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Effects of HIV Status and Vaccination on Long COVID Conditions Within an Integrated Health Care System

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Abstract

Background: COVID infection has been linked to long-term effects known as Long COVID Conditions (PCC), presenting within 30-120 days post-acute COVID infection. Few studies have focused on PCC incidence among people with HIV (PLWH). Additionally, the effect of vaccination, especially among PLWH, is unclear on the risk for PCC. We evaluate PCC incidence among PLWH compared with people without HIV (PWoH), as well as the effect of COVID vaccination, within an integrated closed healthcare system with high ascertainment of COVID-19 testing.

Methods: Adult patients with a positive polymerase chain reaction test for COVID between 1/1/2020-1/31/2022 were matched PLWH to PWoH by month of test, age, race, sex,

vaccination status, using 1:3 variable ratio matching. PCC was defined as presenting with at least one of 17 previously identified conditions incident in the 30-120 days post first positive test date. We determined the effect of COVID vaccination on subsequent development of PCC using an unmatched PLWH/PWoH population analyzed by multivariate regression modeling.

Results: We show that 749 PLWH matched to 2,236 PWoH for PCC incidence evaluation and 492 (PLWH) and 71,844 PWoH for vaccination analysis. PLWH have 25% higher risk of PCC than PWoH. Gastrointestinal and other nervous system disorders are significantly higher among PLWH. Vaccination has significant impact on acute-persistent PCC risk but not late incident PCC without impact by HIV status.

Conclusions: PLWH have higher risk of PCC. Vaccination lowers persistent symptom risk, but not late incident PCC risk. Vaccination and vigilance for PCC is encouraged.

Plain Language Summary

Some people who get COVID-19 develop long-term health problems, known as Long COVID or post COVID conditions (PCC), which can appear one to four months after infection. However, little research has looked at the risk of developing these conditions in people living with HIV (PLWH), or whether COVID-19 vaccination reduces this risk. In this study, we compared the risk of PCC in people living with HIV and those without HIV. We found that people living with HIV had a slightly higher risk of developing PCC, especially conditions affecting the digestive system and nervous system. We also found that people who were not vaccinated had a higher chance of experiencing long-lasting symptoms, regardless of whether

they had HIV. These findings may help guide future vaccination strategies and improve diagnosis of Long COVID.

Introduction

Long COVID conditions (also known as Post-COVID Conditions[1]; herein abbreviated as PCC) are recognized as a potential outcome of acute SARS-CoV-2 (COVID) infection, with continued or new symptoms that can be either short- or long-term. In 2022, it was estimated that 6.9% of adults in the United States had ever had PCC, with 3.4% having current PCC symptoms.[2] Incidence was more common among women than men, and varied by race, ethnicity, and age group. While multiple definitions of PCC have been proposed, the only internationally recognized definition comes from the World Health Organization (WHO), which is continuation or development of new symptoms 3 months after the initial SARS-CoV-2 infection, with these symptoms lasting for at least 2 months with no other explanation, and was last updated in 2022, while others are proposed to be adopted, including that from National Academies of Science, Engineering, and Medicine.[3-6] This definition lacks substance or specificity for clear qualification, even though ICD-10 codes were created to employ PCC in the medical record. However, these codes also suffer from lack of specificity, whether they be inclusion or exclusion criteria; and as such limiting their clinical usage or being informative.

In 2022, we reviewed the Kaiser Permanente Mid-Atlantic States' (KPMAS; serving greater Maryland including Baltimore; District of Columbia, and northern Virginia) data (through December 2020) to better define the constituent and most common conditions among 31,390 members at risk for PCC (30-120 days after COVID diagnosis).[7] We identified

ICD-10 codes corresponding to potential PCC-related conditions utilizing Healthcare Cost and Utilization Project (HCUP) Clinical Classifications Software (CCS) classification,[8] and compared them between matched populations testing positive for SARS-CoV-2 and those testing negative. Matching was performed on multiple factors including age-, sex-, race/ethnicity, geographic location, and test date. Seventeen PCC-related conditions were identified which constituted more refined PCC diagnostic criteria, including anosmia and malaise (Table 1). Of note, many patients who had symptoms consistent with PCC had these symptoms prevalent prior to their infection and many patients who tested negative for SARS-CoV-2 had the same symptoms. While this revised PCC description offered greater clarity to its definition, it did not identify any differences by chronic comorbidities, including HIV.

People living with HIV (PLWH) may be at increased risk for PCC, especially those with more advanced immunodeficiency (CD4<200 cells/μL).[9] However, the incidence of PCC among PLWH compared to people without HIV (PWoH), or those who have not tested positive for HIV, has been inconclusive and limited.[10] Additionally, the impact of COVID vaccination on PCC incidence among PLWH has not been thoroughly explored.[11]

To address these issues, we examine the incidence of PCC overall, and of the specific PCC-related conditions we identified previously among PLWH compared with a matched control group of PWoH within KPMAS. Additionally, we explore the association between the incidence of PCC and COVID vaccination status, and whether the association was modified by HIV status. As an integrated closed healthcare system, KPMAS has high ascertainment of COVID-19 testing and PCC-related diagnoses among both PLWH and PWoH. We find that

HIV does increase risk of long COVID, and vaccination lowers persistent symptom risk, but not risk of late incident long COVID.

Methods

Setting

KPMAS is an integrated health system in the United States, with over 800,000 members in the Mid-Atlantic region, representing Maryland (including greater Baltimore), the District of Columbia, and Northern Virginia. Membership is both diverse and representative of the respective jurisdictions[12] Members are provided comprehensive integrated health care, including, but not limited to, primary and specialty care, ambulatory and inpatient care, with integration among partner hospitals in the Mid- Atlantic region. All healthcare utilization is captured through the Epic® EHR system which includes clinical data on services received internally and externally to KPMAS, including laboratory, radiology, and pharmacy data. External data is captured through health claims data, as well as integrated health information exchange systems (Epic® Care Everywhere and the Maryland/Washington DC health information exchange called Chesapeake Regional Information System for our Patients [CRISP]).[13] Additionally, member geographic and socioeconomic data is ascertained through our Geographically Enriched Member Sociodemographic (GEMS) database.[12] KPMAS is a closed healthcare system with high ascertainment of COVID-19 results and vaccination for our members, as well as capture of PCC and symptoms. Our study was approved by the Kaiser Permanente Mid-Atlantic States Institutional Review Board with a waiver of informed

consent (IRB approval number 1592769). The study received a waiver of informed consent due to minimal risk to participants as a retrospective study and the use of deidentified data.

Study population for this nested study

COVID classification was based on laboratory testing, as described previously.[7] All patients in this analysis tested positive for SARS-CoV-2 by PCR. We identified adult patients (≥18 years) with a positive PCR result between January 1, 2020, through January 31, 2022. The first positive test date for each patient was the index date for our study. We excluded any patient not enrolled in KPMAS during the 120 days post COVID test date. We ended data attainment at end of January, 2022 for the index date, as after that period KPMAS patients began using home COVID antigen test kits in greater numbers and there was concern over bias in data ascertainment.

PLWH were matched with up to three PWoH, without replacement, by month and year of index date, age group at index date (18–29, 30–39, 40–49, 50–64, 65–74, 75–84, ≥85 years), race/ethnicity (Black/African American, White, Hispanic, Asian, Other/Unknown), sex (female or male), and service area (to account for any physician differences in diagnostic practices). When 1:3 matching was not possible, PLWH were matched to PWoH 1:2 or 1:1.

