

Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview for Request: cder_mpl2p_wp042

Request ID: cder_mpl2p_wp042

Request Description: In this report, we identified individuals with COVID-19 in the ambulatory and inpatient settings and examined inpatient arterial thrombotic events and inpatient venous thrombotic events among those individuals, as well as all-cause mortality following an inpatient thrombotic event. This analysis was conducted as a follow-up to the study described here (https://www.sentinelinitiative.org/sites/default/files/documents/Coagulopathy_COVID19_Study_Synopsis_v2.0_0.pdf). It is anticipated that these results will be used in an analysis with international collaborators.

<u>Sentinel Routine Querying Module</u>: Cohort Identification and Descriptive Analysis (CIDA) module, version 10.3.0, with custom programming

Data Source: We distributed this request to six Sentinel Data Partners on January 10, 2023. The study period included data from April 1, 2020 through May 4, 2022.

<u>Study Design</u>: We identified individuals who were at least 18 years of age with incident COVID-19 in either the inpatient care setting or the ambulatory care setting in the time prior to COVID-vaccine availability (March 2020 - November 2020) and the time after COVID-vaccine availability (December 2020 - December 2021), separately. We then identified inpatient arterial thrombotic events and inpatient venous thrombotic events separately, within 90 days after COVID-19. Among those with either an inpatient arterial or venous thrombotic event, we evaluated all-cause mortality within 30 days after the thrombotic event. Individuals with a diagnosis code for influenza or other respiratory virus within 14 days of COVID-19 were excluded. This is a Type 2 analysis in the Query Request Package (QRP) documentation. All of the code lists for this work have been published previously:

https://jamanetwork.com/journals/jama/fullarticle/2795268?utm_campaign=articlePDF&utm_medium=articlePDFlink&utm_sou rce=articlePDF&utm_content=jama.2022.13072#supplemental-tab.

COVID-19: We defined COVID-19 by presence of an International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) code of U07.1 or a positive result for a SARS-COV-2 nucleic acid amplification (NAAT) test. Only the first qualifying (index) COVID-19 diagnosis or test was included; cohort re-entry was not allowed within a time period. However, an individual could be included in the pre-COVID-vaccine availability period and also the post-COVID-vaccine availability period.

<u>Outcomes of Interest</u>: We defined the outcomes of interest as arterial thrombotic events (i.e., myocardial infarction and stroke), and venous thrombotic events (i.e., deep venous thrombosis and pulmonary embolism).

<u>Cohort Eligibility Criteria:</u> We required members to be enrolled in health plans with medical and drug coverage in the 365 days prior to their index date; a gap in coverage of up to 45 days was allowed and treated as continuous enrollment. We excluded patients with either a positive NAAT test for influenza or an ICD-10-CM diagnosis code for influenza or other respiratory virus (e.g., parainfluenza, adenovirus, respiratory syncytial virus, rhinovirus, human metapneumovirus) within 14 days prior to or following the index date.

Follow-up Time: Follow-up time began on the day of the index COVID-19 diagnosis or positive NAAT test and continued until the first occurrence of any of the following: 1) disenrollment from health plan coverage; 2) death; 3) occurrence of the outcome; 4) influenza diagnosis or positive NAAT; 5) end of the 90 day follow up time.

Baseline Characteristics: We assessed the following characteristics in the 365 days prior to the index date of COVID-19: age, sex, number of hospital encounters, number of ambulatory encounters, atrial fibrillation/flutter, cancer, cardiovascular disease, chronic obstructive pulmonary disease, diabetes mellitus, heart failure, hyperlipidemia, hypertension, neurological disease, and prior venous thromboembolism. We assessed dispensings of anticoagulants and of antiplatelets in the 183 days up to three days prior to the index date of COVID-19. ICD-10-CM codes, International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) codes, Healthcare Common Procedure Coding System (HCPCS) codes, and Current Procedural Terminology, Fourth Edition (CPT-4) codes were used to define baseline characteristics.



Overview for Request: cder_mpl2p_wp042

<u>Limitations:</u> Algorithms used to define events, outcomes, exclusion criteria, and covariates are imperfect and may be misclassified. Data should be interpreted with this limitation in mind.

Notes: Please contact the Sentinel Operations Center (info@sentinelsystem.org) for questions and to provide

comments/suggestions for future enhancements to this document. For more information on Sentinel's routine querying modules, please refer to the documentation (https://dev.sentinelsystem.org/projects/SENTINEL/repos/sentinel-routine-querying-tool-documentation/browse).



| | Table of Contents |
|-----------------|---|
| Glossary | List of Terms Found in this Report and their Definitions |
| <u>Table 1a</u> | Baseline Characteristics of Patients with COVID-19 Defined Using a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Hospital/Inpatient Care Settings in the Pre-Vaccine Era |
| <u>Table 1b</u> | Baseline Characteristics of Patients with COVID-19 Defined Using a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Hospital/Inpatient Care Settings in the Post-Vaccine Era |
| <u>Table 1c</u> | Baseline Characteristics of Patients with COVID-19 Defined Using a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Ambulatory/Outpatient Care Settings in the Pre-Vaccine Era |
| <u>Table 1d</u> | Baseline Characteristics of Patients with COVID-19 Defined Using a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Ambulatory/Outpatient Care Settings in the Post-Vaccine Era |
| <u>Table 2a</u> | Numbers and Rates of Inpatient Arterial Thromboembolism (ATE) Events Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Hospital/Inpatient Care Settings in the Pre-Vaccine Era |
| <u>Table 2b</u> | Numbers and Rates of Inpatient Arterial Thromboembolism (ATE) Events Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Hospital/Inpatient Care Settings in the Post-Vaccine Era |
| <u>Table 2c</u> | Numbers and Rates of Inpatient Arterial Thromboembolism (ATE) Events Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Ambulatory/Outpatient Care Settings in the Pre-Vaccine Era |
| <u>Table 2d</u> | Numbers and Rates of Inpatient Arterial Thromboembolism (ATE) Events Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Ambulatory/Outpatient Care Settings in the Post-Vaccine Era |
| <u>Table 2e</u> | Numbers and Rates of All-Cause Mortality Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Any Care Setting, and an Inpatient Arterial Thromboembolism (ATE) Event in the Pre-Vaccine Era |
| <u>Table 2f</u> | Numbers and Rates of All-Cause Mortality Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Any Care Setting, and an Inpatient Arterial Thromboembolism (ATE) Event in the Post-Vaccine Era |
| <u>Table 2g</u> | Numbers and Rates of Inpatient Venous Thromboembolism (VTE) Events Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Hospital/Inpatient Care Settings in the Pre-Vaccine Era |
| <u>Table 2h</u> | Numbers and Rates of Inpatient Venous Thromboembolism (VTE) Events Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Hospital/Inpatient Care Settings in the Post-Vaccine Era |
| <u>Table 2i</u> | Numbers and Rates of Inpatient Venous Thromboembolism (VTE) Events Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Ambulatory/Outpatient Care Settings in the Pre-Vaccine Era |
| <u>Table 2j</u> | Numbers and Rates of Inpatient Venous Thromboembolism (VTE) Events Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Ambulatory/Outpatient Care Settings in the Post-Vaccine Era |
| <u>Table 2k</u> | Numbers and Rates of All-Cause Mortality Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Any Care Setting, and an Inpatient Venous Thromboembolism (VTE) Event in the Pre-Vaccine Era |



| Table of Contents | | | | |
|-------------------|---|--|--|--|
| <u>Table 21</u> | Numbers and Rates of All-Cause Mortality Among Those with COVID-19, Defined by a Positive Nucleic Acid | | | |
| | Amplification Test (NAAT) or Diagnosis Code in Any Care Setting, and an Inpatient Venous Thromboembolism (VTE) Event in the Post-Vaccine Era | | | |



Glossary of Terms for Analyses Using Cohort Identification and Descriptive Analysis (CIDA) Module*

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing. Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency Department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). The Care Setting, along with the Principal Diagnosis Indicator (PDX), forms the Care Setting/PDX parameter.

