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Original Research

Clinical outcomes in immunocompromised adults with COVID-19, based on anti-spike IgG serostatus and monoclonal antibody therapy: a retrospective cohort study in the Omicron period

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Abstract

Background: Immunocompromised adults may experience severe COVID-19 outcomes, necessitating a multifaceted treatment approach. Studies from the Delta period showed benefit from monoclonal antibody (mAb) therapy that was most pronounced among anti-spike IgG seronegative individuals. With widespread vaccination and shifting SARS-CoV-2 variants in the Omicron period, clinical predictors of anti-spike IgG seronegativity, and impacts on clinical outcomes, remain incompletely characterized.

Objectives: We describe outcomes from a cohort of immunocompromised adults with COVID-19 stratified by anti-spike IgG serostatus and receipt of mAb therapy during the Omicron period to evaluate clinical impact.

Design: This was a retrospective study of immunocompromised adults with mild-moderate COVID-19 presenting between December 2021 and October 2022.

Methods: Charts were reviewed to assess anti-spike IgG serostatus, receipt of mAb therapy, and 28-day outcomes including conventional oxygen use, high-flow oxygen use, mechanical ventilation, and death.

Results: A total of 276 individuals were included, of whom 252 (91%) were partially or fully vaccinated, 190 (69%) were anti-spike IgG seropositive, and 225 (82%) received mAb therapy. A majority were solid organ transplant recipients (169, 61%), with anti-spike IgG seronegatively significantly associated with mycophenolate-based immunosuppression or comorbid chronic kidney disease. Conventional oxygen use among seropositive patients receiving mAb, seronegative patients receiving mAb, seropositive patients not receiving mAb, and seronegative patients not receiving mAb were 2/154 (1%), 5/71 (7%), 6/36 (17%), and 4/15 (27%), respectively. Across the cohort, high-flow oxygen use, mechanical ventilation, and death occurred in 6 (2%), 4 (3%), and 3 (1%) individuals, respectively.

Conclusion: Clinical outcomes in a predominantly vaccinated, immunocompromised cohort with mild–moderate COVID-19 during the Omicron period appeared to vary with anti-spike IgG serostatus and receipt of mAb therapy. Observed trends would benefit from prospective studies during future iterations of COVID-19 therapeutics to inform treatment decisions for immunocompromised adults.

Keywords: anti-spike IgG serostatus, COVID-19, immunocompromised host, monoclonal antibody

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Introduction

SARS-CoV-2 infection continues to cause increased morbidity and mortality in immunocompromised adults in the Omicron period.[1,2] Although vaccination has markedly attenuated the impacts of SARS-CoV-2 infection, antibody response to vaccine remains heterogeneous in immunocompromised individuals including those with solid organ transplantation, hematologic malignancies, and anti-B-cell therapies.[3–5] While antibody response reflects only humoral rather than cell-mediated immune response to vaccine, available data suggest that individuals who remain seronegative after vaccine are at greater risk of breakthrough infection and severe clinical outcomes.[6–10] Specific risk factors for suboptimal vaccine response and/or subsequent adverse outcomes in immunocompromised populations are incompletely characterized, thus posing challenges in clinical decision-making around preventive and therapeutic interventions.

During the Delta period of the COVID-19 pandemic, at a time when population immunity against SARS-CoV-2 was low, anti-SARS-CoV-2 monoclonal antibodies (mAbs) such as bamlanivimab–etesevimab and casirivimab–imdevimab showed efficacy in reducing the progression of illness, particularly among anti-spike IgG seronegative individuals.[11–13] Since the onset of the Omicron period, and since population immunity through natural infection or vaccination has markedly increased, sotrovimab and bebtelovimab have each briefly been available for use as a treatment against circulating SARS-CoV-2 variants in 2021 to 2022,[14] while pemivibart remains available as a prophylactic strategy as of 2024.[15] Observational studies to date during the Omicron period show low rates of severe outcomes among those treated with mAbs[16] though potentially a decreasing magnitude of benefit with evolving SARS-CoV-2 variants.[17] It remains unclear to what extent mAb therapy impacts clinical outcomes in the context of shifting SARS-CoV-2 epidemiology, and who among patients considered moderate–severely immunocompromised may experience the greatest benefit from mAb therapy.