HIV status (exposure)

HIV status was ascertained from the dynamic KPMAS HIV registry, which utilizes numerous identification criteria primarily based on laboratory testing (primarily positive HIV antibody test result or quantified HIV RNA level [>20 copies/mL]) and diagnoses. Criteria are (and listed in order of prioritization):

HIV antibody Western Blot positive lab test result or 4th generation confirmatory test

Quantifiable HIV RNA level (≥20 copies/mL or above level of quantification for specific test)

(Note that patients taking HIV PrEP (as noted in the electronic health record and no history of quantifiable HIV RNA or negative HIV antibody test) are excluded.)

At least two fills each of at least two different antiretroviral component medications and at least 1 HIV (ICD-9: 042.xx, 043.xx, 044.xx, V08, 795.7; ICD-10: B20.x, Z21.X, R75.X) coded outpatient diagnosis visits to Infectious Disease (who are responsible for all HIV care within KPMAS; For this criteria, Truvada (tenofovir disoproxil fumarate plus emtricitabine as a fixed-dose combination) or Descovy (tenofovir alafenamide plus emtricitabine as a fixed-dose combination) are to be considered one medication.)

At least 2 HIV RNA level results below limits of quantification and at least 90 days apart and less than or equal 365 days apart and at least 1 HIV (ICD-9: 042.xx, 043.xx, 044.xx, V08, 795.7; ICD-10: B20.x, Z21.X, R75.X) coded outpatient diagnosis visits to Infectious Disease

HIV (ICD-9: 042.xx, 043.xx, 044.xx, V08, 795.7; ICD-10: B20.x, Z21.X, R75.X) coded hospital, emergency department or observation bed discharge with at least one subsequent outpatient HIV diagnosis to Infectious Disease

At least 2 HIV (ICD-9: 042.xx, 043.xx, 044.xx, V08, 795.7; ICD-10: B20.x, Z21.X, R75.X) coded outpatient diagnosis visits to Infectious Disease

COVID-19 vaccination status (exposure)

COVID vaccinations were extracted from our EHR, including vaccinations from non KPMAS sites that were ascertained via a centralized health information exchange system. Those with two or more doses of a Pfizer/Moderna COVID vaccine ≥14 days apart, or one dose of Janssen COVID vaccine, prior to the first PCR-confirmed COVID-19 infection (i.e., the index date) were classified as fully vaccinated.

CCS (outcome)

We employed this methodology as in our previous study to define PCC as a composite outcome of PCC-related conditions.[7] Briefly, Seventeen PCC-related conditions were identified using the standard Healthcare Cost and Utilization Project (HCUP) Clinical Classifications Software (CCS, Table 1) which was modified for better categorical groups.[6,8] To identify these 17 conditions, we abstracted all diagnoses from our EHR and claims systems that occurred within our observation periods. We employed the standard HCUP Clinical Classifications Software (CCS)[8] and enforced mutual exclusivity time requirements at the CCS Category Level. CCS conditions were only counted once per patient and classified based on when the condition was first recorded in the EHR. CCS conditions that were deemed clinically significant by the infectious disease physicians, were considered PCC-related conditions.[7] Those having at least one of the 17 conditions were classified as having PCC.

PCC was further classified based on the timing of the condition diagnosis relative to the date of first COVID-positive test (i.e., the index date, T_0). Mutually exclusive, diagnostic time intervals were identified and anchored on T_0: (1) pre-existing conditions time interval: diagnoses up to four years prior to T_0, (2) acute and persistent time interval: diagnoses

incident in the 0–29 days post-T_0 and persisted, or re-observed, in the 30–120 day period, and (3) late incident interval: new disease diagnoses 30–120 days post-T_0 (Figure 1).

Covariates of Interest

Demographic and other covariates of interest were abstracted from the KPMAS EHR. These covariates included: sex, race/ethnicity (White, Black, Asian, Other/Unknown and Hispanic), age on index date, specific comorbidities prior to index date (chronic kidney disease, chronic obstructive pulmonary disease, diabetes mellitus type 1 or 2, cancer of any type), body mass index (BMI; kg/m^2), insurance type (commercial, Medicare, Medicaid, Charity, individual coverage through the ACA [Affordable Care Act]), service area (to account for any differences in diagnostic practices), and the COVID variant during the time of infection (Alpha: January 1, 2020-December 31, 2020; Delta: January 1, 2021-October 1, 2021; Omicron: October 2, 2021-January 31,2022).

Statistical Analysis

Overall relative risk of PCC in PLWH (vs. PWoH) and 95% confidence intervals (95% CI) were estimated for persistent and late incident PCC using Poisson regression models with cluster robust standard error (an approximation to log-binomial models). The analysis was weighted to account for disproportionate matching. In addition to evaluating overall PCC incidence, we analyzed each PCC condition in the persistent and late incident time intervals separately using the same regression approach; sample size limitations in the matched cohort prevented a regression analysis of the persistent time interval and descriptive statistics were included.

To mitigate the effect of partial or no COVID vaccination (<2 doses of Pfizer/Moderna or no Janssen dose) present during the Alpha variant time period (1/1/2020-12/31/2020), only patients with their first COVID positive test date in the Delta and Omicron variant time periods (1/1/2021 – 1/31/2022) were included in the vaccine analysis. We determined that the whole cohort be used (no matching was performed) on this group allowing for a larger study population to be analyzed. Covariates and demographics including sex, race/ethnicity, age, service area, variant and HIV status, were adjusted for in the model.

Adjusted relative risks, also calculated using Poisson regression with cluster robust standard error, were interpreted to evaluate the association between vaccination and overall and individual PCC conditions in the persistent and late incident time intervals, accounting for differences in sex, race/ethnicity, age at index date, medical service area within KPMAS, COVID variant periods, and HIV status. To further ascertain whether the association of PCC incidence and COVID vaccination status was modified by HIV status, interaction terms were included in the adjusted model and tested for significance using a Wald test.

All analyses were conducted using SAS (version 9.4; Cary, North Carolina) and R version 4.4.0 (R Core Team, 2024). A p-value < 0.05 guided statistical interpretation.

Results

Study population

We identified 103,581 adult patients who tested positive for SARS-CoV-2 by PCR between January 1, 2020 through January 31, 2022, which preceded the scale-up of at- home COVID-19 testing. Of those, 58% were female, 62% were less than 50 years of age, and a

plurality were Black or Hispanic (43% and 20%, respectively) (Table 2). 45% first tested COVID-positive during the Omicron period (10/2/2021-1/31/2022). At the time of infection, 39% were vaccinated and 58% had a BMI ≥ 25 kg/m^2. The most frequent pre-existing comorbidity was diabetes mellitus type 1 or 2 (17%), followed by chronic kidney disease and cancer (4% and 3%, respectively). Only 1% of our total COVID-positive population had prior evidence of HIV infection (inclusion in KPMAS HIV registry, that was based on detectable HIV RNA level or positive HIV antibody testing).

Matching Results PLWH with PWoH

The scaled matching algorithm produced a study population of 2,985 patients (N=749 PLWH and 2,236 PWoH), with 99% matched 1:3 (Table 2). This matched PLWH to PWoH cohort was predominantly male (64%), less than 50 years of age (56%), Black (80%), unvaccinated for COVID (61%), and had a BMI ≥ 25 kg/m^2 (>60%). The most frequent pre-existing condition among the matched cohort was diabetes mellitus type 1 or 2 (17% PLWH and 21% PWoH), followed by chronic kidney disease (9% PLWH and 5% PWoH) and cancer (4% PLWH and 2% PWoH).