Ambulatory Visit (AV) - includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.

Emergency Department (ED) - includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.

Inpatient Hospital Stay (IP) - includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.

Non-Acute Institutional Stay (IS) - includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.

Other Ambulatory Visit (OA) - includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

Charlson/Elixhauser Combined Comorbidity Score - calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (e.g., in the 183 days prior to index).

Code Days - the minimum number of times the diagnosis must be found during the evaluation period in order to fulfill the algorithm to identify the corresponding patient characteristic.

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all valid treatment episodes during the query period; 03:

Computed Start Marketing Date - represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.

Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.

Eligible Members - number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled" sequence.

Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.

Event Deduplication - specifies how events are counted by the Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (HOI) during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

Exposure Episode Length - number of days after exposure initiation that is considered "exposed time."

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions are added after any episode gaps have been bridged.



Lookback Period - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).

Maximum Episode Duration - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Member-Years - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period all divided by 365.25.

Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be considered.

Minimum Episode Duration - specifies a minimum number of days in length of the episode for it to be considered. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Monitoring Period - used to define time periods of interest for both sequential analysis and simple cohort characterization requests.

Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

Query Period - period in which the modular program looks for exposures and outcomes of interest.

Switch Evaluation Step Value - value used to differentiate evaluation step. Each switch pattern can support up to 2 evaluation steps (0 = switch pattern evaluation start; 1 = first evaluation; 2 = second evaluation).

Switch Gap Inclusion Indicator - indicator for whether gaps in treatment episodes that are included in a switch episode will be counted as part of the switch episode duration.

Switch Pattern - specified sequence of drug use within the same patient. Switch patterns can characterize single switches (Drug A to Drug B), switch-backs (Drug A to Drug B to Drug A), and switch-aways (Drug A to Drug B to Drug C).

Switch Pattern Cohort - collection of treatment episodes meeting a given set of inclusion/exclusion criteria.

Switch Pattern Cohort Inclusion Date - indicates which date to use for inclusion into the switch pattern cohort of interest as well as optionally as the index date of the treatment episode initiating the switch pattern. Valid options are the product approval date, product marketing date, other requester defined date, or computed start marketing date.

Switch Pattern Cohort Inclusion Strategy - indicates how the switch pattern cohort inclusion date will be used: 01: used only as a switch cohort entry date. First treatment episode dispensing date is used as index for computing time to first switch; 02: used as switch cohort entry date and as initial switch step index date for computing time to first switch.

Switch Pattern Episode - eligible treatment episode evaluated for one of the switch patterns of interest which ended in a switch.

Treatment Episode Truncation Indicator - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified code.

Washout Period (drug/exposure) - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

Washout Period (event/outcome) - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode. Years at Risk - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

*all terms may not be used in this report



| Characteristic | Number | Percent | |
|--|--------|---------------------------|-----------|
| Total Patients | 41,443 | 100% | |
| Demographics: | Mean | Standard Deviation | Median |
| Age (years) | 72.3 | 13.1 | 60.2-75.2 |
| | Number | Percent | |
| 18-44 | 2,032 | 4.9% | |
| 45-54 | 2,186 | 5.3% | |
| 55-64 | 5,161 | 12.5% | |
| 65-74 | 12,889 | 31.1% | |
| 75-84 | 12,649 | 30.5% | |
| 85+ | 6,526 | 15.7% | |
| Sex | | | |
| Male | 20,890 | 50.4% | |
| Female | 20,553 | 49.6% | |
| Month of COVID-19 Diagnosis: | | | |
| 2020 | | | |
| April | 5,676 | 13.7% | |
| May | 2,960 | 7.1% | |
| June | 3,052 | 7.4% | |
| July | 6,193 | 14.9% | |
| August | 4,110 | 9.9% | |
| September | 3,130 | 7.6% | |
| October | 5,449 | 13.1% | |
| November | 10,873 | 26.2% | |
| Recent Encounters (prior 365 days): | Mean | Standard Deviation | |
| Number of Hospital Encounters | 0.7 | 1.3 | |
| Number of Ambulatory Encounters | 8.4 | 18.3 | |
| Recent Diagnosis History (prior 365 days): | Number | Percent | |
| Atrial Fibrillation/Flutter | 12,435 | 30.0% | |
| Cancer | 10,982 | 26.5% | |
| Cardiovascular Disease (prior) | 23,325 | 56.3% | |
| Chronic Kidney Disease | 21,151 | 51.0% | |
| Chronic Obstructive Pulmonary Disease | 15,012 | 36.2% | |
| Diabetes Mellitus (any type) | 21,775 | 52.5% | |
| Heart Failure | 15,560 | 37.5% | |
| Hyperlipidemia | 31,740 | 76.6% | |
| Hypertension | 36,220 | 87.4% | |
| Neurological Disease | 8,941 | 21.6% | |
| Venous Thromboembolism (prior) | 3,275 | 7.9% | |
| Recent Dispensed Fills (-183 to -3 days): | | | |
| Anticoagulant History | 8,841 | 21.3% | |
| Antiplatelet History | 5,117 | 12.3% | |

 Table 1a. Baseline Characteristics of Patients with COVID-19 Defined Using a Positive Nucleic Acid Amplification

