RATH & COMPANY

Barristers & Solicitors

ESTABLISHED 1995

November 23, 2021

Our File No. 99000

Via email frederick.tappenden@ualberta.ca

Frederick S. Tappenden, Ph.D.
Principal and Dean, and Professor of Theology
St. Stephen's College at the College of Alberta
8810 – 112 Street
Edmonton, AB T6G 2J6

Dear Dr. Tappenden:

Re: Attempted Assault of St. Stephen's College (SSC) Staff, Teachers and Students

Please be advised that we act for both vaccinated and unvaccinated SSC staff, teachers and students of the SSC.

Under the *Freedom of Information and Protection of Privacy Act* (FOIP), they are under no legal obligation to disclose to you private protected medical information. Any demand that anyone disclose their vaccination status constitutes an unlawful request for information under the terms of the FOIP and accordingly requires no response.

Please be further advised that any so-called Exemption Request Policy is unlawful. Under current legislation, no student or employee is required to disclose private medical information to an employer, or College, especially in the circumstance where the College could utilize that information for the purpose of either coercing an employee or student to undertake a medical treatment or procedure without their informed consent, or in threatening an employee with "unpaid leave of absence" or termination of their employment, or a student with expulsion, in the event that they fail to undertake such a procedure.

Feel free to advise our office as to whether the SSC would feel it appropriate to ask that its students and staff disclose their HIV, HPV or Hepatitis C status as a condition of either attendance or employment at SSC facilities.

We hold the legal opinion that the SSC has no legal authority to order any of its students or employees to be vaccinated against their will under the present science as it pertains to COVID-19 Delta variant.

282050 Highway 22 West
Foothills, Alberta T0L 1W2
Phone: (403) 931-4047
Fax: (403) 931-4048
Toll-Free Number: 1-866-231-7284
www.rathandcompany.com

The Standards of Care of the College of Physicians and Surgeons state that the minimum standard of care to be provided to a person in the Province of Alberta is that of "informed consent". Informed consent means expressly, that notwithstanding arguments to the contrary, a person always has the ability to say NO to any proposed medical treatment or procedure. Further, under the *Criminal Code of Canada,* ss. 265(1) and 265(3), coercing a person against their will to be assaulted through the exercise of authority constitutes a criminal assault. NO MEANS NO.

The Supreme Court of Canada in *R. v. Morgentaler* has made it clear in the context of s. 7 *Charter of Rights and Freedoms*, **Security of the Person** rights, that any medical procedure done without consent is a gross invasion of an individual's bodily autonomy and constitutes an assault under common law.

A clear and plain reading of the *Occupational Health and Safety Act*, Alberta, does not open that Statute to an interpretation that that legislation empowers an employer to make the assault of an employee a condition of employment. Reading a contractual provision of that nature into a contract of employment would constitute a contract for an illegal or immoral purpose which would not be enforceable under Canadian law.

On a related note, please be advised that the best available science with regard to Delta wave COVID-19 is that double-vaccinated individuals are as equally transmissible of Delta wave COVID-19 as unvaccinated individuals. We attach for your reference a highlighted copy of documentation from the Public Health Agency of Canada and the Genome Centre University of California – Davis. These documents make it clear that the best available science indicates that any public health measures that take into account vaccination status are ineffective and unnecessary given that fully vaccinated people are now capable of transmitting COVID-19 Delta variant identically to unvaccinated people.

We also provide a hyperlink to the Early COVID Care Experts website. This site is supported by Dr. Harvey Risch, Professor of Epidemiology at Yale University. The hyperlink provides a listing to the most up-to-date medical science with regard to COVID-19 vaccinations and their limitations. It is clear from the scientific journal articles attached below that asymptomatic, double-vaccinated people are capable of spreading COVID at rates as much as 283% higher than the unvaccinated (Riemersma et al).

What this means is that from a scientific perspective, on the basis of actual scientific data (as opposed to misinformation being promulgated by Premier Kenney or Dr. Hinshaw), there is no *bona fide* occupational requirement for anyone to either disclose their vaccine status or to be vaccinated in order to attend at SSC facilities. If the policy was developed on the basis of the mistaken scientific belief that the unvaccinated were more capable than the vaccinated to transmit COVID-19, this is clearly an error and is unsupportable at law.

https://earlycovidcare.org/vaccinestudies/

Please be advised that any coercion of a student or employee of the SSC to be injected against their will is illegal and may in fact give rise to the basis of a criminal complaint.