Previous studies have suggested that SARS-CoV-2 anti-spike IgG serostatus may serve as a useful predictor of disease severity and of treatment benefit from mAbs.[18,19] In this retrospective study, we describe clinical outcomes among moderate–severely immunocompromised individuals presenting with mild–moderate COVID-19 to a large academic transplant and oncology center in New York City during the Omicron period. We compare outcomes among individuals with and without anti-spike IgG antibodies, and among those who did and did not receive mAb therapy, to assess clinical impacts.

Methods

This was a retrospective study conducted at Mount Sinai Hospital and approved by the Mount Sinai Institutional Review Board (STUDY-22-00879-MOD002). Written informed consent from included patients was deemed not to be required by the ethical review board given the retrospective nature of the study and minimal anticipated harm to included patients. The study was conducted in accordance with STROBE guidelines.[20]

Patients eligible for inclusion had mild or moderate COVID-19 infection (as defined by the National Institute of Health (NIH)[21,22] with laboratory confirmation between December 1st, 2021, and October 4th, 2022 and clinical evaluation in the outpatient, emergency department, or inpatient setting; SARS-CoV-2 anti-spike IgG antibody checked after last vaccine dose and within the period 6 months prior to 48 h after COVID-19 diagnosis; moderate–severely immunocompromising condition (as defined by the NIH and Centers for Disease Control (CDC),[21,23] age at least 18 years. Individuals were excluded if they had received tixagevimab/cilgavimab prior to COVID-19 infection, alternate therapies for mild-moderate COVID-19 infection (remdesivir, nirmatrelvir-ritonavir, molnupiravir, casirivimab–imdevimab, bamlanivimab–etesevimab), or if no follow-up was available after COVID-19 diagnosis. Duration of symptoms and prior COVID-19 infection were not applied as exclusion criteria given the inability to consistently ascertain this information from chart review.

Patients were screened for inclusion from three sources (Figure 1). First, all patients who received mAb therapy active against circulating variants (i.e., sotrovimab or bebtelovimab) between December 1st, 2021, and October 4th, 2022, as per hospital pharmacy records, were screened for inclusion. Second, all patients with documented referrals for mAb therapy with sotrovimab or

