventative measure for patients at risk for exposure or after exposure to the SAR-CoV-2 virus. • The potential drug-drug interactions with chemotherapeutic medications and Paxlovid were documented for patients diagnosed with mild-to-moderate COVID-19 infection. NIH guidelines made the following recommendations for transplant and cellular immunotherapy patients at risk for COVID-19 infection or diagnosed with mild-to-moderate COVID-19 infection: • Evusheld was recommended as a PrEP preventative measure for patients at risk for exposure or after exposure to the SAR-CoV-2 virus. • The potential drug-drug interactions with immunosuppressant medications and Paxlovid were documented for patients diagnosed with mild-to-moderate COVID-19 infection. NIH published the COVID-19 vaccination schedules for Pfizer, Moderna, J&J and Novavax for organ and stem cell donors, and for individuals in close contact with transplant and cellular immunotherapy patients.

Date	Key Updates to NIH Guidelines for Therapeutic Use in Adults
June 29, 2022	FDA updated the EUA for Evusheld by recommending administration of a second dosage of Tixagevimab (300 mg) plus Cilgavimab (300 mg) 6 months after the initial dose.

Sources: NIH, "Coronavirus Disease 2019 (COVID-19) Treatment Guidelines," updated 4/1/2022, accessed 9/26/2022, https://files.covid19treatmentguidelines.nih.gov/guidelines/archive/covid19treatmentguidelines-04-01-2022.pdf; NIH, "Coronavirus Disease 2019 (COVID-19) Treatment Guidelines," updated 4/8/2022, accessed 9/26/2022, https://files.covid19treatmentguidelines.nih.gov/guidelines/archive/covid19treatmentguidelines-04-08-2022.pdf; NIH, "Coronavirus Disease 2019 (COVID-19) Treatment Guidelines," updated 4/29/2022, accessed 9/26/2022, https://files.covid19treatmentguidelines.nih.gov/guidelines/archive/covid19treatmentguidelines-04-29-2022.pdf; NIH, "Coronavirus Disease 2019 (COVID-19) Treatment Guidelines," updated 5/13/2022, accessed 9/26/2022,https://files.covid19treatmentguidelines.nih.gov/guidelines/archive/covid19treatmentguidelines-05-13-2022.pdf; NIH, "Coronavirus Disease 2019 (COVID-19) Treatment Guidelines," updated 5/31/2022, accessed 9/26/2022, https://files.covid19treatmentguidelines.nih.gov/guidelines/archive/covid19treatmentguidelines-05-31-2022.pdf. Refs D45, D46, D47, D48, D49; FDA, "FDA Releases Important Information about Risk of COVID-19 Due to Certain Variants Not Neutralized by Evusheld," updated 10/03/2022, accessed 11/18/2022, https://www.fda.gov/drugs/drug-safety-and-availability/fda-releases-important-information-about-risk-covid-19-due-certain-variants-not-neutralized-evusheld. Ref. D223

LONG COVID

During the Annex D Interim Review Period, VHA estimated that 24,800 to 43,400 Veterans had experienced symptoms of Long COVID—4% to 7% of the more than 620,000 Veterans who tested positive for COVID-19, as of July 13, 2022.[445]

In response to the growing Long COVID case count, many VHA facilities established (or continued to operate) dedicated Long COVID programs to assist Veterans suffering from symptoms.[446] VHA continued to research the condition in hopes of developing treatment and tools to help Veterans with Long COVID.[447]

Defining Long COVID

VHA Long COVID Care programs and physicians treating the condition have adopted the CDC case definition for Long COVID, which defines the illness as ongoing, new or returning COVID-19 symptoms that were not present before contracting the virus and were present for four weeks or longer after infection.[448] CDC recognizes that post-COVID conditions can include a wide range of health consequences, both mental and physical.[449]

Long COVID symptoms include the following:[450]