Matched Analysis: PLWH vs PWoH

The risk of having any PCC in the incident time interval (30-120 days post- COVID diagnostic date) was 25% higher among PLWH (15%) than among PWoH (12%; RR=1.25; 95% CI 1.02-1.54; p=.03) (Table 2). Absolute risk difference was 3%. Among those who developed PCC within the PLWH cohort, 34% were female, 82% were Black, 6% were Hispanic, 41% had a BMI ≥ 30 kg/m^2. Among PLWH, 5% had CD4 <200 cells/mm^3, and 85%

had undetectable viral load as measured closest to date of initial COVID diagnosis Within the PLWH cohort, there were no statistically significant associations between sex, race, BMI and the incidence of PCC.

Among the individual PCC conditions, only gastrointestinal disorders, such as constipation and diarrhea (see Supplementary Table 1) and other nervous system disorders had a significantly elevated incidence in the incident time interval among PLWH compared to PWoH (RR=2.00; 95% CI [1.17-3.41]; p=.01 & RR=2.45; 95% CI [1.02-5.90]; p=.04; see Figure 2).

The risk of having any PCC in the persistent time interval (0-29 days post-COVID diagnosis that continued into the 30–120-day period post-COVID diagnosis) was not significantly higher for PLWH than for PWoH (RR=1.11 95% CI [0.73-1.70]; p=.62) (Table 3). Individual conditions could not be analyzed through Poisson regression due to insufficient numbers in PLWH; however, no significant differences in specific PCC conditions were found when comparing PLWH to PWoH.

Total Cohort for Impact of COVID Vaccination

During the Delta and Omicron variant time periods (1/1/2021-1/31/2022), we identified 72,376 patients with a PCR positive for SARS-CoV-2. Of those, the majority were vaccinated (defined as two or more doses of a Pfizer/Moderna COVID vaccine ≥14 days apart, or one dose of Janssen COVID vaccine, prior to the first PCR-confirmed COVID- 19 infection [i.e., the index date]; 56%) at time of COVID infection (Table 2). Overall, this cohort was mostly female (58%), less than 50 years of age (63%), Black or Hispanic (45% and 16%, respectively), and had a BMI ≥ 25 kg/m^2 (~57%). Among those vaccinated, a majority were

female (60%), less than 50 years of age (60%), Black or Hispanic (42% and 16%, respectively), and had a BMI ≥ 25 kg/m^2 (60%). Based on chi- square test of association, sex, age, race/ethnicity and BMI all resulted in statistically significant associations with vaccination status (p<.0001).

Unmatched Analysis: Vaccinated vs Unvaccinated

Among the vaccinated patients who developed COVID, 13% developed PCC, while 13% among those who were unvaccinated at time of COVID diagnosis developed PCC (Table 1). The interaction effect between HIV and vaccination on PCC incidence overall was not significant (p=.97). While we did not find a higher overall risk of having PCC in the incident time interval for unvaccinated patients compared to vaccinated (RR=1.05; 95% CI [1.00-1.10]; p=.05) (Table 4), the analysis of individual PCC conditions in the incident time interval showed multiple conditions were significantly elevated for those unvaccinated compared to those who were vaccinated prior to COVID infection, namely anxiety, cardiac dysrhythmia, fluid and electrolyte disorders, chest pain and mental health conditions such as mood, behavior, alcohol-related, and substance abuse disorders (Figure 3). Conditions associated with dizziness or vertigo showed decreased risk among unvaccinated patients.

The overall risk of PCC in the persistent time interval was significantly higher (90%) in those unvaccinated prior to COVID infection (RR=1.90; 95% CI [1.69-2.15]; p=<0001).Additionally, the risk of all individual PCC conditions, except anosmia, anxiety , malaise and fatigue, and vertigo were higher and statistically significant for unvaccinated patients (compared to those vaccinated) in the persistent time interval (Figure 4).

Discussion

Our study provides greater insight into PCC incidence among persons living with HIV and the effect of COVID vaccination on PCC incidence. Importantly, this work expands the time period under study beyond the initial surges of the pandemic and evaluates PCC across multiple COVID-19 variants; it is also unique in that it evaluates both an overall PCC definition and individual conditions, furthering our understanding of PCC and how it manifests differently within various populations, including PLWH compared with PWoH. As in our previous study, the exclusion of conditions existing prior to incident COVID is a key element, as it enhances our overall signal for PCC and reduces the falsely perceived PCC conditions caused by ongoing medical conditions.[7]

We have provided insight into the individual conditions that constitute PCC diagnoses, and how those conditions vary within different time intervals post-COVID infection. We evaluated PCC incidence for PLWH compared to a matched cohort of PWoH, and compared the incidence of PCC among COVID-19 vaccinated patients both within and outside of the PLWH population. Further research into the impact of controlled versus uncontrolled HIV infection, with new variants, and PCC incidence following booster doses of COVID-19 vaccination, are important next steps in evaluating PCC.

Currently, there is no commonly accepted definition of PCC or what constitutes the condition or syndrome. CDC, WHO, and NASEM have no uniform criteria to define PCC. WHO, for example, has a definition with no specificity, and lacks clinical utility. The NASEM created a definition but lacked defining symptomatology which is of greater clinical efficacy, as we used here.[5] We previously defined PCC and continue to refine its application among

different populations at higher risk of COVID infection. Like other studies, ours demonstrates that symptomatology can be heterogenous, making a simple definition difficult.[4] Complicating the definition and diagnosis of PCC is that no commonly used laboratory testing has proven to be a reliable laboratory marker for PCC.[14] While vaccination has lowered the risk of PCC (by lowering the risk of COVID), it remains a problem in the general population and among high-risk sub-populations, including PLWH.

In an analysis of national data sourced from 69 U.S. health care organizations, Yendewa and colleagues found increased risk of some PCC conditions such as hypertension, heart disease, fatigue, chest pain, and gastrointestinal disorders among PLWH compared to PWoH.[9] As in our study, vaccination significantly reduced some PCC conditions, and they showed this protective effect including PLWH.[9] The Researching COVID to Enhance Recovery study, while not focused on PLWH, also identified similar symptoms to our study.[6]

Our study period, January 2020 - January 2022, precedes the widespread availability of home testing. We closed our nested study at the end of January 2022 to minimize the impact of missed diagnoses through home testing and ensure a higher capture of laboratory validated COVID cases. Similarly to Gottlieb and colleagues, we found persistent symptoms in PCC during the Delta and Omicron time periods.[15] Thus, despite hopes that later variants would come with a lower risk of PCC, this has proven not to be the case.[15] At present, no cure for PCC is identified, as it is not totally clear the biologic cause of PCC or the potential impact of vaccination in altering PCC risk. While spike proteins have been implicated, clinical impact is unclear.[16]