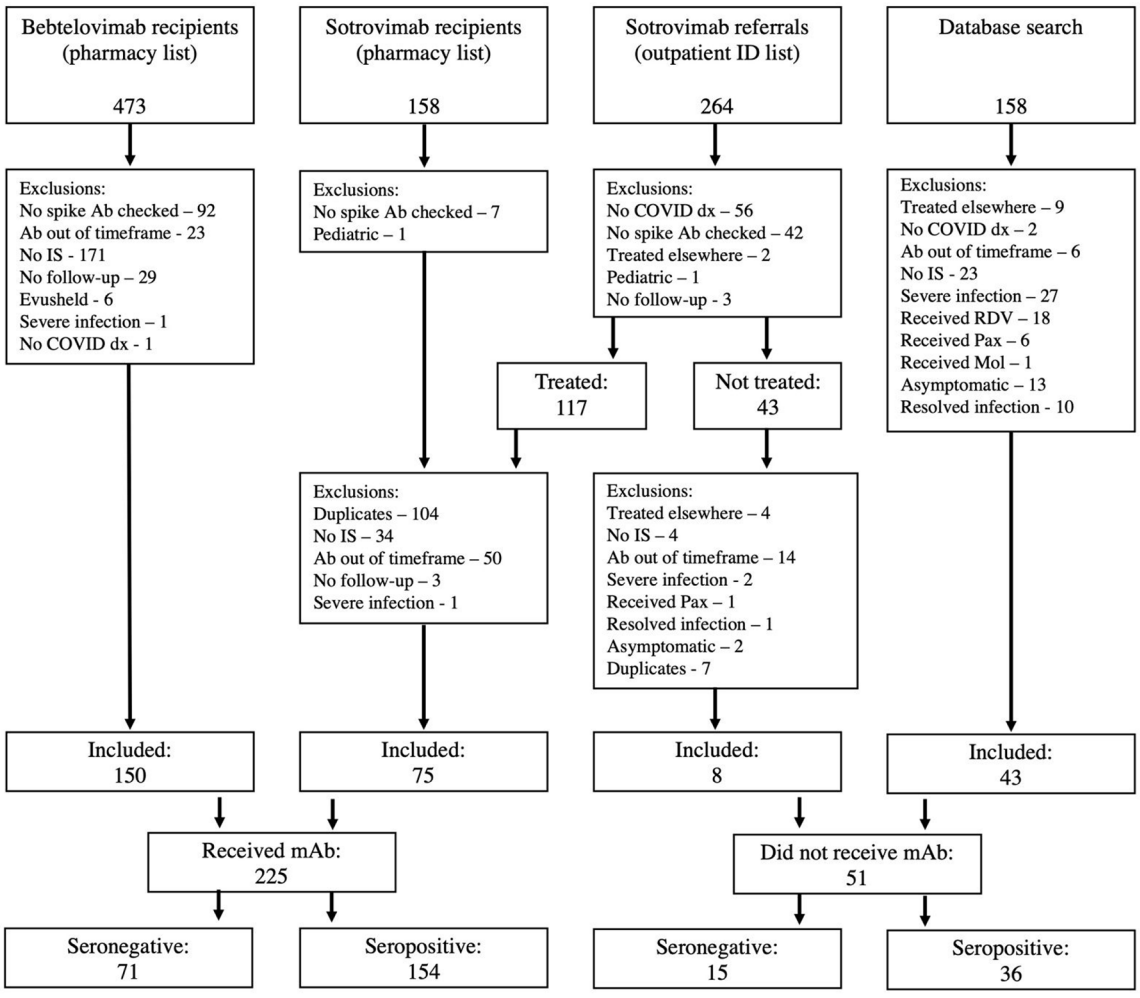

Figure 1. Flowchart for inclusion of individuals meeting study criteria from three data sources, including reasons for exclusion.
dx, Diagnosis; IS, immunosuppression; mAb, monoclonal antibody; Mol, molnupiravir; Pax, nirmatrelvir-ritonavir; RDV, remdesivir.

bebtelovimab through our institution were screened for inclusion. Third, patients were drawn from an institutional COVID-19 database with search terms derived using relevant SARS-CoV-2 and anti-spike IgG antibody results, International Classification of Disease diagnosis codes, and medication orders for immunosuppressive therapies. Database searches were conducted iteratively; following each search, a sample of 50 records was reviewed to assess relevance to the study criteria, and search terms were adjusted accordingly.

Anti-spike IgG antibody testing was conducted using the COVID-SeroKlir Kantaro Semi-Quantitative SARS-CoV-2 IgG Antibody Kit (R&D Systems; Minneapolis, MN, USA), a two-step enzyme-linked immunosorbent assay. Rapid testing was conducted using the SARS-CoV-2 IgG assay (Abbott Alinity I; Chicago, IL, USA), a qualitative chemiluminescent microparticle immunoassay. Indications for testing and choice of the assay were at the provider's discretion.

Clinical outcomes of interest included the following events within 28 days of COVID-19 diagnosis: conventional oxygen use, high-flow nasal cannula (HFNC) or noninvasive ventilation (NIV), invasive mechanical ventilation, and death. Outcomes were assessed as independent (rather than ordinal-scale) events. Because patients diagnosed with COVID-19 in the inpatient setting were eligible for our study, hospitalization was not

included as a clinical outcome. Data were collected manually from the electronic medical record and assembled through the REDCap electronic data capture system[24] hosted at the Icahn School of Medicine at Mount Sinai. Chart review was primarily conducted by one investigator, with select outputs reviewed by two additional investigators to ensure agreement and mitigate bias. Patient characteristics were analyzed statistically for between-group differences using SAS, version 9.4 (SAS Institute, Inc; Cary, NC, USA). Continuous variables were analyzed using a two-sample t-test or Wilcoxon rank-sum test; categorical variables were analyzed using a Chi-square test or Fisher's exact test. Clinical outcomes were assessed descriptively.

Results

A total of 1053 patient records were screened, with 276 patients ultimately included (Figure 1). Eighty-six individuals had negative or weakly positive anti-spike IgG antibodies and were characterized as seronegative, while 190 individuals had moderately or strongly positive anti-spike IgG antibodies and were characterized as seropositive. There were 225 patients who received mAb and 51 patients who did not receive mAb. The most common reasons for excluding those who received mAb were lack of moderate–severely immunocompromising conditions or lack of anti-spike IgG antibody testing. The most common reasons for excluding those who did not receive mAb were lack of mild–moderate SARS-CoV-2 infection (e.g., asymptomatic infection, severe infection) or receipt of alternate therapies for COVID-19 infection (e.g., remdesivir).