It is the legal opinion of our office that any discriminatory testing regime that singles out and requires unvaccinated employees or students to be tested regularly would violate ss. 3, 4, and 7, of the *Alberta Human Rights Act*. All of the scientific information referred to in this letter clearly demonstrates that vaccinated people are equally capable of spreading COVID-19 as unvaccinated people. As such, there is no scientific basis upon which unvaccinated people should be forced to be tested while vaccinated people are exempted from such a requirement, unless the entire testing protocol is to simply coerce unvaccinated people into becoming vaccinated through making their lives miserable. Should you contemplate instituting a testing program, the testing program must apply to everyone and be at the expense of the College, even if you could somehow avoid the issue of mandatory testing being the equivalent of a forced physical interference or assault of an employee or student as a condition of their term of employment or enrollment.

Please be further advised that in the event the SSC continues in its unlawful planned assault of its employees or students, or illegally attempts to terminate anyone's employment, legal action seeking substantial punitive and exemplary damages, as well as injunctive relief, shall be commenced against the SSC and the recipient of this letter in his personal capacity without further notice.

Please govern yourselves accordingly.

Yours very truly,

RATH & COMPANY

Jeffrey R. W. Rath, B.A. (Hons.), LL.B. (Hons.)
Barrister and Solicitor

cc: Premier Jason Kenney
Dr. Deena Hinshaw
Attorney General Madu

Coronavirus disease (COVID-19)

Testing for COVID-19 in vaccinated populations

THIS IS EXHIBIT "E" REFERRED TO IN THE AFFIDAVIT OF
Dr Eric Payne
SWORN BEFORE ME THIS 25
DAY OF October 2021

A Notary Public, A Commissioner for Oaths in and for the Province of Alberta

JEFFREY R.W. RATH
Barrister & Solicitor
My Commission Expires at the pleasure of the Attorney General

Current state of COVID-19 testing

Role of government

The government plays an important role in the health and well-being of Canadians. Health care in Canada is an area of shared responsibility between federal and provincial/territorial governments. The provinces and territories are mainly responsible for health care delivery. The federal government plays a role in a number of areas, including:

- safeguarding the Canada Health Act
- coordinating responses to national emergencies
- managing health care delivery for certain populations
- providing financial support and expertise to provinces and territories
- publishing ethical and technical guidance on COVID-19 for various audiences
- regulating market access in Canada for drugs, medical devices and controlled substances
- communicating health information to people in Canada in a timely, accurate and accessible fashion

COVID-19 trends and vaccination

Rates of COVID-19 in Canada have been declining since the middle of April 2021 and rates of vaccination are increasing. As of July 30, 2021, over 80% of eligible Canadians have received at least 1 vaccine dose and 56% have been fully vaccinated.

As vaccination rates increase, the rate of transmission and incidence of COVID-19, as well as severe outcomes among infected vaccinated people, may decrease. (See *eLife* and Bailly and others.)

Nevertheless, COVID-19 infections and severe disease continue to occur mainly among unvaccinated people, including those who may face health, social and economic barriers. In June 2021, Yukon saw widespread community transmission for the first time, when about 75% of Yukon adults were fully vaccinated. However, 85% of the cases were in people who were not vaccinated.

Israel and the United Kingdom may also provide insight on expected COVID-19 trends in a vaccinated population. The number of cases rose in June in both countries despite high rates of vaccination and the presence of new variants. However, the number of hospitalizations remained relatively low compared to active cases, especially compared with trends earlier in the pandemic. This demonstrates the ability of vaccination to improve outcomes in vaccinated people (for example, reduce hospitalizations and deaths) even if they do become infected.

In response to the changing landscape, the Public Health Agency of Canada released guidance on June 25. This guidance outlines measures that need to be taken by vaccinated adults.

Some research indicates that vaccinated people who test positive for COVID-19 and do not carry the Delta variant are likely to have low viral loads (Teran and others, Bailly and others), particularly when symptoms are mild or the person is asymptomatic. There is also evidence that vaccination can greatly reduce rates of SARS-CoV-2 infections with high viral shedding and symptoms.

Emerging evidence for the Delta variant points to the possibility of high viral loads in some breakthrough cases in fully vaccinated people, which can be as high as in unvaccinated people. Preliminary data from the United States Centres for Disease Control and Prevention (U.S. CDC) and from Public Health England indicate that levels of virus in fully vaccinated people who become infected with Delta may be similar to levels found in unvaccinated people, and therefore they may be as likely to transmit the virus. Based on this evidence, U.S. CDC revised its masking guidance for vaccinated individuals on July 27 to recommend indoor masking in areas of high or substantial transmission. However, further studies are needed to confirm these levels of infectiousness and also the extent of vaccine effectiveness against Delta, which at present appears to be only slightly less than for other variants, such as Alpha. These new studies highlight the importance of monitoring and responding to the ever-evolving science.