- General symptoms (including tiredness or fatigue)
- Respiratory and heart symptoms (shortness of breath)
- Neurological symptoms (brain fog, dizziness)
- Digestive symptoms
- Joint or muscle pain
- Rash
- Changes in menstrual cycle

According to CDC, some patients with Long COVID reported symptoms that were long-lasting, were hard to explain through routine medical tests and exams and were difficult to manage.[451] As a result, some health care providers reported struggles with treating patients with these unexplained symptoms.[452] Specific Long COVID programs could provide more expert guidance and support for these patients.[453]

Health Risks for Veterans with Long COVID

In 2020, a VA research team began studying Long COVID using VA electronic health care records.[454] The team followed nearly 74,000 Veterans who experienced symptoms of COVID-19 for at least 6 months and compared these records to

Veterans who had not tested positive for COVID-19.[455] The study aimed to characterize and learn more about the disorder.[456]

The study found that Veterans who experienced COVID-19 had a greater risk for chronic conditions with a life-long impact on quality of life and life expectancy.[457] These conditions included the following:[458]

- Heart disease
- Diabetes
- Kidney disease
- Nervous system disorders
- Mental health conditions (see more detail in 'Long COVID and Mental Health' below)

VA data also indicated a resurgence of opioid use in cases of Long COVID as Veterans visited VHA medical clinics to treat pain.[459]

VHA Long COVID Care Programs

Early in the pandemic, individual VHA medical facilities recognized the prevalence of Long COVID and a growing need for its clinical treatment among the Veteran population.[460] In response, these VHA medical facilities began developing their own Long COVID Care clinics to serve the unique needs of their populations.[461] In their early development, Long COVID Care clinics were developed independently.[462] Each created its own standard operating procedures and integrative teams, and developed its own assessment resources.[463]

In 2022, VHA took action to create a standardized approach to Long COVID care.[464]

VHA formed a Long COVID CoP, which began the process of creating a cohesive VHA Long COVID program by assessing what each of the individual facilities had done to treat Veterans with Long COVID.[465]

The Long COVID CoP deployed an environmental scan of all VHA medical facilities in the United States to learn about emerging Long COVID Care clinics and their operations.[466]

Community of Practice

A CoP is an interdisciplinary group of people who interact regularly to share and enhance their knowledge and expertise in a particular area, and work towards a common goal to solve problems.

CDC, "Introduction to CoPs," 11/29/2022, accessed 10/4/2022, https://www.cdc.gov/publichealthgateway/phcommunities/resourcekit/intro/introduction-to-cops.html. D70

An environmental scan is a study used to track trends in an organization's internal and external environment that directly impact its current and future success.[467] The

first VHA Long COVID environmental scan was conducted from August through September 2021, and a follow-up was conducted from May through June 2022.[468]

VHA leadership reported that in the first part of the study (August through September 2021) VHA focused on discovery and data collection, while in the second part (May-June 2022, the Interim Review Period) the organization's focus shifted to action and execution.[469]

The scan showed that 18 of 139 VHA medical facilities had established Long COVID Care programs during the review period.[470] All of the facilities that had established clinics planned to maintain their program's operation, and 43 of the 121 medical facilities that did not have a Long COVID Care Program were considering establishing a program.[471]

Data collected from the environmental scan combined with interdisciplinary team collaboration allowed VHA to identify and develop standard processes of care and streamline consistent systems of care to treat Long COVID.[472]

Long COVID Integrated Project Team

As more data about Long COVID and VHA's actions to address it became available through the environmental scan, VHA established a Long COVID IPT, designed to emphasize Long COVID as a clinical priority for VA and to develop a standardized system of care to address it through research.[473] The Long COVID IPT is a PBRN that studied VHA medical facilities' Long COVID clinics that treated thousands of Veterans with the condition.[474] PBRNs are interdisciplinary teams working in primary care that collaborate to answer health questions and carry over information learned in research to clinical practice.[475]

The Long COVID IPT was developed with stakeholders across VHA organizational units to support the care of Veterans suffering from Long COVID by the following actions:[476]