Overall, our analysis indicates HIV status has had a statistically significant, but small, impact on PCC incidence. Although our results showed a 25% elevated risk for PCC in PLWH, further evaluation determined gastrointestinal disorders and other nervous system disorders were the primary drivers of this risk as no other conditions showed statistically significant increased risk of PCC among PLWH. Overall risk of PCC among PLWH, within the persistent time interval, was elevated but not statistically significant compared to PWoH Although HIV RNA levels or lower CD4 cell counts did not impact results in this study, which may have had an impact on PCC incidence within the PLWH population. In other publications, over 90% KPMAS PWH/PLWH are virally suppressed (KPMAS HIV Registry data), likely limiting the incidence of COVID and risk for PCC. Unfortunately, low counts within the persistent time interval (0-29 days post-COVID positive test date) among the PLWH population reduced our ability to evaluate persistent PCC individual conditions. The fact that there was a small sample size of PLWH meeting the persistent time interval classification of PCC is interesting. Given the length of symptoms for acute COVID which may last up to 2 weeks before a person started feeling better[17] it may be challenging to estimate PCC in this short period for PLWH and PWoH. Although not measured here, lower COVID risk (and thus lower PCC risk) has been seen with better HIV viral control and higher CD4 cell count.[18,19] Previous data from the CIVET-II consortium of the North American AIDS Cohort Collaboration on Research Design (NA-ACCORD, which included data from KPMAS and others) did show protection against re- infection and PCC from SARS-CoV-2 with vaccination.[11]

Consistent with current literature, vaccination was shown to have a statistically significant impact on multiple PCC-related conditions.[6,20] Surprisingly, the overall risk for incident

PCC was not significant, but that is driven by conditions that were higher in the vaccinated population, such as conditions associated with dizziness or vertigo. Additionally, this analysis only looked at those who developed COVID-19 after being vaccinated. It is likely that the risk of developing COVID is lower for the vaccinated cohort and therefore, the risk of developing long COVID in the vaccinated population as a whole is likely lower than the results of this analysis. Risk of persistent PCC was significantly higher in the unvaccinated group, which is expected given the acute nature of the persistent time interval. As this was an observational study, interpretation of these results should be with the understanding that patients would likely only seek care if their medical conditions and/or symptoms were severe enough. As seen in the study of the DC HIV Cohort (acknowledging that KPMAS contributes data to that analysis), retired/disabled PLWH were more likely to seek care for PCC than actively employed people with HIV.[21] However, these results also show a protective effect of vaccination on PCC and the impact it can have on severity of symptoms and conditions, especially within the context of persistent PCC conditions.

In contrast to our findings, Peluso and colleagues found higher incidence of PCC among PLWH.[22] The results in this study are likely due to differences in the study methods such as their use of clinical survey assessments as opposed to our large retrospective clinical cohort, utilizing comprehensive Electronic Health Record (EHR) data. We also excluded all prevalent conditions from the PCC incidence definition, which was not listed as an exclusion in their study. Additionally, their study population was limited to those diagnosed prior to December 2020 and did not capture the changes to PCC incidence within Delta and Omicron variants and periods. Xie and colleagues showed decreased, but non-zero incidence of PCC

during subsequent variants, similar to our results.[23] Similar to Xie et al, our results show a similar increase in gastrointestinal related symptoms for PLWH, and we also showed elevated incident conditions in PLWH compared to PWoH. Similar results to ours were seen among an Israeli population, including gastrointestinal symptoms even among patients with a milder COVID-19 infection.[24] While not specific to the US population with HIV, DeVries and colleagues found, using a commercially insured US database, that adults with PCC had greater risk of cardiovascular outcomes compared to a propensity matched population without COVID infection.[25] Further research utilizing larger sample sizes for PLWH would help provide robustness to these analyses.

Al-Aly and colleagues found a similar protective effect of vaccination on the incidence of PCC conditions within the US Veterans Health Administration (VHA) population, during breakthrough infection. Specifically, we found most of this protective effect for persistent PCC conditions, that were incident in the 29 days post-COVID infection and persisted thereafter. Important distinctions in overall member population and PCC definition are likely causes for differences in our results for incident PCC. Their study suggests vaccination should not be the only strategy for mitigating conditions of PCC, as those with breakthrough or re-infections were still at higher risk of Long COVID conditions compared to those who did not contract COVID.[20] Other studies also confirmed higher PCC risk for those re-infected.[26]

There are important limitations of this study. First, although our study period precedes the widespread availability of home testing, there is a potential for missed COVID cases because of early home testing that occurred towards the end of our study period. However, KPMAS had nearly complete capture of PCR testing among our patients during the study

period, whether within KPMAS or not, due to access to multiple testing databases. As patients would likely only seek care if they were symptomatic with COVID, some asymptomatic or mildly symptomatic cases of acute COVID may be unrecorded. Other limitations include conditions that may have not been coded, as well as conditions that may have occurred prior to our four-year prevalent condition period. For example, mild gastrointestinal disorders post-acute COVID may not be recorded because the patient did not seek medical care. Thus, it is possible our results are in fact conservative estimates of the incidence of these PCC. In our previous study, we found no impact on the significance of results when removing the pre-existing condition criteria.[7] As in other observational studies, we could not ascertain resolution or severity of PCC within our population. Of course, the hope would be with better immunity status the resolution of symptoms would improve or be prevented in the first place. Lastly, no adjustments for multiple testing were performed, which may have increased the likelihood that some of our significant findings occurred by chance.

Strengths of this study include a well-defined patient population of over 800,000 members which has been shown to be both diverse and representative of the District of Columbia, Maryland (including greater Baltimore), and Virginia area.[12] Data captured from our EHR, as well as from both claims and health information exchanges, provide a robust data source that comprehensively captures our members' care both internal and external to KPMAS. Lastly, the ability to compare to a matched cohort and compare conditions within various time intervals post-acute COVID infection, provides a complete picture of PCC incidence for members afflicted by this condition.

Our examination enhances previous research on PCC and provides additional context for specific PCC conditions, the timing of symptom/condition manifestation, the effects of vaccination on PCC and demonstrates the risk of PCC among PLWH. Although our study showed overall PCC incidence for PLWH is higher than in PWoH, much of that signal was driven by gastrointestinal conditions and other nervous system disorders, whereas no other PCC defining conditions showed significant increased risk. Additionally, we provide supporting evidence that vaccination has a protective effect on PCC incidence, especially for those conditions that persist post the acute phase of COVID infection. These findings build upon previous research and can be utilized by clinicians to promote vaccination among their patients. Further research is needed on PLWH within larger cohorts to determine if unsuppressed viral load would have an impact on PCC incidence.

Data Availability

The datasets generated and analyzed in this study are stored in SAS format and stored on internal MAPRI servers. These datasets consist of individual level data derived from internal Kaiser Permanente Mid-Atlantic States electronic health record and claims databases utilized for clinical care. For privacy and legal requirements, data is only available upon request which must comply with the Mid-Atlantic Permanente Research Institute (MAPRI) security, privacy, and intellectual property standards. All data requests should be directed to the corresponding author and will be reviewed by the MAPRI compliance officer and principal investigator within 30 business days upon receipt of request. All requesters will be required to provide a statement of need and comply with MAPRI policy and requirements. Failure to produce sufficient information and/or a request that doesn't meet MAPRI policy, may be

denied. Information on the structure and name of the tables used in these databases are proprietary and cannot be shared publicly and no datasets associated with this study have been deposited in a public repository; therefore, no accession codes, DOIs, or public identifiers are available. The underlying data used to generate Figures 2, 3, and 4 are provided as individual tabs within the Supplementary Data 1 file.