No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups Infected with SARS-CoV-2 Delta Variant

Charlotte B. Acharya[1], John Schrom[2], Anthea M. Mitchell[3], David A. Coil[1], Carina Marquez[2,4], Susana Rojas[2], Chung Yu Wang[3], Jamin Liu[5], Genay Pilarowski[2,6], Leslie Solis[1], Elizabeth Georgian[1], Maya Petersen[2,7], Joseph DeRisi[3], Richard Michelmore[1], Diane Havlir[2,4]

[1]Genome Center, University of California, Davis, USA

[2]Unidos en Salud, San Francisco, CA, USA

[3]Chan Zuckerberg Biohub, and Dept of Biochemistry & Biophysics, University of California, San Francisco, USA

[4]Department of Medicine, Division of HIV, Infectious Disease and Global Medicine, University of California, San Francisco, USA

[5]Joint UCB/UCSF Bioengineering Program, University of California, Berkeley and University of California, San Francisco, USA

[6]The Public Health Company, Oakland, California, USA

[7]School of Public Health, University of California, Berkeley, USA

Joint Authors for Correspondence: Diane Havlir, Richard Michelmore

Abstract: We found no significant difference in cycle threshold values between vaccinated and unvaccinated, asymptomatic and symptomatic groups infected with SARS-CoV-2 Delta. Given the substantial proportion of asymptomatic vaccine breakthrough cases with high viral levels, interventions, including masking and testing, should be considered for all in settings with elevated COVID-19 transmission.

Background

Vaccines reduce infection, severe disease, and death from SARS-CoV-2 (COVID-19) [1], yet breakthrough cases occur [2]. Several reports show no difference in cycle threshold values (Ct-values) between vaccinated and unvaccinated individuals [2, 3, 4]; however, others have suggested that breakthrough infections, particularly among asymptomatic individuals, have a lower viral load and therefore may be less likely to result in transmission [5, 6].

Effective epidemic control requires contemporary data to guide public health mitigation measures. Here, we report on Ct-values among fully vaccinated and unvaccinated individuals, asymptomatic and symptomatic at time of testing, during a period of high transmission of the Delta variant in two distinct populations: a Unidos en Salud (UeS) community-based site in the Mission District of San Francisco and Healthy Yolo Together (HYT) asymptomatic testing through the University of California (UC), Davis.

Materials and Methods

Study Populations

Data was collected on individuals who voluntarily sought testing for SARS-CoV-2 from two demographically distinct populations in California during a two-month period from June 17 to August 31, 2021, during which Delta was the predominant variant.

HYT: As part of the response to the COVID-19 pandemic, UC Davis deployed an extensive free asymptomatic testing program that included the City of Davis and Yolo County (Healthy Yolo Together). Asymptomatic individuals over the age of 2 were eligible for testing. Asymptomatic cases were classified as individuals not reporting symptoms at the time of testing. Samples were collected through a supervised method in which individuals transferred their saliva into a barcoded tube (COVID-19 Testing | Campus Ready). Smaller numbers of symptomatic

individuals were processed using a different workflow and an antigen test; therefore, they were not included in this study.

UeS: The study population included individuals who sought SARS-CoV-2 testing at the UeS walk-up site, an ongoing academic (UC San Francisco, CZ Biohub, and UC Berkeley), community organization (Latino Task Force), and government (SFDPH) partnership. The outdoor, free BinaxNOW™ testing site was located at a public transport and commercial hub in the Mission District, a setting of ongoing transmission in San Francisco [7]. Individuals one year of age and older, with or without symptoms, were eligible for testing.

Measurements

Infections were classified as breakthrough infections if the individual was fully vaccinated (two weeks following receipt of all vaccine doses). Individuals that had had only one dose or were tested within two weeks of the second dose, in the case of Pfizer and Moderna vaccines, were not included in the analysis.

HYT: Demographic information was collected from individuals at the time of registration. Vaccination status information was obtained at the time of contact tracing and confirmed in the California Vaccine Registry. Only confirmed, fully vaccinated individuals were used in the analysis; discordant samples, self-reported as vaccinated but unconfirmed, were treated as status unknown. Saliva samples from asymptomatic individuals were tested for the presence of the N1 and N2 regions of the viral nucleocapsid (N) gene using primers and probes described in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel, using IntelliQube high-throughput quantitative PCR instruments (LGC Biosearch Technologies). Ct-values were calculated with FastFinder software (UgenTec | FastFinder).

Genotypes of all N1/N2 positive samples were determined using RT-PCR SNP analysis at 11 loci diagnostic for variants of concern (SARS-CoV-2 Variant ValuPanel assays | LGC Biosearch Technologies). A subset of samples (39%) were also sequenced using the Illumina MiSeq sequencing platform. Consensus genomes were generated with Viralrecon2 and variants called in Pangolin version 3.1.11 and PLEARN-v1.2.66. Sequencing confirmed the variants called by genotyping.