The final cohort had a median age of 57 years and included 138 (50%) females. In all, 105 (38%) identified as White and 42 (15%) as Black; 82 (30%) identified as Hispanic. There were 169 (61%) solid organ transplant (SOT) recipients and 17 (6%) stem cell transplant or chimeric antigen receptor T-cell (CAR-T) recipients; 26 (9%) had received B-cell depleting therapy within the past 6 months. Among SOT recipients, the largest proportion were kidney transplant recipients (68, 25%) followed by liver transplant recipients (47, 17%); the median time from transplantation was 3.9 years. Immunocompromising conditions and therapies are otherwise as noted in Table 1.

Among 276 included individuals, 166 (60%) were completely vaccinated with a primary three-dose series, 86 (31%) were partially vaccinated with one or two doses, and 24 (9%) were unvaccinated. The time from the last vaccine dose to infection was approximately 5 months. SARS-CoV-2 anti-spike IgG seropositivity was observed in 122 (73%) of completely vaccinated individuals, 56 (65%) of partially vaccinated individuals, and 12 (50%) of unvaccinated individuals. Anti-spike IgG seronegativity was more commonly observed in individuals with incomplete or no vaccination, shorter time from the last vaccine dose, mycophenolate-based immunosuppression, and chronic kidney disease (Table 1).

Among the 86 anti-spike IgG seronegative individuals evaluated across the outpatient, emergency department, and inpatient settings, 9 (10%) required low-flow oxygen, 4 (5%) required high-flow oxygen, 3 (3%) required mechanical ventilation, and 1 (1%) experienced death within 28 days. Among 190 anti-spike IgG seropositive individuals, 8 (4%) required low-flow oxygen, 2 (1%) required high-flow oxygen, 1 (0.5%) required mechanical ventilation, and 2 (1%) experienced death. Clinical outcomes stratified by anti-spike IgG serostatus and receipt of mAb therapy are noted in Table 2.

Discussion

In this retrospective single-center cohort of 276 moderate–severely immunocompromised individuals presenting with mild–moderate COVID-19, we found that while over 90% (252/276) were at least partially vaccinated, nearly one-third (31%, or 86/276) of individuals were seronegative as measured by anti-spike IgG antibody. In addition to incomplete or no vaccination, factors significantly associated with anti-spike IgG seronegativity included immunosuppression with mycophenolate and chronic kidney disease. Additional factors that trended toward significance included immunosuppression with calcineurin inhibitors and shorter time from organ transplantation. These findings align with those of prior literature[25–27] but exclude some previously identified risk factors for vaccine non-response such as hematologic malignancy and anti-CD-20 therapy, perhaps reflecting the lower proportion of individuals with these conditions in our cohort.

Table 1. Characteristics of immunocompromised adults presenting with mild–moderate COVID-19 during the Omicron period, stratified by anti-spike IgG serostatus.

Characteristic	Seronegative group (negative or weakly positive anti-spike IgG) *N* = 86	Seropositive group (moderately or strongly positive anti-spike IgG) *N* = 190	Between-group difference (*p* value)
Age, median (IQR), years	59 (43,67)	57 (45,67)	0.8585
Sex, *n* (%), female	40 (47%)	98 (52%)	0.4355
Race			
White	31 (36%)	74 (39%)	0.5888
Black	15 (17%)	27 (14%)	
Asian	11 (13%)	14 (7%)	
Other/multiple	28 (33%)	70 (37%)	
Unknown	1 (1%)	3 (2%)	
Ethnicity			
Hispanic	20 (23%)	62 (33%)	0.1454
Non-Hispanic	64 (74%)	119 (63%)	
Unknown	2 (2%)	9 (5%)	
Immunosuppressive condition			
Solid organ transplant	61 (71%)	108 (57%)	0.2337
Stem cell transplant or CAR-T	3 (3%)	12 (6%)	
Hematologic malignancy	12 (14%)	38 (20%)	
Solid tumor	3 (3%)	13 (7%)	
Autoimmune disease	6 (7%)	18 (9%)	
Immunosuppressive therapies			
Calcineurin inhibitor	58 (67%)	107 (56%)	0.0808
Mycophenolate	51 (59%)	79 (42%)	0.0187
Chemotherapy	7 (8%)	29 (15%)	0.1036
B-cell depleting therapy	8 (9%)	18 (9%)	0.9640
MTOR inhibitor	3 (3%)	9 (5%)	0.6376
High-dose steroids	3 (3%)	5 (3%)	0.6944
Other	22 (26%)	61 (32%)	0.2737
Solid organ transplant			
Kidney	25 (31%)	43 (23%)	0.7941
Liver	13 (15%)	34 (18%)	
Heart	9 (10%)	13 (7%)	