 Test (NAAT) or Diagnosis Code in Hospital/Inpatient Care Settings in the Pre-Vaccine Era



| Characteristic | Number | Percent | |
|--|--------|---------------------------|-----------|
| Total Patients | 91,433 | 100% | |
| Demographics: | Mean | Standard Deviation | Median |
| Age (years) | 71.7 | 13 | 58.2-74.4 |
| | Number | Percent | |
| 18-44 | 4,728 | 5.2% | |
| 45-54 | 4,836 | 5.3% | |
| 55-64 | 11,828 | 12.9% | |
| 65-74 | 29,868 | 32.7% | |
| 75-84 | 27,382 | 29.9% | |
| 85+ | 12,791 | 14.0% | |
| Sex | | | |
| Male | 45,347 | 49.6% | |
| Female | 46,086 | 50.4% | |
| Month of COVID-19 Diagnosis: | | | |
| 2020 | | | |
| December | 13,703 | 15.0% | |
| 2021 | | | |
| January | 13,466 | 14.7% | |
| February | 6,020 | 6.6% | |
| March | 4,291 | 4.7% | |
| April | 4,423 | 4.8% | |
| Мау | 2,795 | 3.1% | |
| June | 1,627 | 1.8% | |
| July | 3,983 | 4.4% | |
| August | 10,134 | 11.1% | |
| September | 8,491 | 9.3% | |
| October | 5,619 | 6.1% | |
| November | 5,939 | 6.5% | |
| December | 10,942 | 12.0% | |
| Recent Encounters (prior 365 days): | Mean | Standard Deviation | |
| Number of Hospital Encounters | 0.6 | 1.2 | |
| Number of Ambulatory Encounters | 23.7 | 30.6 | |
| Recent Diagnosis History (prior 365 days): | Number | Percent | |
| Atrial Fibrillation/Flutter | 27,229 | 29.8% | |
| Cancer | 23,641 | 25.9% | |
| Cardiovascular Disease (prior) | 48,877 | 53.5% | |
| Chronic Kidney Disease | 43,396 | 47.5% | |
| Chronic Obstructive Pulmonary Disease | 33,152 | 36.3% | |
| Diabetes Mellitus (any type) | 45,763 | 50.1% | |
| Heart Failure | 32,956 | 36.0% | |
| Hyperlipidemia | 68,324 | 74.7% | |

 Table 1b. Baseline Characteristics of Patients with COVID-19 Defined Using a Positive Nucleic Acid Amplification

 Test (NAAT) or Diagnosis Code in Hospital/Inpatient Care Settings in the Post-Vaccine Era



 Table 1b. Baseline Characteristics of Patients with COVID-19 Defined Using a Positive Nucleic Acid Amplification

 Test (NAAT) or Diagnosis Code in Hospital/Inpatient Care Settings in the Post-Vaccine Era

| Characteristic | Number | Percent | |
|--|--------|---------|--|
| Recent Diagnosis History (prior 365 days): | | | |
| Hypertension | 77,953 | 85.3% | |
| Neurological Disease | 15,746 | 17.2% | |
| Venous Thromboembolism (prior) | 6,464 | 7.1% | |
| Recent Dispensed Fills (-183 to -3 days): | | | |
| Anticoagulant History | 19,584 | 21.4% | |
| Antiplatelet History | 10,880 | 11.9% | |



| Characteristic | Number | Percent | |
|--|------------|--------------------|-----------|
| Total Patients | 272,065 | 100% | |
| Demographics: | Mean | Standard Deviation | Median |
| Age (years) | 55.6 | 17.5 | 43.4-70.3 |
| | Number | Percent | |
| 18-44 | 86,564 | 31.8% | |
| 45-54 | 38,454 | 14.1% | |
| 55-64 | 42,182 | 15.5% | |
| 65-74 | 57,089 | 21.0% | |
| 75-84 | 33,535 | 12.3% | |
| 85+ | 14,241 | 5.2% | |
| Sex | | | |
| Male | 121,048 | 44.5% | |
| Female | 151,017 | 55.5% | |
| Month of COVID-19 Diagnosis: | | | |
| 2020 | | | |
| April | 14,127 | 5.2% | |
| May | 15,926 | 5.9% | |
| June | 22,176 | 8.2% | |
| July | 38,414 | 14.1% | |
| August | 26,537 | 9.8% | |
| September | 24,648 | 9.1% | |
| October | 42,288 | 15.5% | |
| November | 87,949 | 32.3% | |
| Recent Encounters (prior 365 days): | Mean | Standard Deviation | |
| Number of Hospital Encounters | 0.1 | 0.5 | |
| Number of Ambulatory Encounters | 14.8 | 19.4 | |
| Recent Diagnosis History (prior 365 days): | Number | Percent | |
| Atrial Fibrillation/Flutter | 19,861 | 7.3% | |
| Cancer | 33,201 | 12.2% | |
| Cardiovascular Disease (prior) | 61,737 | 22.7% | |
| Chronic Kidney Disease | 39,610 | 14.6% | |
| Chronic Obstructive Pulmonary Disease | 30,803 | 11.3% | |
| Diabetes Mellitus (any type) | 61,249 | 22.5% | |
| Heart Failure | 21,430 | 7.9% | |
| Hyperlipidemia | 119,851 | 44.1% | |
| Hypertension | 125,942 | 46.3% | |
| Neurological Disease | 18,184 | 6.7% | |
| Venous Thromboembolism (prior) | 5,979 | 2.2% | |
| Recent Dispensed Fills (-183 to -3 days): | | | |
| Anticoagulant History | 19,219 | 7.1% | |
| Antiplatelet History | 12,362 | 4.5% | |

 Table 1c. Baseline Characteristics of Patients with COVID-19 Defined Using a Positive Nucleic Acid Amplification

 Test (NAAT) or Diagnosis Code in Ambulatory/Outpatient Care Settings in the Pre-Vaccine Era



| Characteristic | Number | Percent | |
|--|---------|---------------------------|-----------|
| Total Patients | 753,454 | 100% | |
| Demographics: | Mean | Standard Deviation | Median |
| Age (years) | 56 | 16.9 | 42.5-69.9 |
| | Number | Percent | |
| 18-44 | 236,287 | 31.4% | |
| 45-54 | 105,290 | 14.0% | |
| 55-64 | 114,298 | 15.2% | |
| 65-74 | 171,320 | 22.7% | |
| 75-84 | 95,921 | 12.7% | |
| 85+ | 30,338 | 4.0% | |
| Sex | | | |
| Male | 336,334 | 44.6% | |
| Female | 417,120 | 55.4% | |
| Month of COVID-19 Diagnosis: | | | |
| 2020 | | | |
| December | 110,215 | 14.6% | |
| 2021 | | | |
| January | 102,643 | 13.6% | |
| February | 42,638 | 5.7% | |
| March | 36,121 | 4.8% | |
| April | 34,545 | 4.6% | |
| May | 18,380 | 2.4% | |
| June | 10,513 | 1.4% | |
| July | 30,143 | 4.0% | |
| August | 81,365 | 10.8% | |
| September | 67,004 | 8.9% | |
| October | 44,611 | 5.9% | |
| November | 49,352 | 6.6% | |
| December | 125,924 | 16.7% | |
| Recent Encounters (prior 365 days): | Mean | Standard Deviation | |
| Number of Hospital Encounters | 0.1 | 0.5 | |
| Number of Ambulatory Encounters | 15.5 | 18.8 | |
| Recent Diagnosis History (prior 365 days): | Number | Percent | |
| Atrial Fibrillation/Flutter | 54,528 | 7.2% | |
| Cancer | 96,421 | 12.8% | |
| Cardiovascular Disease (prior) | 172,992 | 23.0% | |
| Chronic Kidney Disease | 104,342 | 13.8% | |

 Table 1d. Baseline Characteristics of Patients with COVID-19 Defined Using a Positive Nucleic Acid Amplification