UeS: Individuals provided demographic data and information on symptoms immediately prior to testing using BinaxNOW™ kits. COVID-19 vaccine status, including date of final shot, was obtained through the California Vaccine Registry. Anterior-nasal swab samples (iClean, Chenyang Global) collected by certified lab assistants from BinaxNOW positive individuals were placed in DNA/RNA Shield (Zymo, Inc.) and processed for qRT-PCR, genome recovery, and variant/lineage determination as previously described [8, 9]. Ct-values for the detection of N and E genes [8] were determined via the single threshold Cq-determination mode using Bio-Rad CFX Maestro v4.1 (Bio-Rad Inc). SARS-CoV-2 genomes were sequenced using the Illumina NovaSeq platform. Consensus genomes were generated via the COVID module of the IDseq pipeline (https://idseq.net) as described [9].

Analysis

Ct-values were plotted, stratified by site; fully vs. not vaccinated; and symptom status. Partially vaccinated samples and stratification by age and vaccine type are reported in supplementary materials. Ct-values between strata were compared using a two sided t-test.

Ethics Statement

HYT: The Genome Center laboratory that conducted COVID-19 testing was CLIA approved as an extension to the Student Health Center's laboratory. The UC Davis IRB

Administration determined that the study met criteria for public health reporting and was exempt from IRB review and approval.

UeS: The UC San Francisco Committee on Human Research determined the study met criteria for public health surveillance. All participants provided informed consent for testing.

Results

A total of 869 samples, 500 from HYT and 369 from UeS, were included in the analysis. All analyzed samples from HYT were asymptomatic at the time of collection and 75% of the positive samples were from unvaccinated individuals (N=375). Positive samples from UeS were from both symptomatic (N=237) and asymptomatic individuals (N=132). The frequency of vaccine breakthroughs among the UeS samples (171 fully vaccinated, 198 unvaccinated) was greater than among the HYT samples reflecting the different types of populations sampled. The Delta variant was the predominant variant detected in both populations (Supplementary Table 1).

There were no statistically significant differences in mean Ct-values of vaccinated (UeS: 23.1; HYT: 25.5) vs. unvaccinated (UeS: 23.4; HYT: 25.4) samples. In both vaccinated and unvaccinated, there was great variation among individuals, with Ct-values of <15 to >30 in both UeS and HYT data (Fig. 1A, 1B). Similarly, no statistically significant differences were found in the mean Ct-values of asymptomatic (UeS: 24.3; HYT: 25.4) vs. symptomatic (UeS: 22.7) samples, overall or stratified by vaccine status (Fig. 1B). Similar Ct-values were also found among different age groups, between genders, and vaccine types (Supplemental Figure 1).

In all groups, there were individuals with low Ct-values indicative of high viral loads. A total of 69 fully vaccinated individuals had Ct-values <20. Of these, 24 were asymptomatic at the time of testing.

Discussion

In our study, mean viral loads as measured by Ct-value were similar for large numbers of asymptomatic and symptomatic individuals infected with SARS-Cov-2 during the Delta surge, regardless of vaccine status, age, or gender. This contrasts with a large ongoing UK community cohort in which the median Ct-value was higher for vaccinated individuals (27.6) than for unvaccinated individuals (23.1) [5]. Also, a study from San Francisco reported that 10 fully vaccinated asymptomatic individuals had significantly lower viral loads than 28 symptomatic, vaccinated individuals [6]. Our study is consistent with other recent reports showing similar viral loads among vaccinated and unvaccinated individuals in settings with transmission of the Delta variant. In a Wisconsin study, Ct-values were similar and culture positivity was not different in a subset of analyses between 11 vaccinated and 24 unvaccinated cases [4]. In both Massachusetts and Singapore, individuals with vaccination breakthroughs caused by the Delta variant had similar Ct-values as unvaccinated individuals [3, 10]. Our findings are supported by consistency across large sample sets using different assays from two distinct locations.

A substantial proportion of asymptomatic, fully vaccinated individuals in our study had low Ct-values, indicative of high viral loads. Given that low Ct-values are indicative of high levels of virus, culture positivity, and increased transmission [11], our detection of low Ct-values in asymptomatic, fully vaccinated individuals is consistent with the potential for transmission from breakthrough infections prior to any emergence of symptoms. Interestingly, the viral loads decreased more rapidly in vaccinated than unvaccinated individuals in Singapore [3], suggesting that vaccinated individuals may remain infectious for shorter periods of time.

Over 20% of positive, vaccinated individuals had low Ct-values (<20), a third of which were asymptomatic when tested. This highlights the need for additional studies of the immunological status of such vaccine escapes and how infectious they are. If such individuals

carry high loads of active virus, asymptomatic vaccinated individuals may increasingly contribute to the ongoing pandemic as the proportion of vaccinated individuals grows.