- Accelerating the execution of research needed to inform and operationalize Long COVID Care Programs
- Standardizing Long COVID care
- Expanding the accessibility of Long COVID Care programs

The mission of this team was to help VHA provide access to Long COVID care to every Veteran in the United States through the production and distribution of a Long COVID care guide.[477] The Long COVID IPT created a variety of tools and resources to increase the medical understanding of Long COVID and its treatment, including a Whole Health System Approach to Long COVID PACT Guide.[478]

Whole Health Long COVID PACT Guide

Published on August 1, 2022, the Whole Health System Approach to Long COVID PACT Guide was designed to support health care providers across disciplines in defining, diagnosing and treating Long COVID symptoms and other possible comorbid conditions.[479] The guide supported and standardized Long COVID Care for VHA and also made a high-level VHA contribution to the general medical community's understanding of Long COVID.[480]

The Long COVID PACT Guide was created by an interdisciplinary team, consisting of VHA ORD, the Long COVID CoP and the Long COVID IPT.[481]

The Long COVID PACT Guide serves as a general guidance and training resource for standardizing Long COVID care across all VHA Long COVID Care Programs.[482]

VHA Long COVID Care Program Operations and Practices

As of July 31, 2022, VHA Long COVID Care Programs were operating across VHA nationwide.[483] Most Long COVID Programs offered some element of virtual care.[484] Most of the program types were hybrid (part in-person, part virtual care); some were operated through all virtual care; and one program, located at VA Southern Nevada Healthcare System, was in-person only.[485]

Results from the environmental scan showed that virtual care (telehealth) was the most efficient and served the largest volume of Veterans, seeing an average of seven times more Veterans than other program formats.[486] During the pandemic, the use of telehealth services rapidly expanded.[487] In 2021, a total of 2.3 million Veterans accessed VHA care virtually.[488] Virtual care made connecting to VHA care easier, whether a Veteran was at home, at a VA facility (connection site) or somewhere else in their community.[489] All Long COVID Care Programs, virtual or in-person, operated as outpatient clinic programs.[490]

Workforce

VHA leadership reported that Long COVID Care Programs spanned a variety of clinical areas.[491] Based on results from the environmental scan, VHA leadership found that physical therapy was the medical specialty area with the highest demand in Long COVID Care Programs, followed by cardiology.[492] VHA leadership shared that Physical Medicine and Rehabilitation (PM&R) and pulmonary physicians were also common specialties of high demand in the Long COVID Care Programs.[493] Other medical specialties that were relevant in Long COVID Care programs were infectious disease staff, social workers and case managers, neurologists, occupational therapists and dieticians.[494]

A cardiologist based at the Washington, DC VAMC. (Photo credit: VA)

For clinics to function at their best, VHA leadership emphasized the essential need for support staff such as administrative staff, schedulers and environmental support persons.[495] Results from the environmental scan showed that programs with dedicated administrative staff saw an average of 48% more patients than programs without such staff.[496] VHA administration reported that many Veterans in Long COVID Care Programs needed the aid of thorough follow-up and referral support for connection to additional services.[497] Veterans were often referred to additional services such as mental health care, psychological assessment, psychiatry and physical therapy.[498]

Screening

Some VHA medical facilities engaged in active screening for Long COVID, a process that included dedicating resources to identify and follow up with at-risk Veterans.[499] The environmental scan reported that nursing staff were critical in identifying Veterans to admit to Long COVID Programs, conducting initial screening and facilitating patient communication.[500]

Although some facilities were able to automate a good portion of their identification and screening processes, they still requested additional support from nursing staff and case managers to coordinate follow-up appointments and Veteran communication.[501]

Testing and Diagnosis

In October 2021 a dedicated International Classification of Diseases, Tenth Revision (ICD-10) diagnostic code for Long COVID was released—U09.9 Post COVID-19 Condition.[502]