 Test (NAAT) or Diagnosis Code in Ambulatory/Outpatient Care Settings in the Post-Vaccine Era

Heart Failure

Hyperlipidemia

Chronic Obstructive Pulmonary Disease

Diabetes Mellitus (any type)

84,459

165,313

57,086

344,096

11.2%

21.9%

7.6%

45.7%



Table 1d. Baseline Characteristics of Patients with COVID-19 Defined Using a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Ambulatory/Outpatient Care Settings in the Post-Vaccine Era

| Characteristic | Number | Percent | |
|--|---------|---------|--|
| Recent Diagnosis History (prior 365 days): | | | |
| Hypertension | 352,949 | 46.8% | |
| Neurological Disease | 34,888 | 4.6% | |
| Venous Thromboembolism (prior) | 16,372 | 2.2% | |
| Recent Dispensed Fills (-183 to -3 days): | | | |
| Anticoagulant History | 57,670 | 7.7% | |
| Antiplatelet History | 35,517 | 4.7% | |



| resitive Nucleic Acid Amplification Test (NAAT) of Diagnosis Code in Hospital/impatient Care Settings in the FIE-Vaccine Era | | | | | | |
|--|------------------|------------------|-------------------------------|--|--|--|
| Characteristic | Number in Cohort | Number of Events | Absolute Risk (%) with 95% Cl | | | |
| Overall | 41,443 | 6,559 | 15.83 (15.48, 16.18) | | | |
| Age (years): | | | | | | |
| 18-44 | 2,032 | 70 | 3.44 (2.71, 4.36) | | | |
| 45-54 | 2,186 | 197 | 9.01 (7.86, 10.31) | | | |
| 55-64 | 5,161 | 666 | 12.90 (12.01, 13.86) | | | |
| 65-74 | 12,889 | 2,086 | 16.18 (15.55, 16.83) | | | |
| 75-84 | 12,649 | 2,319 | 18.33 (17.66, 19.02) | | | |
| 85+ | 6,526 | 1,221 | 18.71 (17.77, 19.68) | | | |
| Sex: | | | | | | |
| Male | 20,890 | 3,580 | 17.14 (16.63, 17.66) | | | |
| Female | 20,553 | 2,979 | 14.49 (14.02, 14.98) | | | |
| Month of COVID-19 Diagnosis: | | | | | | |
| 2020 | | | | | | |
| April | 5,676 | 910 | 16.03 (15.09, 17.02) | | | |
| May | 2,960 | 519 | 17.53 (16.19, 18.96) | | | |
| June | 3,052 | 521 | 17.07 (15.76, 18.46) | | | |
| July | 6,193 | 974 | 15.73 (14.83, 16.66) | | | |
| August | 4,110 | 632 | 15.38 (14.29, 16.52) | | | |
| September | 3,130 | 529 | 16.90 (15.61, 18.27) | | | |
| October | 5,449 | 808 | 14.83 (13.90, 15.81) | | | |
| November | 10,873 | 1,666 | 15.32 (14.65, 16.02) | | | |
| Prior Cardiovascular Disease (prior 365 days) | 23,325 | 4,901 | 21.01 (20.49, 21.54) | | | |
| Prior Anticoagulant Therapy (-183 to -3 days) | 7,131 | 1,648 | 23.11 (22.14, 24.11) | | | |
| Prior Venous Thromboembolism (prior 365 days) | 3,275 | 661 | 20.18 (18.83, 21.61) | | | |
| Prior Anticoagulant Therapy (-183 to -3 days) | 2,016 | 399 | 19.79 (18.09, 21.61) | | | |
| Anticoagulant History (-183 to -3 days) | 8,841 | 1,818 | 20.56 (19.73, 21.42) | | | |
| Antiplatelet History (-183 to -3 days) | 5,117 | 1,393 | 27.22 (26.01, 28.47) | | | |

Table 2a. Numbers and Rates of Inpatient Arterial Thromboembolism (ATE) Events Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Hospital/Inpatient Care Settings in the Pre-Vaccine Era



Table 2b. Numbers and Rates of Inpatient Arterial Thromboembolism (ATE) Events Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Hospital/Inpatient Care Settings in the Post-Vaccine Era

| Characteristic | Number in Cohort | Number of Events | Absolute Risk (%) with 95% CI |
|---|------------------|------------------|-------------------------------|
| Overall | 91,433 | 14,966 | 16.37 (16.13, 16.61) |
| Age (years): | | | |
| 18-44 | 4,728 | 139 | 2.94 (2.49, 3.47) |
| 45-54 | 4,836 | 444 | 9.18 (8.39, 10.04) |
| 55-64 | 11,828 | 1,620 | 13.70 (13.08, 14.33) |
| 65-74 | 29,868 | 4,904 | 16.42 (16 <i>,</i> 16.85) |
| 75-84 | 27,382 | 5,279 | 19.28 (18.81 <i>,</i> 19.75) |
| 85+ | 12,791 | 2,580 | 20.17 (19.48, 20.88) |
| Sex: | | | |
| Male | 45,347 | 8,162 | 18.00 (17.65 <i>,</i> 18.36) |
| Female | 46,086 | 6,804 | 14.76 (14.44, 15.09) |
| Month of COVID-19 Diagnosis: | | | |
| 2020 | | | |
| December | 13,703 | 2,248 | 16.41 (15.79 <i>,</i> 17.04) |
| 2021 | | | |
| January | 13,466 | 2,267 | 16.83 (16.21, 17.48) |
| February | 6,020 | 1,009 | 16.76 (15.83 <i>,</i> 17.73) |
| March | 4,291 | 722 | 16.83 (15.73 <i>,</i> 17.99) |
| April | 4,423 | 671 | 15.17 (14.13, 16.27) |
| Мау | 2,795 | 441 | 15.78 (14.46, 17.19) |
| June | 1,627 | 285 | 17.52 (15.72, 19.47) |
| July | 3,983 | 631 | 15.84 (14.73, 17.02) |
| August | 10,134 | 1,619 | 15.98 (15.27, 16.71) |
| September | 8,491 | 1,361 | 16.03 (15.26, 16.83) |
| October | 5,619 | 920 | 16.37 (15.42, 17.37) |
| November | 5,939 | 942 | 15.86 (14.95, 16.82) |
| December | 10,942 | 1,850 | 16.91 (16.21, 17.63) |
| Prior Cardiovascular Disease (prior 365 days) | 48,877 | 10,478 | 21.44 (21.07, 21.80) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 15,518 | 3,425 | 22.07 (21.42, 22.73) |
| Prior Venous Thromboembolism (prior 365 days) | 6,464 | 1,309 | 20.25 (19.28, 21.26) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 4,279 | 804 | 18.79 (17.64, 20.0) |
| Anticoagulant History (-183 to -3 days) | 19,584 | 3,919 | 20.01 (19.45, 20.58) |
| Antiplatelet History (-183 to -3 days) | 10,880 | 2,923 | 26.87 (26.04, 27.71) |