Ct-values in some children under 12 who are not yet eligible for vaccination were also low. Twenty out of 109 (18.3%) children under 12 years of age had Ct-values <20, of which 14 were asymptomatic at the time of testing. Low Ct indicates that the children had high viral loads and were likely infectious. This emphasizes the value of regular, rapid testing for school children to detect infection early and block chains of transmission in settings where the Delta variant is circulating.

The data gathered in this study during the surge of the Delta variant strongly support the notion that neither vaccine status nor the presence or absence of symptoms should influence the recommendation and implementation of good public health practices, including mask wearing, testing, social distancing, and other measures designed to mitigate the spread of SARS-CoV-2.

Author Contribution Statement:

JD, RWM, DH, and MP conceived the project. DC, CM, SR, DH, and GP helped collect the data. CA, AM, CYW, and JL helped perform the tests, genotyping, and sequencing. CA, JH, LS, JD, AM, CYW, JS, and JL prepared the data for publication. RM, EG, DH, MP, DC, JS, and JD contributed to the writing of the manuscript. All authors read and approved the final manuscript.

Funding: This work was supported by the Chan Zuckerberg Biohub, Healthy Yolo Together, the University of California, San Francisco, the Chan Zuckerberg Initiative, and The University of California, Davis.

Acknowledgements: Many people were responsible for collecting the samples, running the tests, performing the genotyping and sequencing, and processing the data as listed in Supplementary Table 2.

Conflict of Interest: Dr. DeRisi reports being a scientific advisor to the Public Health Co. and a scientific advisor to Allen & Co. Dr. Havlir reports non-financial support from Abbott outside of the submitted work. The other authors declare no competing interests.

References

1. Abu-Raddad LJ, Chemaitelly H, Butt AA, National Study Group for C-V. Effectiveness of the BNT162b2 Covid-19 Vaccine against the B.1.1.7 and B.1.351 Variants. *N Engl J Med* 2021; 385: 187-9. DOI: 10.1056/NEJMc2104974.
2. Pouwels KB, Pritchard E, Matthews PC, et al. Impact of Delta on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK. Pre-print 2021 https://www.medrxiv.org/content/10.1101/2021.08.18.21262237v1
3. Chia PY, Ong SWX, Chiew CJ, et al. Virological and serological kinetics of SARS-CoV-2 Delta variant vaccine-breakthrough infections: a multi-center cohort study. Pre-print 2021. https://www.medrxiv.org/content/10.1101/2021.07.28.21261295v1
4. Riemersma KK, Grogan BE, Kita-Yarbro A, et al. Shedding of Infectious SARS-CoV-2 Despite Vaccination. Pre-Print 2021. https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v4
5. Elliott P, Haw D, Wang H, et al. REACT-1 round 13 final report: exponential growth, high prevalence of SARS-CoV-2 and vaccine effectiveness associated with Delta variant in England during May to July 2021. Pre-print 2021. https://spiral.imperial.ac.uk/bitstream/10044/1/90800/2/react1_r13_final_preprint_final.pdf
6. Servellita V, Morris MK, Sotomayor-Gonzalez A, et al. Predominance of antibody-resistant SARS-CoV-2 variants in vaccine breakthrough cases from the San Francisco Bay Area, California. Pre-print 2021. https://www.medrxiv.org/content/10.1101/2021.08.19.21262139v1

7. Pilarowski G, Lebel P, Sunshine S, et al. Performance Characteristics of a Rapid Severe Acute Respiratory Syndrome Coronavirus 2 Antigen Detection Assay at a Public Plaza Testing Site in San Francisco. *J Infect Dis* 2021; 223(7): 1139-1144. DOI: 10.1093/infdis/jiaa802.

8. Crawford E, Acosta I, Ahyong V, et al. Rapid deployment of SARS-CoV-2 testing: The CLIAHUB. *PLoS Pathog* 2020 16(10):e1008966. doi: 10.1371/journal.ppat.1008966.

9. Peng J, Liu J, Mann SA, et al. Estimation of secondary household attack rates for emergent spike L452R SARS-CoV-2 variants detected by genomic surveillance at a community-based testing site in San Francisco. *Clin Infect Dis* 2021; ciab283. DOI: 10.1093/cid/ciab283.

