

## COVID-19 Evidence Digest 4/28/21

### Health Care Utilization and Clinical Characteristics of Nonhospitalized Adults in an Integrated Health Care System 28–180 Days After COVID-19 Diagnosis — Georgia, May 2020–March 2021 (MMWR)

**Bottom Line:** In this study of over 3,100 non-hospitalized adults with COVID-19, over 2/3<sup>rd</sup> had 1 or more outpatient visits 1-6 months following diagnosis. Of those, 1/3<sup>rd</sup> had a new specialist visit and 2/3<sup>rd</sup> had a new primary diagnosis visit; new diagnoses included shortness of breath, cough, chest or throat pain, and fatigue.

**Details:** Using electronic health record data from an integrated health care system, this study looked at clinical characteristics and healthcare utilization of non-hospitalized adults with COVID-19 1-6 months post-diagnosis. Of 3,171 participants, 69% (n=2,177) had 1 or more outpatient visits in the 28-180 days post-COVID-19 diagnosis. Compared with patients who did not have any outpatient visits during the study period, those who did were more likely to be 50 or older, women, identify as non-Hispanic Black, and have underlying health conditions. 68% (n=1,617) and 38% (n=823) of those with outpatient visits had a new primary diagnosis visit and new specialist visit, respectively. New specialist visits potentially related to COVID-19 were most commonly dermatology (16%), behavioral/mental health (11%), gastroenterology (11%), and cardiology (10%). Potential COVID-19 symptoms and active COVID-19 diagnoses were among the top 20 new visit diagnoses (3-7% and 10% of patients with 1 or more outpatient visits during the study period, respectively). New diagnoses included shortness of breath, cough, chest or throat pain, and fatigue. Visits for these diagnoses declined 2 months post-diagnosis (from 2-24 visits per 10,000 person days 28-59 days post-diagnosis to 1-4 visits per 10,000 person days 120-180 days post-diagnosis).

#### **Key Takeaways:**

- While visits for COVID-19 related symptoms decreased overall after 2 months, some patients continued to have such visits through 6 months post-diagnosis, pointing to the need for clinicians and health care systems to be aware of the potential for continued health care needs related to COVID-19, including among those not initially hospitalized for the disease.
- This study did not compare the number of visits among non-hospitalized adults with COVID-19 1-6 months post-diagnosis with adults without COVID-19; more research is needed to explore the finding that a higher proportion of non-Hispanic Black individuals and women had 1 or more outpatient visits than did persons of other racial/ethnic groups and men.

### Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons (NEJM)

**Bottom Line:** Preliminary data from the CDC's V-Safe After Vaccination Health Checker Surveillance System, V-Safe Pregnancy Registry, and Vaccine Adverse Event Reporting System of pregnant people who received mRNA COVID-19 vaccines did not raise any obvious safety concerns.

**Details:** This study looked at data from the CDC's V-Safe After Vaccination Health Checker Surveillance System (Health Checker), V-Safe Pregnancy Registry, and Vaccine Adverse Event Reporting System (VAERS) to explore the initial safety of mRNA COVID-19 vaccines

## COVID-19 Evidence Digest 4/28/21

in pregnant people. 35,691 participants in V-Safe Health Checker identified as pregnant. Pregnant people reported injection site pain more frequently than non-pregnant people, while fever, chills, headache, and body aches were reported less frequently. 827 of 3958 participants in the Pregnancy Registry had a completed pregnancy (live-born infant, stillbirth, spontaneous abortion, induced abortion); of those, 86% (n=712) and 13% (n=104) resulted in a live birth and spontaneous abortion, respectively; the proportion of spontaneous abortion is similar to the expected miscarriage rate. No neonatal deaths were reported; other adverse outcomes reported were small size for gestational age (3%) and preterm birth (9%). Though not directly comparable, the proportion of these adverse events was similar their reported occurrence, described in the literature, among pregnant people prior to the pandemic. 221 pregnancy-related adverse events were reported to VAERS; the most common was spontaneous abortion/miscarriage (46/221). People can report any adverse event that occurred after vaccination to VAERS, whether or not it is plausibly related; causality cannot be determined from these data.

### Key Takeaways:

- There were no statistically significant differences in reported side effects among pregnant vs non-pregnant people who received mRNA COVID-19 vaccines.
- The proportion of adverse pregnancy and neonatal outcomes among vaccinees with a completed pregnancy was similar to those reported in the literature among pregnant people prior to the pandemic, though these findings are not directly comparable.
- Large longitudinal studies are needed, including among those vaccinated earlier in pregnancy, to better understand and characterize pregnancy, maternal, and neonatal outcomes among COVID-19 vaccinees.

### COVID-19 Vaccine Coverage in Health-Care Workers in England and Effectiveness of BNT162b2 mRNA Vaccine against Infection (SIREN): A Prospective, Multicentre, Cohort Study

**Bottom Line:** In this study, there were 14 SARS-CoV-2 infections per 10,000 person-days in unvaccinated health care workers, compared with 8 per 10,000 person-days in those who received at least 1 vaccine dose 21 days prior and 4 per 10,000 person-days in those who received their second vaccine dose at least 7 days prior.