VHA leadership worked to size the population of Veterans impacted by Long COVID by tracking the dedicated ICD-10 diagnostic code for Long COVID through employing advanced machine learning and natural language processing (NLP) efforts.[503] Yet, despite these efforts, it was challenging to determine the exact number of Veterans impacted by Long COVID because the ICD-10 diagnostic code identified to track Long COVID was not used consistently across all VHA medical facilities, and there was a lack of back-coding after the dedicated code became widely available.[504]

An important outcome of the environmental scan was a request from VHA medical facilities for additional resources, such as standardized reporting templates and guidance for data entry and tracking patient numbers.[505] In response, VHA's Whole Health System Approach to Long COVID PACT Guide included recommended ICD-10 codes to consider in PACT Management.[506] VHA's Whole Health System Approach to Long COVID PACT Guide also outlined a series of assessments suggested for Long COVID Care Programs to use in their patient evaluations.[507] Suggested assessments included the following:[508]

- Olfactory Training/Testing
- Fatigue and Activity Intolerance Testing
- 30-Second Sit to Stand Test
- Composite Autonomic Symptom Scale 31 (COMPASS 31)

Long COVID and Mental Health

A June 2022 study released by NIH investigated the impacts of Long COVID on golden hamsters—small animals widely used to study respiratory infections.[509] The study found that prolonged inflammation after COVID-19 infection in the hamsters caused permanent damage to organs (including the lungs and kidneys) and also had serious impacts on the brain that correlated with behavioral changes consistent with anxiety and depression.[510]

VA researchers, Xie et al., found that Veterans in the post-acute phase of COVID-19 (four weeks post-infection) had an increased risk for a number of types of incidental mental health disorders.[511] According to their controlled study, these incident mental health disorders included the following:[512]

- Anxiety disorders
- Depressive disorders
- Stress and adjustment disorders
- Opioid use disorder
- Other (non-opioid) substance use disorders
- Neurocognitive decline
- Sleep disorders

VA researchers reported that these mental health risks were evident during Long COVID in Veterans who were hospitalized during the acute phase of COVID-19 and in those who were not hospitalized, but Veterans who were hospitalized were at greater risk.[513] Additionally, this controlled study found that Veterans with COVID-19 were at increased risk of developing mental health disorders than Veterans with seasonal influenza.[514]

According to VA researchers, this evidence suggested the importance of prioritizing the treatment of mental health disorders among Veterans in the post-acute phase of COVID-19.[515]

Long COVID Care Program Mental Health Treatment

VHA's Whole Health System Approach to Long COVID PACT Guide included guidance for mental health considerations in the treatment of Long COVID.[516] The guidance was organized in the following four sections:[517]

- Things to Keep in Mind
- Evaluation: Labs and Tests to Consider
- PACT Management to Consider
- Consultations to Consider

Things to Keep in Mind included a suggestion to consider suicide assessment, given the overall increase in suicides and increased risk for mental health symptoms following COVID-19.[518] Some of the other suggestions to consider listed in this section were the following:[519]

- Completing mental health screenings
- Normalizing and validating symptoms
- Assessing sleep hygiene and symptoms
- Assessing pregnancy and lactation status

As part of Long COVID PACT management, the guide included suggestions for ICD-10 code use, medication and holistic approaches to care, such as diaphragmatic breathing, guided meditation audio files and the use of fish oil (with guidance).[520] Additionally, PACT management shared a list of resources to provide to Veterans, such as the Veteran Crisis line contact information and instructions, a COVID-19 Coach App and an Insomnia Coach App.[521]

Consultations to consider included mental health follow-up, Long COVID support groups, nutrition services, physical therapy, peer support specialists, Whole Health System support and chaplain support.[522]

Implications for Future VHA Long COVID Programming

VHA leadership reported that they do not expect Long COVID to go away.[523] Long COVID care will be included in VHA's long-term planning.[524] As a novel condition, VHA acknowledges the inevitable evolution of knowledge about Long COVID and its treatment, and pledges to update and develop the guide as the body of knowledge grows.[525]