10. Brown CM, Vostok J, Johnson H, et al. Outbreak of SARS-CoV-2 infections, including COVID-19 vaccine breakthrough infections, associated with large public gatherings-Barnstable County, Massachusetts, July 2021. MMWR Morb Mortal Wkly Rep 2021; 70: 1059-1062. DOI: http://dx.doi.org/10.15585/mmwr.mm7031e2

11. Jefferson T, Spencer EA, Brassey J, Heneghan C. Viral cultures for COVID-19 infectious potential assessment – a systematic review. *Clin Infect Dis* 2020; ciaa1764. DOI: 10.1093/cid/ciaa1764

Figures

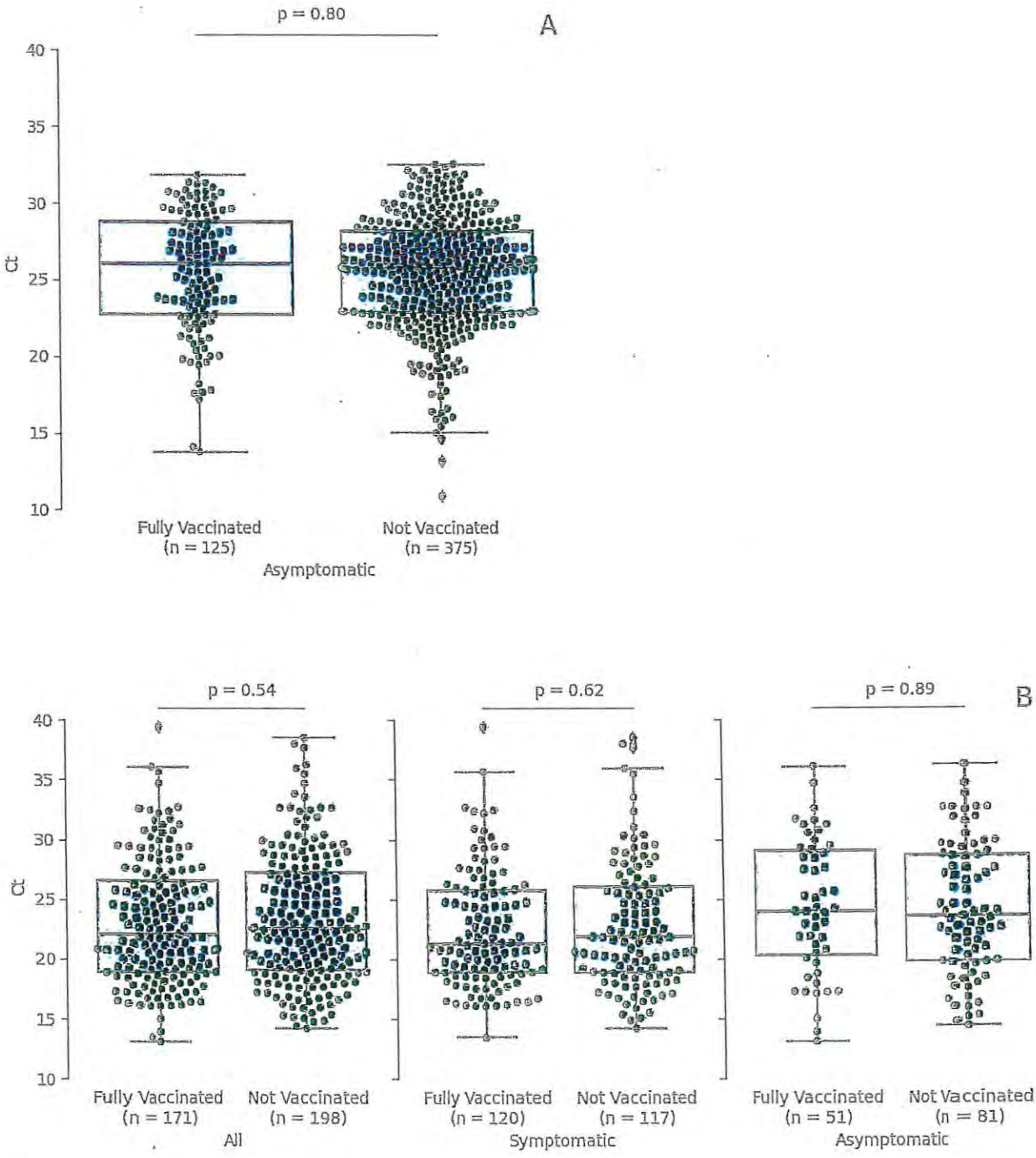

Figure 1. SARS-CoV-2 cycle threshold values in asymptomatic, symptomatic, vaccinated, and unvaccinated individuals in California. SARS-CoV-2 reverse transcription-polymerase chain reaction cycle threshold values for specimens from patients by vaccine status from Healthy

Yolo Together (City of Davis and Yolo County, California) (Panel A) and from specimens by vaccine and symptom status from Unidos en Salud (Mission District, San Francisco, California) (Panel B). Box plots show first quartile, median, and third quartiles in shaded region; diamonds indicate outliers beyond 1.5 times the interquartile range; p-values were calculated with two-sided t-tests.