**Details:** This study looked at the effectiveness of BioNTech's mRNA vaccine in a real world setting among a cohort of health care workers (HCWs) completing routine asymptomatic testing for SARS-CoV-2. HCW participants in this study were broken into 2 groups – those who had previously tested positive for COVID-19 or had antibodies against the virus and those with a negative antibody test with no previous positive test. Symptom status was collected every 2 weeks, and participants underwent SARS-CoV-2 PCR testing every 2 weeks and antibody testing every month. The key outcomes of interest were vaccinated participants (indicated by at least 1 vaccine dose) and lab-confirmed SARS-CoV-2 infection. 23,324 HCWs were enrolled in the study and followed up for 2 months; at the start of the analysis period, 35% (n=8203) and 65% (n=15,121) were assigned to the “positive” and “negative” cohort of the study, respectively. By the end of the study period (2/5/21), 89% of the sample was vaccinated, the majority of whom received the BioNTech vaccine (94%). During the follow up period, there were 977 infections among unvaccinated individuals (14

## COVID-19 Evidence Digest 4/28/21

infections per 10,000 person-days); by contrast, there were 71 new infections among vaccinated individuals 21 or more days after their first dose (8 infections per 10,000 person-days) and 9 infections 7 days after their second dose (4 infections per 10,000 person days). 56% of participants in the unvaccinated group (n=543) had COVID-19 symptoms compared to 36% (n=29) in the vaccinated group. In this study population, vaccine effectiveness estimates were 70% and 85% 21 days after the first dose and 7 days after the second dose, respectively.

### Key Takeaways:

- In this study population, vaccine effectiveness estimates were 70% and 85% 21 days after the first dose and 7 days after the second dose, respectively.

### [COVID-19 Outbreak Associated with a SARS-CoV-2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program — Kentucky, March 2021 \(MMWR\)](#)

**Bottom Line:** In this study at a skilled nursing facility (SNF) experiencing a COVID-19 outbreak, unvaccinated residents and health care staff had 3 and 4 times the risk of SARS-CoV-2 infection as residents and staff who were vaccinated, and the vaccine was 87% protective against symptomatic illness among residents and staff.

**Details:** This investigation reports on findings from a COVID-19 outbreak at a skilled nursing facility (SNF) after residents and staff had the opportunity to be vaccinated using Pfizer-BioNTech's mRNA vaccine. 90% (n=75) and 53% (n=61) of residents and staff, respectively, received 2 vaccine doses. Residents and staff underwent symptom screening, and staff also completed screening testing twice per week. Screening testing identified a positive result in an unvaccinated symptomatic staff person (index case) on 3/1/21. Thereafter, daily point of care antigen testing, regardless of symptoms, was carried out for all residents. In total, 46 COVID-19 cases were identified; 26 in residents (18 of whom were fully vaccinated, or received their second vaccine dose  $\geq 14$  days before the outbreak began) and 20 in staff (4 of whom were fully vaccinated); 2 cases in residents were excluded from analysis because they received their second vaccine dose within 14 days of the outbreak. Unvaccinated residents and health care staff had 3 and 4 times the risk of SARS-CoV-2 infection as residents and staff who were vaccinated, respectively (attack rates of 75% vs 25% for residents and 30% vs 7% for staff). Whole genome sequencing identified an R.1 lineage variant in the samples from the SNF, which contains the D614G and E484K mutations that may make the virus more transmissible and have shown evidence of reduced neutralization (elimination or reduction of the virus' ability to replicate) by the blood of recovered individuals and those who have been vaccinated against SARS-CoV-2. The estimated vaccine effectiveness (VE) against SARS-CoV-2 infection was 66% and 76% among residents and staff, respectively. Staff and residents were 87% less likely to have symptomatic COVID-19 compared with those who were not vaccinated; vaccinated residents were 94% less likely to be hospitalized than unvaccinated residents. There were 4 possible reinfections identified (positive SARS-CoV-2 test  $>90$  days after a previous lab-confirmed infection) in 1 resident and 3 staff; of these individuals, 1 staff person was vaccinated. 3 residents died (2 were unvaccinated, 1 was vaccinated).

## COVID-19 Evidence Digest 4/28/21

### Key Takeaways:

- During this COVID-19 outbreak at an SNF, 4 of 6 unvaccinated, infected residents were hospitalized, resulting in 2 deaths.
- While vaccination was protective against symptomatic illness, 25% and 7% of vaccinated residents and staff, respectively, were infected; these findings may support the potential reduced protective immunity of the vaccine against the R.1 variant identified in this study, which contains the D614G and E484K mutations. However, study limitations/caveats that may have impacted these vaccine effectiveness estimates were a small sample size, higher exposure risk (congregate setting), and testing regardless of symptoms.
- Findings underscore the importance of vaccination among SNF residents and staff, as well as the continued need for infection prevention and control.