(Continued)

Table 1. (Continued)

Characteristic	Seronegative group (negative or weakly positive anti-spike IgG) *N* = 86	Seropositive group (moderately or strongly positive anti-spike IgG) *N* = 190	Between-group difference (*p* value)
Lung	1 (1%)	2 (1%)	
Bowel	1 (1%)	2 (1%)	
Multiorgan	11 (13%)	14 (7%)	
Time from solid organ transplant, median (IQR), years	3.2 (1.1,7.2)	4.0 (1.2,10.8)	0.0562
Comorbidities			
Diabetes mellitus	36 (42%)	64 (34%)	0.1906
Obesity	28 (33%)	52 (27%)	0.3788
Cardiovascular disease	11 (13%)	31 (16%)	0.4502
Chronic kidney disease	13 (15%)	14 (7%)	0.0448
Chronic lung disease	6 (7%)	14 (7%)	0.9075
Vaccination status			
Complete (primary + booster)	44 (51%)	122 (64%)	0.0450
Partial (at least one dose ever)	30 (35%)	56 (29%)	
None	12 (14%)	12 (6%)	
Vaccination type			
Pfizer (New York, NY)	54 (63%)	127 (67%)	0.6902
Moderna (Cambridge, MA)	16 (19%)	43 (23%)	
Time from last vaccine dose, median (IQR), months	5.0 (3.7,8.4)	6.5 (4.0,9.7)	0.0118
Monoclonal antibody treatment			
Received	71 (83%)	154 (81%)	0.7654
Sotrovimab	43 (50%)	32 (17%)	
Bebtelovimab	28 (33%)	122 (64%)	
Not received	15 (17%)	36 (19%)	
Treatment setting for COVID-19			
Outpatient	30 (35%)	34 (18%)	<0.0001
Emergency department	33 (38%)	130 (68%)	
Inpatient	23 (27%)	26 (14%)	

CAR-T, chimeric antigen receptor T-cell; IQR, interquartile range; mAb, monoclonal antibody; *n*, absolute number.

Table 2. Clinical outcomes at 28 days among immunocompromised adults presenting with mild–moderate COVID-19 during the Omicron period, stratified by (a) SARS-CoV-2 anti-spike IgG serostatus, (b) receipt of monoclonal antibody therapy.

Clinical outcome	Seronegative group (negative or weakly positive anti-spike IgG) *N* = 86		Seropositive group (moderately or strongly positive anti-spike IgG) *N* = 190	
Conventional oxygen	9 (10%)		8 (4%)	
HFNC/NIV	4 (5%)		2 (1%)	
MIV	3 (3%)		1 (0.5%)	
Death	1 (1%)		2 (1%)	
	Did not receive mAb treatment *N* = 15	Received mAb treatment *N* = 71	Did not receive mAb treatment *N* = 36	Received mAb treatment *N* = 154
Conventional oxygen	4 (27%)	5 (7%)	6 (17%)	2 (1%)
HFNC/NIV	3 (20%)	1 (1%)	2 (6%)	0 (0%)
MIV	2 (13%)	1 (1%)	1 (3%)	0 (0%)
Death	1 (7%)	0	1 (3%)	1 (0.6%)

HFNC, high-flow nasal cannula, mAb, monoclonal antibody, MIV, mechanical invasive ventilation, NIV, noninvasive ventilation.

In aggregate, severe COVID-19 outcomes in our immunocompromised cohort were rare, with 17 (6%) requiring low-flow oxygen, 6 (2%) requiring high-flow oxygen, 4 (3%) requiring mechanical ventilation, and 3 (1%) experiencing death. These rates are lower than those reported among SOT recipients in other studies from this time period[28–30] and may reflect the heterogeneity of our population, which included individuals with a broad range of NIH-defined moderate to severely immunocompromising conditions including solid tumor and autoimmune disease.

We found in our cohort that rates of severe COVID-19 outcomes were variable when stratified by anti-spike IgG serostatus as well as receipt of mAb therapy. For example, among seropositive patients receiving mAb, seronegative patients receiving mAb, seropositive patients not receiving mAb, and seronegative patients not receiving mAb, rates of conventional oxygen use were 2/154 (1%), 5/71 (7%), 6/36 (17%), and 4/15 (27%), respectively. Meaningful comparison among these groups is precluded by small group size and low event rate; however, observed trends may offer signals into the variability of risk for severe illness based on anti-spike IgG serostatus and receipt of mAb therapy.