National Long COVID Research

On June 1, 2022, the CDC National Center for Health Sciences added questions to the Household Pulse Survey—a collaboration between CDC, NCHS and the U.S. Census Bureau—to determine how many U.S. adults aged 18 and over had experienced COVID-19 symptoms lasting 3 months or longer.[526] The survey found that approximately 35% of respondents who had tested positive for COVID-19 reported having had a long duration of COVID-19 symptoms (3 months or longer).[527]

These survey questions gathered data from June 1, 2022, to June 13, 2022.[528]

The Household Pulse Survey was designed to quickly inform the Federal statistical system of relevant information regarding the COVID-19 pandemic's impact in the United States.[529]

People at Risk for Long COVID

CDC reported that the risk of developing Long COVID was greater for certain groups of people.[530] These groups included people with underlying conditions, people who experience Multisystem Inflammatory Syndrome (MIS) and people who had more severe COVID-19 symptoms, especially those who were hospitalized or received intensive care.[531]

CDC also reported that health inequities may put racial and ethnic minorities at a higher risk of getting sick from COVID-19 and developing Long COVID.[532]

Household Pulse Survey data agreed with this report; data from the survey showed that Long COVID impacted diverse populations differently across race, age and gender.[533] Of the respondents of the Household Pulse Survey who had COVID-19 and experienced Long COVID, select racial groups had the following results:[534]

- Hispanic or Latino adults had the highest prevalence of Long COVID compared to other racial groups (39.6%).
- Non-Hispanic Black (single race) adults had the second-highest prevalence of Long COVID (37.8%).
- Non-Hispanic other races (multiple race) adults were the third highest (35.7%).
- Non-Hispanic White (single race) adults followed (33.8%).
- Non-Hispanic Asian (single race) adults had the lowest prevalence of Long COVID (25.4%).

Based on age, Household Pulse Survey respondents aged 50-59 reported the highest prevalence of Long COVID (38.2%), followed by respondents aged 40-49 (36.7%).[535] From a gender perspective, the survey indicated that transgender adults reported having had Long COVID at a higher rate (49.1%) than cis-gender male and female adults.[536] Cis-gender females had the second highest prevalence (41.3%), and cis-gender males had the third (27.1%).[537]

Additionally, according to VHA leadership, a high percentage of Veterans had comorbidities that could be uncovered and exacerbated by Long COVID, indicating the need for appropriate access to quality care.[538]

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APPENDICES

APPENDIX A: STAKEHOLDER INTERVIEWS

Table 9.1 below lists the stakeholders who contributed their knowledge to the creation of the Annex D Interim Report. Interviews were conducted by the COVID-19 Response Report Team. All titles and positions were as of April 1, 2022.

Table 9.1: *Stakeholder Interviews for the Annex D Interim Review Period*

Interview Date	Interview Name	Position
9/20/2022	Dr. Carolyn Clancy	Assistant Under Secretary for Health for Discovery, Education and Affiliate Networks
9/22/2022	Dr. Grant Huang	Deputy Chief Research and Development Officer Director, VHA Office of Research and Development
9/14/2022 9/21/2022	Dr. Jennifer Martin	Deputy Chief Consultant for Pharmacy Benefits Management
9/14/2022	Dr. Sophia Califano	Deputy Chief Consultant for Preventive Medicine
9/14/2022	Ms. Maria Bouchard	Senior Clinician Consultant, Office of Veterans Access to Care, Nurse Practitioner
9/15/2022	Dr. Peter Kaboli	Acting Executive Director, VHA Office of Rural Health
9/13/2022	Dr. Gio Baracco Lira	Staff Infectious Disease Physician, Miami VAMC
9/13/2022	Dr. Michael Gelman	Staff Infectious Disease Physician, Bronx VAMC
9/13/2022	Ms. RimaAnn Nelson	Assistant Under Secretary for Health for Operations
9/14/2022	Ms. Tammy Czarnecki	Assistant Deputy Under Secretary for Health for Operations
9/30/2022	Dr. Erica Scavella	Assistant Under Secretary for Health for Clinical Services
9/16/2022	Dr. Ralph Schapira	Staff Physician, Southeast Louisiana Veterans Health Care System
9/16/2022	Ms. Marian Adly	Previous White House Presidential Innovation Fellow, Office of Chief Technology Officer
9/16/2022	Dr. Amanda Purnell	Director of Data and Analytics, VHA Office of Healthcare Innovation and Learning
9/16/2022	Dr. Joseph Francis	Executive Director, Analytics and Performance Integration
9/16/2022	Dr. Makoto Jones	Director, Biosurveillance, Antimicrobial Stewardship and Infection Control (BASIC), VHA Office of Analytics and Performance Integration
10/20/2022	Dr. Beth Ripley	Deputy Chief Officer, VHA Office of Healthcare Innovation and Learning
10/21/2022	Dr. Lisa Backus	Executive Director of Population Health, VHA Office of Health Solutions