Code Availability

For privacy and legal requirements, project specific analytical code/scripts developed for this study are considered intellectual property and are not publicly available. The code was used for data management and statistical analyses and was executed within a secure Mid-Atlantic Permanente Research Institute (MAPRI) computing environment. Project related code is only available upon request which must comply with the Mid-Atlantic Permanente Research Institute (MAPRI) security, privacy, and intellectual property standards. All code requests should be directed to the corresponding author and will be reviewed by the MAPRI compliance officer and principal investigator within 30 business days upon receipt of request. All requesters will be required to provide a statement of need and comply with MAPRI policy and requirements. Failure to produce sufficient information and/or a request that doesn't meet MAPRI policy, may be denied. All data were collected from internal Kaiser Permanente Mid-Atlantic States databases that are utilized for clinical care and claims. The analytical code uses proprietary data structures and variables within these databases, which prevents public sharing of the code.

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Author contributions

M. Horberg conceived the project's idea and design, collected and analyzed the data, and authored the manuscript. C. Jefferson contributed to the project's idea and design, collected and analyzed the data, and authored the manuscript. E. Watson contributed to the project's idea and design, collected and analyzed the data, and authored the manuscript. S. Kim contributed to the project’s design, analyzed the data, and reviewed and edited the manuscript. A. Deneal managed the project and manuscript submission. K. Gebo assisted with study design, analyzed the data, and edited the manuscript. B. Hogan assisted in data analysis and authored the manuscript. E. Humes contributed data analysis and reviewed and edited the manuscript. K. Althof contributed to the project's idea and design, analyzed the data, and secured funding. All authors discussed the results and commented on the manuscript

Competing interests

K. Gebo receives royalties from UpToDate, has served on a scientific advisory board for Shionogi and Pfizer (non-compensated), and has received personal consulting fees from Spark HealthCare, Premier HealthCare, Harrison Consulting and MedEd Learning. All other authors declare no competing interests.

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Table 1. AHRQ Clinical Classification Software (CSS) Categories identified as Post COVID-Conditions

Post-COVID Conditions		
Abdominal pain	Fluid and electrolyte disorders	Nausea and vomiting
Anosmia	Gastrointestinal disease	Nonspecific chest pain
Anxiety disorders	Genitourinary symptoms and ill-defined conditions	Other lower respiratory disease
Cardiac dysrhythmias	Malaise and fatigue	Other nervous system disorders
Conditions associated with dizziness or vertigo	Mental health	Other nutritional, endocrine, and metabolic disorders
Diabetes		Respiratory failure; insufficiency; arrest (adult)

AHRQ Clinical Classification Software (CCS) categories identified as post-COVID conditions based on a previously published study. See Supplementary Table 1 for diagnoses that contributed to these classifications

Table 2. Matched and Unmatched Demographics

Category	Matching Cohort		Unmatched Cohort (1/1/2021-1/31/2022)				All Patients Tested COVID + During Study Period
	PLWH	PWOH	PLWH	PWOH	Vaccinated	Unvaccinated	
Total , n (%)							
Total	749 (100%)	2,236 (100%)	492 (100%)	71,884 (100%)	40,620 (100%)	31,756 (100%)	103,581 (100%)
Sex, n (%)							
Female	270 (36%)	804 (36%)	173 (35%)	42,065 (59%)	24,320 (60%)	17,918 (56%)	59,780 (58%)
Male	479 (64%)	1,432 (64%)	319 (65%)	29,819 (42%)	16,300 (40%)	13,838 (44%)	43,801 (42%)
Age (in years), n (%)							
18-29	75 (10%)	225 (10%)	48 (10%)	15,347 (21%)	7,321 (18%)	8,074 (25%)	21,648 (21%)
30-39	167 (22%)	500 (22%)	117 (24%)	15,699 (22%)	8,440 (21%)	7,376 (23%)	21,962 (21%)
40-49	179 (24%)	536 (24%)	117 (24%)	14,329 (20%)	8,576 (21%)	5,870 (19%)	20,606 (20%)
50-64	273 (37%)	814 (36%)	168 (34%)	18,528 (26%)	11,150 (27%)	7,546 (24%)	27,652 (27%)
65-74	47 (6%)	137 (6%)	35 (7%)	5,780 (8%)	3,674 (9%)	2,141 (7%)	8,492 (8%)
75+	8 (1%)	24 (1%)	7 (1%)	2,201 (3%)	1459 (4%)	749 (2%)	3,221 (3%)
Race/Ethnicity (self-reported), n (%)							
Asian	9 (1%)	26 (1%)	9 (2%)	8,818 (12%)	5,920 (15%)	2,907 (9%)	12,063 (12%)
Black	600 (80%)	1,794 (80%)	402 (82%)	32,344 (45%)	16,861 (42%)	15,885 (50%)	44,944 (43%)
Hispanic	67 (9%)	201 (9%)	26 (5%)	11,445 (16%)	6,601 (16%)	4,870 (15%)	20,509 (20%)
White	68 (9%)	201 (9%)	51 (10%)	15,865 (22%)	9,479 (23%)	6,437 (20%)	21,347 (21%)
Other/Unknown	5 (1%)	14 (1%)	4 (1%)	3,412 (5%)	1,759 (4%)	1,657 (5%)	4,718 (5%)
BMI (kg/m^2), n (%)							
<18.5	5 (1%)	13 (1%)	3 (1%)	560 (1%)	308 (1%)	255 (1%)	711 (1%)
18.5-24.9	130 (17%)	261 (12%)	88 (18%)	11,442 (16%)	7,047 (17%)	4,483 (14%)	15,560 (15%)
25-29.9 (Overweight)	196 (26%)	472 (21%)	134 (27%)	16,442 (23%)	10,175 (25%)	6,401 (20%)	23,790 (23%)
30-39.9 (Obesity)	240 (32%)	705 (32%)	150 (31%)	18,946 (26%)	11,116 (27%)	7,980 (25%)	28,061 (27%)
40+ (Severe Obesity)	63 (8%)	201 (9%)	42 (9%)	5,710 (8%)	3,186 (8%)	2,566 (8%)	8,312 (8%)
No Result	115 (15%)	584 (26%)	75 (15%)	18,784 (26%)	8,788 (22%)	10,071 (32%)	27,147 (26%)
Variant, n (%)							
ALPHA - (1/1/2020-12/31/2020)	262 (35%)	782 (35%)					31,205 (30%)
DELTA - (1/1/2021-10/1/2021)	170 (23%)	505 (23%)	175 (36%)	25,228 (35%)	3,444 (8%)	21,959 (69%)	25,403 (25%)
OMICRON- (10/2/2021-1/31/2022)	317 (42%)	949 (42%)	317 (64%)	46,656 (65%)	37,176 (92%)	9,797 (31%)	46,973 (45%)
Vaccination Status, n (%)							
Unvaccinated	453 (61%)	1,354 (61%)	192 (39%)	31,564 (44%)		31,756 (100%)	62,961 (61%)
Vaccinated	296 (40%)	882 (40%)	300 (61%)	40,320 (56%)	40,620 (100%)		40,620 (39%)
CD4 Category, n (%)							
<200	27(4%)		23(5%)				
200-499	161(21%)		105(21%)				
>500	468(62%)		302(61%)				
No CD4	92(12%)	2236(100%)	62(13%)	71,884(100 %)			
VL Category , n (%)							
<200 UNDETECTABLE	639(85%)		415(85%)				
200 -10,000 LOW	21(3%)		15(3%)				
10,000 - 100,000 MODERATE	14(2%)		13(3%)				
>100,000 HIGH	1(0%)		1(0%)				
NO VIRAL LOAD	74(10%)	2236(100%)	48(10%)	71,884(100 %)			
Comorbidities in pre-existing conditions period, n (%)							
CKD	64 (9%)	101 (5%)	46 (9%)	2,633 (4%)	1,676 (4%)	1,003 (3%)	3,908 (4%)
COPD	11 (2%)	25 (1%)	8 (2%)	753 (1%)	479 (1%)	282 (1%)	1,077 (1%)
Diabetes	125 (17%)	464 (21%)	68 (14%)	11,715 (16%)	6,979 (17%)	4,804 (15%)	17,879 (17%)
HIV	749 (100%)		492 (100%)		300 (1%)	192 (1%)	755 (1%)
Malignancy	33 (4%)	49 (2%)	24 (5%)	1,938 (3%)	1,287 (3%)	675 (2%)	2,777 (3%)
Service Area, n (%)							
BALT	140 (19%)	413 (19%)	90 (18%)	13,459 (19%)	6,808 (17%)	6,741 (21%)	19,094 (18%)
DCSM	495 (66%)	1,485 (66%)	320 (65%)	33,799 (47%)	18,652 (46%)	15,467 (49%)	49,179 (48%)
NOVA	114 (15%)	338 (15%)	82 (17%)	24,591 (34%)	15,141 (37%)	9,532 (30%)	35,255 (34%)
NETWORK				30 (0%)	16 (0%)	14 (0%)	45 (0%)
Unknown				5 (0%)	3 (0%)	2 (0%)	8 (0%)
Match Ratio, n (%)							
1:1	2 (0%)	2 (0%)					
1:2	7 (1%)	14 (1%)					
1:3	740 (99%)	2,220 (99%)					
PCC Outcome, n (%)							
Incident PCC	111 (15%)	263 (12%)	77 (16%)	9,549 (13%)	5,347 (13%)	4,279 (13%)	13,984 (14%)
Persistent PCC	28 (4%)	75 (3%)	11 (2%)	1,994 (3%)	719 (2%)	1,214 (4%)	3,362 (3%)
Relative Risk PLWH to PWoH, RR [95% CI]	1.25 [1.02,1.54] Persistent: 1.11 [.73,1.70]		Incident: 1.25 [1.02,1.54]				