Our study has important limitations. We were able to identify only 276 immunocompromised patients with COVID-19 in our study period, of whom only 86 were seronegative and only 51 did not receive mAb therapy. These small group sizes limit our ability to rigorously compare outcomes between groups. There are also important confounding variables that may have contributed to differential outcomes between groups. Seronegative individuals were significantly more likely to be evaluated in the outpatient or inpatient setting as compared with the emergency department, perhaps hinting toward systemic differences in triage or management of individuals felt to be at increased risk of COVID-19 complications. In addition, individuals who did not receive mAb therapy were less likely to have completed vaccination and more likely to be hospitalized at the time of COVID-19 diagnosis, perhaps reflecting broader differences in healthcare utilization or access between groups that may have impacted clinical outcomes.

Additional limitations include the retrospective, chart-based nature of data collection for this study. Some variables of interest including symptom duration could not be consistently determined; therefore, we are unable to assess the impact of the timing of presentation on the variable clinical outcomes observed. Prior COVID-19 infection and nucleocapsid antibody status were also not available from chart review, precluding comparison of those with vaccine-induced versus natural or hybrid immunity. In addition, anti-spike IgG serostatus was captured from both standard and rapid assays across a broad time range of 6 months prior to 48 h after COVID-19 diagnosis and may not have always precisely reflected antibody status at the time of acute infection.

At the time of our writing, there are no currently available mAbs for treatment against circulating SARS-CoV-2 subvariants.[31] However, mAbs remain an active area of drug development,[32] and effective COVID-19 risk stratification remains a priority for appropriate use of future mAb therapies.[33] Our findings, while limited to a small and heterogeneous cohort, suggest variation in COVID-19 clinical outcomes based on anti-spike IgG serostatus and receipt of mAb therapy that extends into the Omicron period and populations with high rates of vaccination. We share here our center's experience to add to the collective understanding of COVID-19 clinical outcomes among immunocompromised hosts, which may inform clinical decisions at the individual and health system levels during future iterations of antibody-based therapeutics.

Conclusion

Clinical outcomes of COVID-19 infection in immunocompromised adults in the Omicron period may vary on the basis of anti-spike IgG serostatus and receipt of mAb therapy. Prospective study during future iterations of mAb therapy would be beneficial in identifying patients who experience the greatest benefit.

Declarations

Ethics approval and consent to participate

This study was approved by the Mount Sinai Institutional Review Board (STUDY-22-00879-MOD002). Written informed consent from included patients was deemed not required by the ethical review board given the retrospective nature of the study and minimal anticipated harm to included patients.

Consent for publication

Not applicable.

Author contributions

Shilpa Vasishta: Conceptualization; Formal analysis; Investigation; Methodology; Writing – original draft.

Judith Aberg: Conceptualization; Funding acquisition; Investigation; Methodology; Resources; Supervision; Writing – review & editing.

Gopi Patel: Data curation; Investigation; Methodology; Resources; Writing – review & editing.

Pooja Anand Gownivaripally: Data curation; Formal analysis; Investigation; Methodology; Software; Validation; Visualization; Writing – review & editing.

Meenakshi Rana: Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Project administration; Resources; Supervision; Writing – review & editing.

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Competing interests

All have provided consent for publication of this work and approved the final manuscript. S.V. was affiliated during the study period with Mount Sinai Hospital, New York, NY; she has since

relocated to Montefiore Medical Center, Bronx, NY. J.A. has participated in clinical trials for Emergent Biosolutions, Frontier Technology, Gilead Sciences, Glaxo-Smith-Kline, Janssen, Merck, Pfizer, Regeneron, and ViiV Healthcare, for which her institution received grants, and has received personal fees for scientific advisory board participation from Glaxo-Smith-Kline, Merck, and ViiV Healthcare and for membership of the DSMB for Kintor Pharmaceuticals. All activities are unrelated to this project and manuscript. M.R. has participated in clinical trials for Pfizer, Merck, and Regeneron for which her institution has received grants, and has received personal fees previously for scientific advisory board participation from Eli Lilly. All activities are unrelated to this project and manuscript.

Availability of data and materials

All supporting data referenced in this manuscript are available upon request from the corresponding author.

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