Table 2c. Numbers and Rates of Inpatient Arterial Thromboembolism (ATE) Events Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Ambulatory/Outpatient Care Settings in the Pre-Vaccine Era

| Characteristic | Number in Cohort | Number of Events | Absolute Risk (%) with 95% Cl |
|---|------------------|------------------|-------------------------------|
| Overall | 272,065 | 2,752 | 1.01 (0.97, 1.05) |
| Age (years): | | | |
| 18-44 | 86,564 | 41 | 0.05 (0.03, 0.06) |
| 45-54 | 38,454 | 109 | 0.28 (0.23, 0.34) |
| 55-64 | 42,182 | 313 | 0.74 (0.66, 0.83) |
| 65-74 | 57,089 | 912 | 1.60 (1.50, 1.70) |
| 75-84 | 33,535 | 911 | 2.72 (2.55, 2.90) |
| 85+ | 14,241 | 466 | 3.27 (2.99, 3.58) |
| Sex: | | | |
| Male | 121,048 | 1,535 | 1.27 (1.21, 1.33) |
| Female | 151,017 | 1,217 | 0.81 (0.76, 0.85) |
| Month of COVID-19 Diagnosis: | | | |
| 2020 | | | |
| April | 14,127 | 210 | 1.49 (1.30, 1.70) |
| May | 15,926 | 173 | 1.09 (0.93, 1.26) |
| June | 22,176 | 204 | 0.92 (0.80, 1.06) |
| July | 38,414 | 390 | 1.02 (0.92, 1.12) |
| August | 26,537 | 294 | 1.11 (0.99, 1.24) |
| September | 24,648 | 231 | 0.94 (0.82, 1.07) |
| October | 42,288 | 432 | 1.02 (0.93, 1.12) |
| November | 87,949 | 818 | 0.93 (0.87, 1.00) |
| Prior Cardiovascular Disease (prior 365 days) | 61,737 | 1,917 | 3.11 (2.97, 3.25) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 13,143 | 596 | 4.53 (4.19, 4.91) |
| Prior Venous Thromboembolism (prior 365 days) | 5,979 | 213 | 3.56 (3.11, 4.07) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 3,762 | 142 | 3.77 (3.20, 4.45) |
| Anticoagulant History (-183 to -3 days) | 19,219 | 679 | 3.53 (3.28, 3.81) |
| Antiplatelet History (-183 to -3 days) | 12,362 | 563 | 4.55 (4.20, 4.94) |



Table 2d. Numbers and Rates of Inpatient Arterial Thromboembolism (ATE) Events Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Ambulatory/Outpatient Care Settings in the Post-Vaccine Era

| Characteristic | Number in Cohort | Number of Events | Absolute Risk (%) with 95% Cl |
|---|------------------|------------------|-------------------------------|
| Overall | 753,454 | 7,801 | 1.04 (1.01, 1.06) |
| Age (years): | | | |
| 18-44 | 236,287 | 158 | 0.07 (0.06, 0.08) |
| 45-54 | 105,290 | 375 | 0.36 (0.32, 0.39) |
| 55-64 | 114,298 | 931 | 0.81 (0.76, 0.87) |
| 65-74 | 171,320 | 2,585 | 1.51 (1.45, 1.57) |
| 75-84 | 95,921 | 2,633 | 2.74 (2.64, 2.85) |
| 85+ | 30,338 | 1,119 | 3.69 (3.48, 3.91) |
| Sex: | | | |
| Male | 336,334 | 4,221 | 1.26 (1.22, 1.29) |
| Female | 417,120 | 3,580 | 0.86 (0.83, 0.89) |
| Month of COVID-19 Diagnosis: | | | |
| 2020 | | | |
| December | 110,215 | 1,172 | 1.06 (1.00, 1.13) |
| 2021 | | | |
| January | 102,643 | 1,153 | 1.12 (1.06, 1.19) |
| February | 42,638 | 485 | 1.14 (1.04, 1.24) |
| March | 36,121 | 314 | 0.87 (0.78, 0.97) |
| April | 34,545 | 331 | 0.96 (0.86, 1.07) |
| Мау | 18,380 | 208 | 1.13 (0.99, 1.30) |
| June | 10,513 | 110 | 1.05 (0.86, 1.26) |
| July | 30,143 | 354 | 1.17 (1.06, 1.30) |
| August | 81,365 | 942 | 1.16 (1.09, 1.23) |
| September | 67,004 | 829 | 1.24 (1.16, 1.32) |
| October | 44,611 | 455 | 1.02 (0.93, 1.12) |
| November | 49,352 | 487 | 0.99 (0.90, 1.08) |
| December | 125,924 | 961 | 0.76 (0.72, 0.81) |
| Prior Cardiovascular Disease (prior 365 days) | 172,992 | 5,096 | 2.95 (2.87, 3.03) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 39,024 | 1,690 | 4.33 (4.13, 4.54) |
| Prior Venous Thromboembolism (prior 365 days) | 16,372 | 519 | 3.17 (2.91, 3.45) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 10,741 | 361 | 3.36 (3.03, 3.72) |
| Anticoagulant History (-183 to -3 days) | 57,670 | 1,954 | 3.39 (3.24, 3.54) |
| Antiplatelet History (-183 to -3 days) | 35,517 | 1,502 | 4.23 (4.02, 4.44) |



Table 2e. Numbers and Rates of All-Cause Mortality Among Those with COVID-19, Defined by a Positive Nucleic AcidAmplification Test (NAAT) or Diagnosis Code in Any Care Setting, and an Inpatient Arterial Thromboembolism (ATE) Event in thePre-Vaccine Era

| Characteristic | Number with ATE Events | Number of Deaths | Absolute Risk (%) with 95% Cl |
|---|------------------------|------------------|-------------------------------|
| Overall | 9,421 | 2,039 | 21.64 (20.82, 22.49) |
| Age (years): | | | |
| 18-44 | 113 | 11 | 9.73 (5.20, 17.12) |
| 45-54 | 313 | 50 | 15.97 (12.19, 20.62) |
| 55-64 | 1,006 | 127 | 12.62 (10.67, 14.87) |
| 65-74 | 3,025 | 631 | 20.86 (19.43, 22.36) |
| 75-84 | 3,264 | 788 | 24.14 (22.69, 25.66) |
| 85+ | 1,700 | 432 | 25.41 (23.37, 27.57) |
| Sex: | | | |
| Male | 5,188 | 1,250 | 24.09 (22.94 <i>,</i> 25.29) |
| Female | 4,233 | 789 | 18.64 (17.48 <i>,</i> 19.85) |
| Month of COVID-19 Diagnosis: | | | |
| 2020 | | | |
| April | 1,130 | 292 | 25.84 (23.33 <i>,</i> 28.52) |
| May | 696 | 143 | 20.55 (17.64, 23.78) |
| June | 730 | 145 | 19.86 (17.07, 22.98) |
| July | 1,378 | 314 | 22.79 (20.61, 25.11) |
| August | 933 | 178 | 19.08 (16.64, 21.78) |
| September | 769 | 160 | 20.81 (18.02, 23.88) |
| October | 1,259 | 245 | 19.46 (17.33 <i>,</i> 21.78) |
| November | 2,526 | 562 | 22.25 (20.65 <i>,</i> 23.93) |
| Care Setting at COVID-19 Diagnosis: | | | |
| Ambulatory/Outpatient/Emergency | 2,752 | 534 | 19.40 (17.95 <i>,</i> 20.94) |
| Inpatient | 6,559 | 1,482 | 22.59 (21.59 <i>,</i> 23.63) |
| Unknown | 110 | 23 | 20.91 (13.98, 29.92) |
| Prior Cardiovascular Disease (prior 365 days) | 6,871 | 1,447 | 21.06 (20.10, 22.05) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 2,262 | 453 | 20.03 (18.41, 21.75) |
| Prior Venous Thromboembolism (prior 365 days) | 879 | 171 | 19.45 (16.92, 22.26) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 545 | 104 | 19.08 (15.92, 22.69) |
| Anticoagulant History (-183 to -3 days) | 2,516 | 512 | 20.35 (18.8, 21.99) |
| Antiplatelet History (-183 to -3 days) | 1,974 | 399 | 20.21 (18.48, 22.07) |