Relative Risk Unvaccinated to Vaccinated, RR [95% CI]			Incident 1.05 [1.00-1.10] | Persistent 1.90 [1.69,2.15]	

All differences in characteristics by HIV status in the matched cohort are not statistically significant with the exception of BMI, CKD, Diabetes, Malignancy, and Post-COVID Conditions (PCC). We set an a priori difference of ≥5% for signaling clinical or public health significant differences in the characteristics. Among the matched cohort, the single characteristic with a clinical or public health significant difference in distribution by HIV status is BMI. Statistically significant characteristics, by HIV status, in the unmatched cohort include Sex, Age Group, Race, BMI, Vaccination Status, CKD, Malignancy, and Service Area. Among the unmatched cohort, the characteristics with a clinical or public health significant difference in distribution, by HIV status, are Sex, Age Group, Race, BMI, Vaccination Status, CKD, and Service Area

Table 3. PLWH vs PWoH Individual Condition Distributions (Persistent Period)

Condition	HIV Status	% of Population	Count (N)	P-Value
Abdominal pain	PLWH	0.00%	0	1.00
	PWOH	0.04%	1	
Anosmia	PWOH	0.00%	0	1.00
Anxiety disorders	PLWH	0.00%	0	0.33
	PWOH	0.22%	5	
Cardiac dysrhythmias	PLWH	0.53%	4	0.51
	PWOH	0.36%	8	
Nonspecific chest pain	PLWH	0.27%	2	1.00
	PWOH	0.22%	5	
Diabetes	PLWH	0.67%	5	0.33
	PWOH	0.36%	8	
Other nutritional, endocrine, and metabolic disorders	PLWH	0.00%	0	0.58
	PWOH	0.13%	3	
Malaise and fatigue	PLWH	0.40%	3	0.38
	PWOH	0.18%	4	
Fluid and electrolyte disorders	PLWH	0.27%	2	1.00
	PWOH	0.36%	8	
Genitourinary symptoms and ill-defined conditions	PLWH	0.00%	0	0.58
	PWOH	0.18%	4	
Gastrointestinal disease	PLWH	0.40%	3	1.00
	PWOH	0.40%	9	
Other lower respiratory disease	PLWH	0.93%	7	1.00
	PWOH	0.94%	21	
Mental health	PLWH	0.40%	3	0.38
	PWOH	0.18%	4	
Nausea and vomiting	PLWH	0.00%	0	*
	PWOH	0.00%	0	
Other nervous system disorders	PLWH	0.27%	2	0.26
	PWOH	0.09%	2	
Respiratory failure; insufficiency; arrest (adult)	PLWH	0.53%	4	0.80
	PWOH	0.72%	16	
Conditions associated with dizziness or vertigo	PLWH	0.40%	3	0.72
	PWOH	0.31%	7	
Overall PCC**	1.11 [.073,1.70]			0.62

*Unable to analyze because of a 0 value

**Overall results were estimated using Poisson regression models with cluster-robust standard errors.

P-values were calculated using two-sided statistical tests; Fisher's exact test was used where applicable.

Table 4. Unmatched Analysis Results

	Unvaccinated n(%); N = 31,756	Vaccinated n(%); N = 40,620	Reference & Relative Risk [95% CI]
Sex			
Female	17,918 (56%)	24,320 (60%)	Ref = Female; Male - 0.78 [0.76,0.81]
Male	13,838 (44%)	16,300 (40%)	
Age			
18-29	8,074 (25%)	7,321 (18%)	
30-39	7,376 (23%)	8,440 (21%)	
40-49	5,870 (19%)	8,576 (21%)	Ref = 18-29; Highest RR: [85+ Age Group] - 1.52 [1.27,1.82]
50-64	7,546 (24%)	11,150 (27%)	
65-74	2,141 (7%)	3,674 (9%)	
75+	749 (2%)	1459 (4%)	
Race			
Asian	2,907 (9%)	5,920 (15%)	
Black	15,885 (50%)	16,861 (42%)	
Hispanic	4,870 (15%)	6,601 (16%)	Ref = White; Highest RR Hispanic - 1.14
White	6,437 (20%)	9,479 (23%)	
Other/Unknown	1,657 (5%)	1,759 (4%)	
Variant Time			
Delta	21,959 (69%)	3,444 (8%)	Ref = Delta: Omicron -
Omicron	9,797 (31%)	37,176 (92%)	
HIV	192 (1%)	300 (1%)	Ref = PWoH; PLWH – 1.25
Relative Risk Unvaccinated to Vaccinated		1.05 [1.00-1.10]	

Overall risk of post-COVID conditions (PCC) during the incident time interval comparing unvaccinated and vaccinated patients within the unmatched analysis. Counts, percentages, PCC risk estimates and corresponding 95% confidence intervals are shown and stratified by demographic subgroups, including sex, age, race/ethnicity, variant, and HIV status.