APPENDIX B: ACRONYMS

Acronym	Expansion
AI/AN	American Indian or Alaska Native
BARDA	Biomedical Advanced Research and Development Authority
BMI	body mass index
CCC	Clinical Contact Center
CDC	Centers for Disease Control and Prevention
CDT	clinical deployment team
CI	confidence interval
CMO	Chief Medical Officer
CMS	Centers for Medicare and Medicaid Services
CNO	Chief Nursing Officer
COMPASS	Composite Autonomic Symptom Score
CoP	Community of Practice
COPD	chronic obstructive pulmonary disease
COPE-VA	COVID-19 Pharmacotherapy Effectiveness in the VA Healthcare System
CORC	Health Services Researchers through the COVID-19 Observational Research Collaboratory
CPRS	Computerized Patient Record System
CRM	Customer Relationship Management
EBP	evidence-based practice
ED	emergency department
EHR	electronic health record
EPOC	Evaluation of Point-of-Care
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
HSR&D	Health Services Research and Development
ICD	International Classification of Diseases
ICI	Anti-Coronavirus Immunoglobulin
ICN	International Classification of Diseases
ICU	intensive care unit
IPT	Integrated Project Team
ITAC	Inpatient Treatment of COVID-19 With Anti-Coronavirus Immunoglobulin
IV	intravenous
MIS	Multisystem Inflammatory Syndrome
mRNA	messenger ribonucleic acid
MSA	Medical Support Assistant
MV	mechanical ventilation
NAAT	nucleic acid amplification test
NCHS	National Center for Health Sciences
ND	Network Director

Acronym	Expansion
NHLBI	National Heart, Lung, and Blood Institute
NHOPI	Native Hawaiian or Other Pacific Islander
NIH	National Institutes of Health
NLP	Natural Language Processing
OHE	Office of Health Equity
OHIL	Office of Healthcare Innovation and Learning
ORD	Office of Research and Development
PACT	Patient Aligned Care Team
PBM	Pharmacy Benefits Management
PBRN	Practice-Based Research Network
PCMHI	Primary Care Mental Health Integration
PCR	polymerase chain reaction
PHE	public health emergency
PM&R	Physical Medicine and Rehabilitation
PPE	personal protective equipment
PrEP	pre-exposure prophylaxis
PTSD	Post-Traumatic Stress Disorder
RSV	respiratory syncytial virus
RWE	real-world evidence
SDoH	Social Determinants of Health
SeqCURE	Sequencing Collaborations United for Research and Epidemiology
SLTT	state, local, tribal and territorial
SUD	substance use disorder
SUPERNOVA	Surveillance Platform for Enteric and Respiratory Infectious Organisms in the Veterans Affairs population
USVETS	United States Veterans Eligibility Trends and Statistics
VAMC	VA Medical Center
VHA	Veterans Health Administration
VISN	Veterans Integrated Services Network

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