Table 2f. Numbers and Rates of All-Cause Mortality Among Those with COVID-19, Defined by a Positive Nucleic AcidAmplification Test (NAAT) or Diagnosis Code in Any Care Setting, and an Inpatient Arterial Thromboembolism (ATE) Event in thePost-Vaccine Era

| Characteristic | Number with ATE Events | Number of Deaths | Absolute Risk (%) with 95% Cl |
|---|------------------------|------------------|-------------------------------|
| Overall | 23,026 | 5,266 | 22.87 (22.33, 23.42) |
| Age (years): | | | |
| 18-44 | 312 | 31 | 9.94 (6.95 <i>,</i> 13.94) |
| 45-54 | 838 | 120 | 14.32 (12.06, 16.92) |
| 55-64 | 2,604 | 455 | 17.47 (16.04, 19.00) |
| 65-74 | 7,562 | 1,760 | 23.27 (22.33, 24.25) |
| 75-84 | 7,991 | 1,982 | 24.8 (23.86, 25.77) |
| 85+ | 3,719 | 918 | 24.68 (23.31, 26.11) |
| Sex: | | | |
| Male | 12,540 | 3,101 | 24.73 (23.98, 25.50) |
| Female | 10,486 | 2,165 | 20.65 (19.88, 21.44) |
| Month of COVID-19 Diagnosis: | | | |
| 2020 | | | |
| December | 3,470 | 826 | 23.80 (22.4, 25.26) |
| 2021 | | | |
| January | 3,474 | 759 | 21.85 (20.49, 23.27) |
| February | 1,513 | 310 | 20.49 (18.50, 22.63) |
| March | 1,048 | 176 | 16.79 (14.61, 19.23) |
| April | 1,014 | 187 | 18.44 (16.13, 21.00) |
| May | 656 | 111 | 16.92 (14.18, 20.06) |
| June | 398 | 71 | 17.84 (14.28, 22.04) |
| July | 994 | 271 | 27.26 (24.54, 30.17) |
| August | 2,583 | 691 | 26.75 (25.06, 28.51) |
| September | 2,202 | 547 | 24.84 (23.06, 26.71) |
| October | 1,385 | 338 | 24.40 (22.18, 26.77) |
| November | 1,449 | 377 | 26.02 (23.79, 28.37) |
| December | 2,840 | 602 | 21.20 (19.72, 22.76) |
| Care Setting at COVID-19 Diagnosis: | | | |
| Ambulatory/Outpatient/Emergency | 7,801 | 1,698 | 21.77 (20.86, 22.70) |
| Inpatient | 14,966 | 3,517 | 23.50 (22.82, 24.19) |
| Unknown | 259 | 51 | 19.69 (15.13, 25.17) |
| Prior Cardiovascular Disease (prior 365 days) | 15,709 | 3,399 | 21.64 (21, 22.29) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 5,151 | 1,098 | 21.32 (20.21, 22.47) |
| Prior Venous Thromboembolism (prior 365 days) | 1,843 | 392 | 21.27 (19.44, 23.22) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 1,175 | 253 | 21.53 (19.24, 24.02) |
| Anticoagulant History (-183 to -3 days) | 5,916 | 1,312 | 22.18 (21.13, 23.26) |
| Antiplatelet History (-183 to -3 days) | 4,467 | 966 | 21.63 (20.43, 22.87) |



Table 2g. Numbers and Rates of Inpatient Venous Thromboembolism (VTE) Events Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Hospital/Inpatient Care Settings in the Pre-Vaccine Era

| Characteristic | Number in Cohort | Number of Events | Absolute Risk (%) with 95% Cl |
|---|------------------|------------------|-------------------------------|
| Overall | 41,443 | 3,984 | 9.61 (9.33, 9.90) |
| Age (years): | | | |
| 18-44 | 2,032 | 104 | 5.12 (4.22, 6.19) |
| 45-54 | 2,186 | 185 | 8.46 (7.35, 9.73) |
| 55-64 | 5,161 | 537 | 10.40 (9.59, 11.28) |
| 65-74 | 12,889 | 1,316 | 10.21 (9.70, 10.75) |
| 75-84 | 12,649 | 1,262 | 9.98 (9.46, 10.52) |
| 85+ | 6,526 | 580 | 8.89 (8.21, 9.61) |
| Sex: | | | |
| Male | 20,890 | 2,064 | 9.88 (9.48, 10.29) |
| Female | 20,553 | 1,920 | 9.34 (8.95, 9.75) |
| Month of COVID-19 Diagnosis: | | | |
| 2020 | | | |
| April | 5,676 | 507 | 8.93 (8.21, 9.71) |
| May | 2,960 | 289 | 9.76 (8.73, 10.9) |
| June | 3,052 | 299 | 9.80 (8.78, 10.92) |
| July | 6,193 | 571 | 9.22 (8.52, 9.97) |
| August | 4,110 | 442 | 10.75 (9.83, 11.75) |
| September | 3,130 | 285 | 9.11 (8.13, 10.18) |
| October | 5,449 | 530 | 9.73 (8.96, 10.55) |
| November | 10,873 | 1,061 | 9.76 (9.21, 10.33) |
| Prior Cardiovascular Disease (prior 365 days) | 23,325 | 2,372 | 10.17 (9.79, 10.57) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 7,131 | 867 | 12.16 (11.41, 12.94) |
| Prior Venous Thromboembolism (prior 365 days) | 3,275 | 992 | 30.29 (28.73, 31.90) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 2,016 | 634 | 31.45 (29.43, 33.53) |
| Anticoagulant History (-183 to -3 days) | 8,841 | 1,133 | 12.82 (12.13, 13.53) |
| Antiplatelet History (-183 to -3 days) | 5,117 | 493 | 9.63 (8.85, 10.48) |