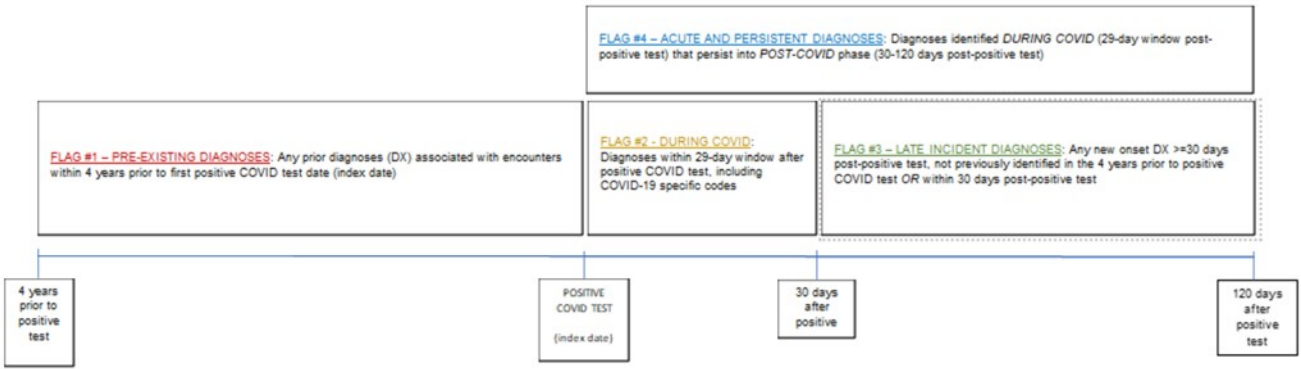
Figure Captions

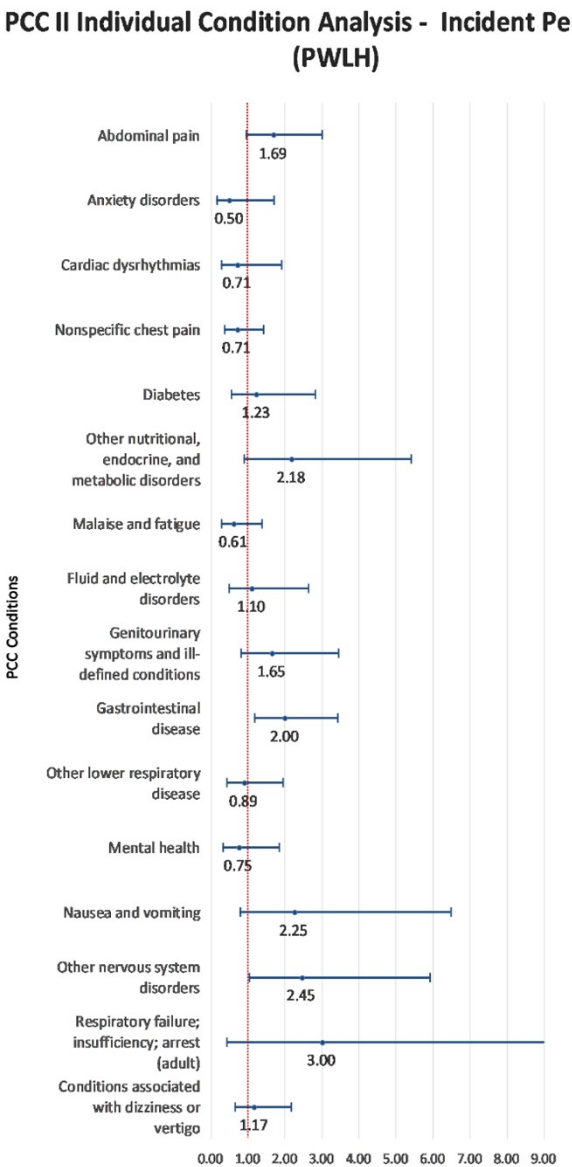
Figure 1. Diagnosis Observation Periods. Diagnostic observation timeline for CCS conditions in relation to the COVID testing date as the index date. The time periods used in this study were defined as follows: Late Incident: 30–120 days post positive COVID test date; Acute and persistent: 0–29 days post COVID positive test date and persisted 30–120 days; Pre-existing conditions: four years prior to the COVID test date.

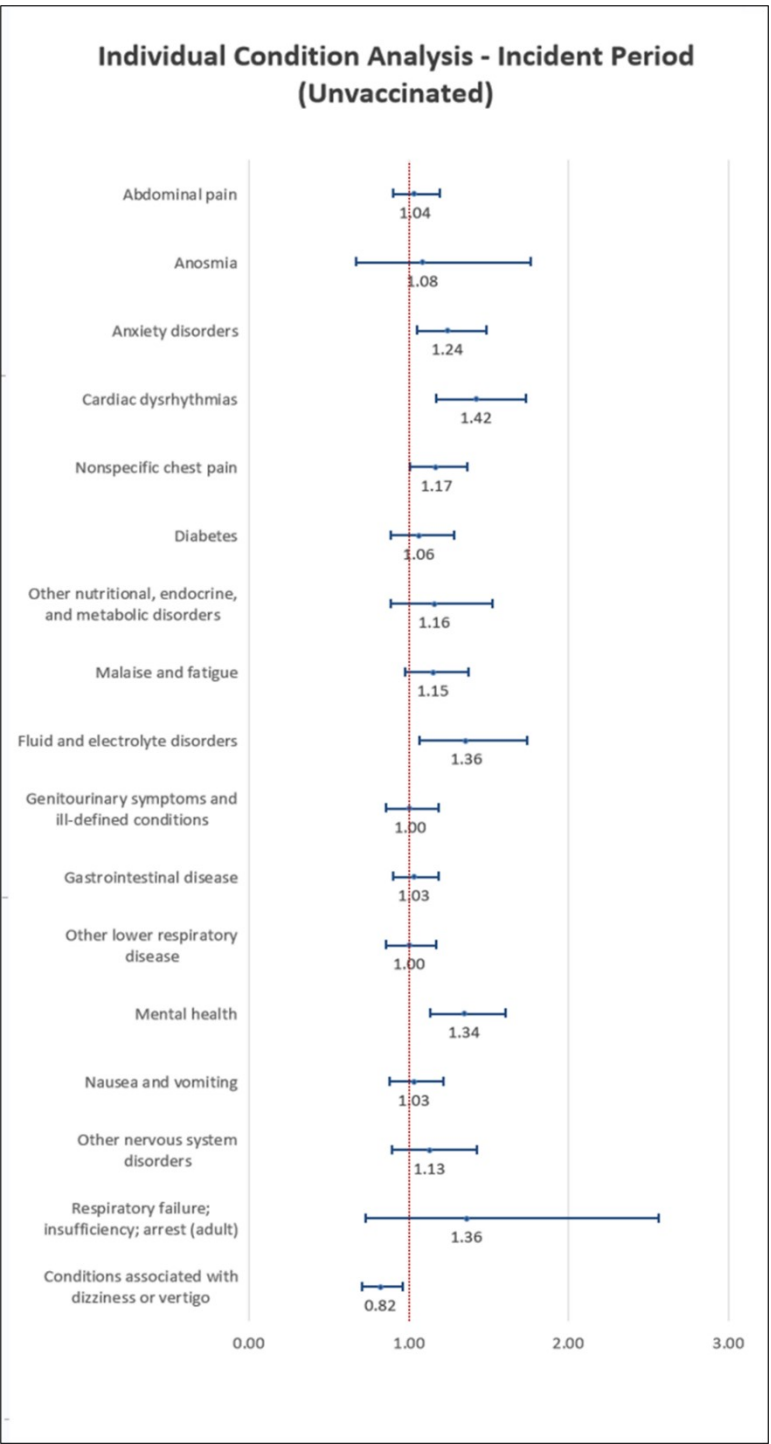
Figure 2. Unadjusted risk ratios and 95% confidence intervals for PCC and PCC-related conditions within the incident period (30-120 days post COVID) for the matched analysis.
PCC condition risk ratio forest plot with 95% confidence intervals comparing the PLWH population to a matched PWoH population during the incident time period. Each point represents the risk ratio for a given CCS condition, defined as the ratio of incident CCS conditions in the PLWH population (n = 749) to those in the PWoH population (n = 2,236). Horizontal bands represent the corresponding 95% confidence intervals. The vertical red reference line at a risk ratio of 1 indicates no difference between groups. Conditions are considered statistically significant when the 95% confidence interval does not include 1. Insufficient observations were available to calculate risk ratios and confidence intervals for anosmia. Respiratory failure, insufficiency, or arrest (adult) has an upper 95% confidence interval of 21.30; the x-axis has been truncated for display purposes.