Coronavirus disease (COVID-19)

Testing for COVID-19 in vaccinated populations

THIS IS EXHIBIT "E" REFERRED TO IN THE AFFIDAVIT OF
Dr Eric Payne
SWORN BEFORE ME THIS 25
DAY OF October, 2021

~~A Notary Public~~, A Commissioner for Oaths in and for the Province of Alberta

JEFFREY R.W. RATH
Barrister & Solicitor
My Commission Expires at the pleasure of the Attorney General

Current state of COVID-19 testing

Role of government

The government plays an important role in the health and well-being of Canadians. Health care in Canada is an area of shared responsibility between federal and provincial/territorial governments. The provinces and territories are mainly responsible for health care delivery. The federal government plays a role in a number of areas, including:

- safeguarding the Canada Health Act
- coordinating responses to national emergencies
- managing health care delivery for certain populations
- providing financial support and expertise to provinces and territories
- publishing ethical and technical guidance on COVID-19 for various audiences
- regulating market access in Canada for drugs, medical devices and controlled substances
- communicating health information to people in Canada in a timely, accurate and accessible fashion

COVID-19 trends and vaccination

Rates of COVID-19 in Canada have been declining since the middle of April 2021 and rates of vaccination are increasing. As of July 30, 2021, over 80% of eligible Canadians have received at least 1 vaccine dose and 56% have been fully vaccinated.

As vaccination rates increase, the rate of transmission and incidence of COVID-19, as well as severe outcomes among infected vaccinated people, may decrease. (See *eLife* and Bailly and others.)

Nevertheless, COVID-19 infections and severe disease continue to occur mainly among unvaccinated people, including those who may face health, social and economic barriers. In June 2021, Yukon saw widespread community transmission for the first time, when about 75% of Yukon adults were fully vaccinated. However, 85% of the cases were in people who were not vaccinated.

Israel and the United Kingdom may also provide insight on expected COVID-19 trends in a vaccinated population. The number of cases rose in June in both countries despite high rates of vaccination and the presence of new variants. However, the number of hospitalizations remained relatively low compared to active cases, especially compared with trends earlier in the pandemic. This demonstrates the ability of vaccination to improve outcomes in vaccinated people (for example, reduce hospitalizations and deaths) even if they do become infected.

In response to the changing landscape, the Public Health Agency of Canada released guidance on June 25. This guidance outlines measures that need to be taken by vaccinated adults.

Some research indicates that vaccinated people who test positive for COVID-19 and do not carry the Delta variant are likely to have low viral loads (Teran and others, Bailly and others), particularly when symptoms are mild or the person is asymptomatic. There is also evidence that vaccination can greatly reduce rates of SARS-CoV-2 infections with high viral shedding and symptoms.

Emerging evidence for the Delta variant points to the possibility of high viral loads in some breakthrough cases in fully vaccinated people, which can be as high as in unvaccinated people. Preliminary data from the United States Centres for Disease Control and Prevention (U.S. CDC) and from Public Health England indicate that levels of virus in fully vaccinated people who become infected with Delta may be similar to levels found in unvaccinated people, and therefore they may be as likely to transmit the virus. Based on this evidence, U.S. CDC revised its masking guidance for vaccinated individuals on July 27 to recommend indoor masking in areas of high or substantial transmission. However, further studies are needed to confirm these levels of infectiousness and also the extent of vaccine effectiveness against Delta, which at present appears to be only slightly less than for other variants, such as Alpha. These new studies highlight the importance of monitoring and responding to the ever-evolving science.

No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups Infected with SARS-CoV-2 Delta Variant

Charlotte B. Acharya[1], John Schrom[2], Anthea M. Mitchell[3], David A. Coil[1], Carina Marquez[2, 4], Susana Rojas[2], Chung Yu Wang[3], Jamin Liu[5], Genay Pilarowski[2, 6], Leslie Solis[1], Elizabeth Georgian[1], Maya Petersen[2, 7], Joseph DeRisi[3], Richard Michelmore[1], Diane Havlir[2, 4]

[1]Genome Center, University of California, Davis, USA

[2]Unidos en Salud, San Francisco, CA, USA

[3]Chan Zuckerberg Biohub, and Dept of Biochemistry & Biophysics, University of California, San Francisco, USA

[4]Department of Medicine, Division of HIV, Infectious Disease and Global Medicine, University of California, San Francisco, USA

[5]Joint UCB/UCSF Bioengineering Program, University of California, Berkeley and University of California, San Francisco, USA

[6]The Public Health Company, Oakland, California, USA

[7]School of Public Health, University of California, Berkeley, USA

Joint Authors for Correspondence: Diane Havlir, Richard Michelmore

Abstract: We found no significant difference in cycle threshold values between vaccinated and unvaccinated, asymptomatic and symptomatic groups infected with SARS-CoV-2 Delta. Given the substantial proportion of asymptomatic vaccine breakthrough cases with high viral levels, interventions, including masking and testing, should be considered for all in settings with elevated COVID-19 transmission.