Table 2h. Numbers and Rates of Inpatient Venous Thromboembolism (VTE) Events Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Hospital/Inpatient Care Settings in the Post-Vaccine Era

| Characteristic | Number in Cohort | Number of Events | Absolute Risk (%) with 95% Cl |
|---|------------------|------------------|-------------------------------|
| Overall | 91,433 | 10,366 | 11.34 (11.13, 11.54) |
| Age (years): | | | |
| 18-44 | 4,728 | 283 | 5.99 (5.33, 6.71) |
| 45-54 | 4,836 | 540 | 11.17 (10.30, 12.10) |
| 55-64 | 11,828 | 1,390 | 11.75 (11.18 <i>,</i> 12.35) |
| 65-74 | 29,868 | 3,676 | 12.31 (11.94, 12.69) |
| 75-84 | 27,382 | 3,238 | 11.83 (11.45, 12.21) |
| 85+ | 12,791 | 1,239 | 9.69 (9.18, 10.22) |
| Sex: | | | |
| Male | 45,347 | 5,450 | 12.02 (11.72, 12.32) |
| Female | 46,086 | 4,916 | 10.67 (10.39 <i>,</i> 10.95) |
| Month of COVID-19 Diagnosis: | | | |
| 2020 | | | |
| December | 13,703 | 1,438 | 10.49 (9.99, 11.02) |
| 2021 | | | |
| January | 13,466 | 1,547 | 11.49 (10.96, 12.04) |
| February | 6,020 | 681 | 11.31 (10.53, 12.15) |
| March | 4,291 | 477 | 11.12 (10.20, 12.10) |
| April | 4,423 | 503 | 11.37 (10.46, 12.35) |
| Мау | 2,795 | 304 | 10.88 (9.76, 12.10) |
| June | 1,627 | 182 | 11.19 (9.72, 12.84) |
| July | 3,983 | 408 | 10.24 (9.33, 11.24) |
| August | 10,134 | 1,139 | 11.24 (10.63, 11.87) |
| September | 8,491 | 997 | 11.74 (11.07, 12.45) |
| October | 5,619 | 659 | 11.73 (10.9, 12.60) |
| November | 5,939 | 733 | 12.34 (11.52, 13.21) |
| December | 10,942 | 1,298 | 11.86 (11.27, 12.49) |
| Prior Cardiovascular Disease (prior 365 days) | 48,877 | 5,564 | 11.38 (11.10, 11.67) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 15,518 | 1,905 | 12.28 (11.77, 12.81) |
| Prior Venous Thromboembolism (prior 365 days) | 6,464 | 2,015 | 31.17 (30.05, 32.32) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 4,279 | 1,327 | 31.01 (29.63, 32.43) |
| Anticoagulant History (-183 to -3 days) | 19,584 | 2,516 | 12.85 (12.38, 13.33) |
| Antiplatelet History (-183 to -3 days) | 10,880 | 1,088 | 10.00 (9.45, 10.58) |



Table 2i. Numbers and Rates of Inpatient Venous Thromboembolism (VTE) Events Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Ambulatory/Outpatient Care Settings in the Pre-Vaccine Era

| Characteristic | Number in Cohort | Number of Events | Absolute Risk (%) with 95% Cl |
|---|------------------|------------------|-------------------------------|
| Overall | 272,065 | 2,175 | 0.80 (0.77, 0.83) |
| Age (years): | | | |
| 18-44 | 86,564 | 118 | 0.14 (0.11, 0.16) |
| 45-54 | 38,454 | 161 | 0.42 (0.36, 0.49) |
| 55-64 | 42,182 | 311 | 0.74 (0.66, 0.82) |
| 65-74 | 57,089 | 755 | 1.32 (1.23, 1.42) |
| 75-84 | 33,535 | 594 | 1.77 (1.63, 1.92) |
| 85+ | 14,241 | 236 | 1.66 (1.46, 1.88) |
| Sex: | | | |
| Male | 121,048 | 1,169 | 0.97 (0.91, 1.02) |
| Female | 151,017 | 1,006 | 0.67 (0.63, 0.71) |
| Month of COVID-19 Diagnosis: | | | |
| 2020 | | | |
| April | 14,127 | 130 | 0.92 (0.77, 1.10) |
| May | 15,926 | 116 | 0.73 (0.6, 0.88) |
| June | 22,176 | 150 | 0.68 (0.57, 0.80) |
| July | 38,414 | 301 | 0.78 (0.70, 0.88) |
| August | 26,537 | 247 | 0.93 (0.82, 1.06) |
| September | 24,648 | 185 | 0.75 (0.65, 0.87) |
| October | 42,288 | 377 | 0.89 (0.81, 0.99) |
| November | 87,949 | 669 | 0.76 (0.70, 0.82) |
| Prior Cardiovascular Disease (prior 365 days) | 61,737 | 1,050 | 1.70 (1.60, 1.81) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 13,143 | 339 | 2.58 (2.32, 2.87) |
| Prior Venous Thromboembolism (prior 365 days) | 5,979 | 372 | 6.22 (5.63, 6.87) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 3,762 | 257 | 6.83 (6.06 <i>,</i> 7.70) |
| Anticoagulant History (-183 to -3 days) | 19,219 | 470 | 2.45 (2.23, 2.68) |
| Antiplatelet History (-183 to -3 days) | 12,362 | 201 | 1.63 (1.41, 1.87) |



Table 2j. Numbers and Rates of Inpatient Venous Thromboembolism (VTE) Events Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Ambulatory/Outpatient Care Settings in the Post-Vaccine Era

| Characteristic | Number in Cohort | Number of Events | Absolute Risk (%) with 95% Cl |
|---|------------------|------------------|-------------------------------|
| Overall | 753,454 | 7,650 | 1.02 (0.99, 1.04) |
| Age (years): | | | |
| 18-44 | 236,287 | 428 | 0.18 (0.16, 0.20) |
| 45-54 | 105,290 | 647 | 0.61 (0.57, 0.66) |
| 55-64 | 114,298 | 1,202 | 1.05 (0.99, 1.11) |
| 65-74 | 171,320 | 2,645 | 1.54 (1.49, 1.60) |
| 75-84 | 95,921 | 2,009 | 2.09 (2.01, 2.19) |
| 85+ | 30,338 | 719 | 2.37 (2.20, 2.55) |
| Sex: | | | |
| Male | 336,334 | 4,161 | 1.24 (1.20, 1.28) |
| Female | 417,120 | 3,489 | 0.84 (0.81, 0.86) |
| Month of COVID-19 Diagnosis: | | | |
| 2020 | | | |
| December | 110,215 | 1,026 | 0.93 (0.88, 0.99) |
| 2021 | | | |
| January | 102,643 | 1,034 | 1.01 (0.95, 1.07) |
| February | 42,638 | 425 | 1.00 (0.91, 1.10) |
| March | 36,121 | 323 | 0.89 (0.80, 1.00) |
| April | 34,545 | 351 | 1.02 (0.91, 1.13) |
| Мау | 18,380 | 199 | 1.08 (0.94, 1.25) |
| June | 10,513 | 141 | 1.34 (1.13, 1.58) |
| July | 30,143 | 371 | 1.23 (1.11, 1.36) |
| August | 81,365 | 1,047 | 1.29 (1.21, 1.37) |
| September | 67,004 | 807 | 1.20 (1.12, 1.29) |
| October | 44,611 | 499 | 1.12 (1.02, 1.22) |
| November | 49,352 | 545 | 1.10 (1.01, 1.2) |
| December | 125,924 | 882 | 0.70 (0.66, 0.75) |
| Prior Cardiovascular Disease (prior 365 days) | 172,992 | 3,425 | 1.98 (1.91, 2.05) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 39,024 | 1,091 | 2.80 (2.64, 2.97) |
| Prior Venous Thromboembolism (prior 365 days) | 16,372 | 1,058 | 6.46 (6.09, 6.85) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 10,741 | 779 | 7.25 (6.77, 7.76) |
| Anticoagulant History (-183 to -3 days) | 57,670 | 1,528 | 2.65 (2.52, 2.78) |
| Antiplatelet History (-183 to -3 days) | 35,517 | 701 | 1.97 (1.83, 2.13) |