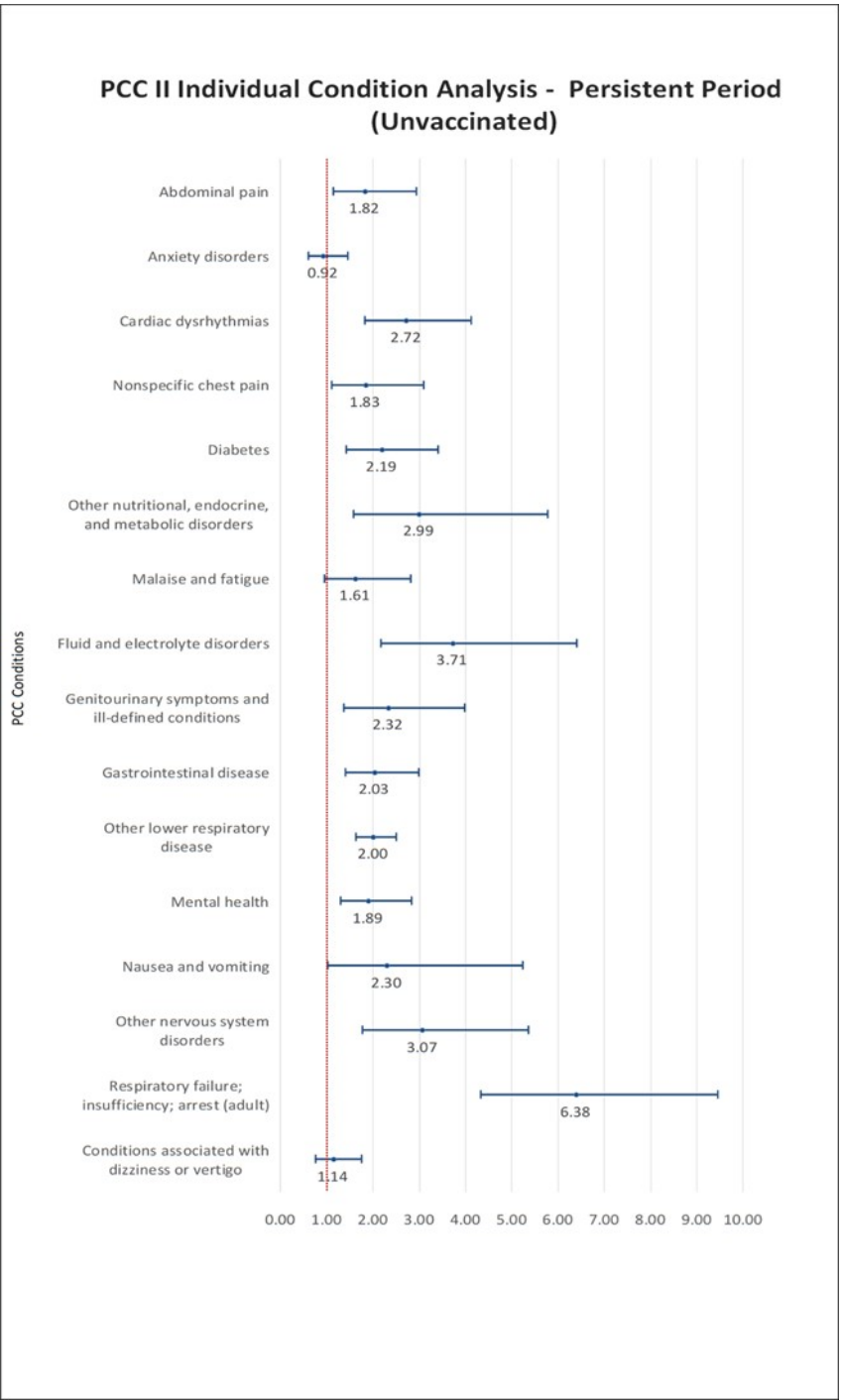
Figure 3. Adjusted risk ratios and 95% confidence intervals for PCC and PCC-related conditions within the incident period (30-120 days post COVID) for the unmatched analysis. PCC condition risk ratio forest plot with 95% confidence intervals comparing an unvaccinated population to an unmatched vaccinated population during the incident time period. Each point represents the risk ratio for a given CCS condition, defined as the ratio of incident CCS conditions in the unvaccinated population (n = 31,756) to those in the vaccinated population (n = 40,620). Horizontal bands represent the corresponding 95% confidence intervals. The vertical red reference line at a risk ratio of 1 indicates no difference between groups. Conditions are considered statistically significant when the 95% confidence interval does not include 1.

Figure 4. Adjusted risk ratios and 95% confidence intervals for PCC and PCC-related conditions within the persistent period (0-29 days post COVID) for the unmatched analysis. PCC condition risk ratio forest plot with 95% confidence intervals comparing an unvaccinated population to an unmatched vaccinated population during the persistent time period. Each point represents the risk ratio for a given CCS condition, defined as the ratio of the number of incident CCS conditions observed in the unvaccinated population (n = 31,756) to those observed in the vaccinated population (n = 40,620). Horizontal bands represent the corresponding 95% confidence intervals. The vertical red reference line at a risk ratio of 1 indicates no difference between groups. Conditions are considered statistically significant when the 95% confidence interval does not include 1.






Individual Condition Analysis - Incident Period (Unvaccinated)
Abdominal pain
1.04
Anosmia
1.08
Anxiety disorders
1.24
Cardiac dysrhythmias
1.42
Nonspecific chest pain
1.17
Diabetes
1.06
Other nutritional, endocrine, and metabolic disorders
1.16
Malaise and fatigue
1.15
Fluid and electrolyte disorders
1.36
Genitourinary symptoms and ill-defined conditions
1.00
Gastrointestinal disease
1.03
Other lower respiratory disease
1.00
Mental health
1.34
Nausea and vomiting
1.03
Other nervous system disorders
1.13
Respiratory failure; insufficiency; arrest (adult)
1.36
Conditions associated with dizziness or vertigo
0.82
0.00
1.00
2.00
3.00


PCC II Individual Condition Analysis - Persistent Period (Unvaccinated)
PCC Conditions
Abdominal pain
1.82
Anxiety disorders
0.92
Cardiac dysrhythmias
2.72
Nonspecific chest pain
1.83
Diabetes
2.19
Other nutritional, endocrine, and metabolic disorders
2.99
Malaise and fatigue
1.61
Fluid and electrolyte disorders
3.71
Genitourinary symptoms and ill-defined conditions
2.32
Gastrointestinal disease
2.03
Other lower respiratory disease
2.00
Mental health
1.89
Nausea and vomiting
2.30
Other nervous system disorders
3.07
Respiratory failure; insufficiency; arrest (adult)
6.38
Conditions associated with dizziness or vertigo
1.14
0.00 1.00 2.00 3.00 4.00 5.00 6.00 7.00 8.00 9.00 10.00