Table 2k. Numbers and Rates of All-Cause Mortality Among Those with COVID-19, Defined by a Positive Nucleic Acid Amplification Test (NAAT) or Diagnosis Code in Any Care Setting, and an Inpatient Venous Thromboembolism (VTE) Event in the Pre-Vaccine Era

| Characteristic | Number with VTE Events | Number of Deaths | Absolute Risk (%) with 95% CI |
|---|------------------------|------------------|-------------------------------|
| Overall | 6,307 | 1,045 | 16.57 (15.66, 17.51) |
| Age (years): | | | |
| 18-44 | 241 | 12 | 4.98 (2.72, 8.76) |
| 45-54 | 376 | 36 | 9.57 (6.88, 13.12) |
| 55-64 | 883 | 104 | 11.78 (9.76, 14.13) |
| 65-74 | 2,106 | 341 | 16.19 (14.66, 17.85) |
| 75-84 | 1,881 | 388 | 20.63 (18.83, 22.54) |
| 85+ | 820 | 164 | 20.0 (17.35, 22.94) |
| Sex: | | | |
| Male | 3,323 | 655 | 19.71 (18.38, 21.11) |
| Female | 2,984 | 390 | 13.07 (11.89, 14.34) |
| Month of COVID-19 Diagnosis: | | | |
| 2020 | | | |
| April | 654 | 115 | 17.58 (14.79, 20.77) |
| May | 420 | 64 | 15.24 (12.01, 19.12) |
| June | 465 | 65 | 13.98 (11.02, 17.54) |
| July | 892 | 151 | 16.93 (14.56, 19.59) |
| August | 695 | 100 | 14.39 (11.91, 17.27) |
| September | 483 | 74 | 15.32 (12.29, 18.92) |
| October | 934 | 162 | 17.34 (15.0, 19.96) |
| November | 1,764 | 314 | 17.80 (16.06, 19.68) |
| Care Setting at COVID-19 Diagnosis: | | | |
| Ambulatory/Outpatient/Emergency | 2,175 | 318 | 14.62 (13.18, 16.19) |
| Inpatient | 3,984 | 715 | 17.95 (16.77, 19.18) |
| Unknown | 148 | 12 | 8.11 (4.45, 14.04) |
| Prior Cardiovascular Disease (prior 365 days) | 3,460 | 635 | 18.35 (17.08, 19.69) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 1,219 | 208 | 17.06 (15.02, 19.32) |
| Prior Venous Thromboembolism (prior 365 days) | 1,375 | 180 | 13.09 (11.38, 15.02) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 898 | 121 | 13.47 (11.34, 15.92) |
| Anticoagulant History (-183 to -3 days) | 1,620 | 255 | 15.74 (14.02, 17.63) |
| Antiplatelet History (-183 to -3 days) | 702 | 139 | 19.8 (16.95, 22.98) |



Table 2I. Numbers and Rates of All-Cause Mortality Among Those with COVID-19, Defined by a Positive Nucleic AcidAmplification Test (NAAT) or Diagnosis Code in Any Care Setting, and an Inpatient Venous Thromboembolism (VTE) Event in thePost-Vaccine Era

| Characteristic | Number with VTE Events | Number of Deaths | Absolute Risk (%) with 95% Cl |
|---|------------------------|------------------|-------------------------------|
| Overall | 18,337 | 3,719 | 20.28 (19.70, 20.87) |
| Age (years): | | | |
| 18-44 | 741 | 56 | 7.56 (5.81, 9.76) |
| 45-54 | 1,233 | 149 | 12.08 (10.34, 14.07) |
| 55-64 | 2,656 | 476 | 17.92 (16.49, 19.45) |
| 65-74 | 6,423 | 1,410 | 21.95 (20.95, 22.99) |
| 75-84 | 5,308 | 1,238 | 23.32 (22.20, 24.49) |
| 85+ | 1,976 | 390 | 19.74 (18.02, 21.58) |
| Sex: | | | |
| Male | 9,798 | 2,189 | 22.34 (21.52, 23.18) |
| Female | 8,539 | 1,530 | 17.92 (17.11, 18.75) |
| Month of COVID-19 Diagnosis: | | | |
| 2020 | | | |
| December | 2,521 | 486 | 19.28 (17.77, 20.88) |
| 2021 | | | |
| January | 2,649 | 490 | 18.50 (17.05, 20.04) |
| February | 1,122 | 212 | 18.89 (16.67, 21.34) |
| March | 824 | 140 | 16.99 (14.52, 19.77) |
| April | 868 | 138 | 15.90 (13.56, 18.54) |
| May | 510 | 82 | 16.08 (13.06, 19.62) |
| June | 327 | 59 | 18.04 (14.12, 22.74) |
| July | 798 | 180 | 22.56 (19.73, 25.65) |
| August | 2,211 | 512 | 23.16 (21.42, 24.98) |
| September | 1,831 | 413 | 22.56 (20.67, 24.55) |
| October | 1,170 | 257 | 21.97 (19.65, 24.47) |
| November | 1,295 | 283 | 21.85 (19.65, 24.23) |
| December | 2,211 | 467 | 21.12 (19.45, 22.90) |
| Care Setting at COVID-19 Diagnosis: | | | |
| Ambulatory/Outpatient/Emergency | 7,650 | 1,386 | 18.12 (17.26, 19.00) |
| Inpatient | 10,366 | 2,293 | 22.12 (21.33, 22.93) |
| Unknown | 321 | 40 | 12.46 (9.15, 16.70) |
| Prior Cardiovascular Disease (prior 365 days) | 9,098 | 1,956 | 21.50 (20.66, 22.36) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 3,030 | 583 | 19.24 (17.86, 20.70) |
| Prior Venous Thromboembolism (prior 365 days) | 3,105 | 468 | 15.07 (13.84, 16.39) |
| Prior Anticoagulant Therapy (-183 to -3 days) | 2,133 | 312 | 14.63 (13.17, 16.21) |
| Anticoagulant History (-183 to -3 days) | 4,092 | 765 | 18.70 (17.52, 19.93) |
| Antiplatelet History (-183 to -3 days) | 1,803 | 439 | 24.35 (22.40, 26.41) |