Background

Vaccines reduce infection, severe disease, and death from SARS-CoV-2 (COVID-19) [1], yet breakthrough cases occur [2]. Several reports show no difference in cycle threshold values (Ct-values) between vaccinated and unvaccinated individuals [2, 3, 4]; however, others have suggested that breakthrough infections, particularly among asymptomatic individuals, have a lower viral load and therefore may be less likely to result in transmission [5, 6].

Effective epidemic control requires contemporary data to guide public health mitigation measures. Here, we report on Ct-values among fully vaccinated and unvaccinated individuals, asymptomatic and symptomatic at time of testing, during a period of high transmission of the Delta variant in two distinct populations: a Unidos en Salud (UeS) community-based site in the Mission District of San Francisco and Healthy Yolo Together (HYT) asymptomatic testing through the University of California (UC), Davis.

Materials and Methods

Study Populations

Data was collected on individuals who voluntarily sought testing for SARS-CoV-2 from two demographically distinct populations in California during a two-month period from June 17 to August 31, 2021, during which Delta was the predominant variant.

HYT: As part of the response to the COVID-19 pandemic, UC Davis deployed an extensive free asymptomatic testing program that included the City of Davis and Yolo County (Healthy Yolo Together). Asymptomatic individuals over the age of 2 were eligible for testing. Asymptomatic cases were classified as individuals not reporting symptoms at the time of testing. Samples were collected through a supervised method in which individuals transferred their saliva into a barcoded tube (COVID-19 Testing | Campus Ready). Smaller numbers of symptomatic

individuals were processed using a different workflow and an antigen test; therefore, they were not included in this study.

UeS: The study population included individuals who sought SARS-CoV-2 testing at the UeS walk-up site, an ongoing academic (UC San Francisco, CZ Biohub, and UC Berkeley), community organization (Latino Task Force), and government (SFDPH) partnership. The outdoor, free BinaxNOW™ testing site was located at a public transport and commercial hub in the Mission District, a setting of ongoing transmission in San Francisco [7]. Individuals one year of age and older, with or without symptoms, were eligible for testing.

Measurements

Infections were classified as breakthrough infections if the individual was fully vaccinated (two weeks following receipt of all vaccine doses). Individuals that had had only one dose or were tested within two weeks of the second dose, in the case of Pfizer and Moderna vaccines, were not included in the analysis.

HYT: Demographic information was collected from individuals at the time of registration. Vaccination status information was obtained at the time of contact tracing and confirmed in the California Vaccine Registry. Only confirmed, fully vaccinated individuals were used in the analysis; discordant samples, self-reported as vaccinated but unconfirmed, were treated as status unknown. Saliva samples from asymptomatic individuals were tested for the presence of the N1 and N2 regions of the viral nucleocapsid (N) gene using primers and probes described in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel, using IntelliQube high-throughput quantitative PCR instruments (LGC Biosearch Technologies). Ct-values were calculated with FastFinder software (UgenTec | FastFinder).

Genotypes of all N1/N2 positive samples were determined using RT-PCR SNP analysis at 11 loci diagnostic for variants of concern (SARS-CoV-2 Variant ValuPanel assays | LGC Biosearch Technologies). A subset of samples (39%) were also sequenced using the Illumina MiSeq sequencing platform. Consensus genomes were generated with Viralrecon2 and variants called in Pangolin version 3.1.11 and PLEARN-v1.2.66. Sequencing confirmed the variants called by genotyping.

UeS: Individuals provided demographic data and information on symptoms immediately prior to testing using BinaxNOW™ kits. COVID-19 vaccine status, including date of final shot, was obtained through the California Vaccine Registry. Anterior-nasal swab samples (iClean, Chenyang Global) collected by certified lab assistants from BinaxNOW positive individuals were placed in DNA/RNA Shield (Zymo, Inc.) and processed for qRT-PCR, genome recovery, and variant/lineage determination as previously described [8, 9]. Ct-values for the detection of N and E genes [8] were determined via the single threshold Cq-determination mode using Bio-Rad CFX Maestro v4.1 (Bio-Rad Inc). SARS-CoV-2 genomes were sequenced using the Illumina NovaSeq platform. Consensus genomes were generated via the COVID module of the IDseq pipeline (https://idseq.net) as described [9].

Analysis

Ct-values were plotted, stratified by site; fully vs. not vaccinated; and symptom status. Partially vaccinated samples and stratification by age and vaccine type are reported in supplementary materials. Ct-values between strata were compared using a two sided t-test.

Ethics Statement

HYT: The Genome Center laboratory that conducted COVID-19 testing was CLIA approved as an extension to the Student Health Center's laboratory. The UC Davis IRB

Administration determined that the study met criteria for public health reporting and was exempt from IRB review and approval.

UeS: The UC San Francisco Committee on Human Research determined the study met criteria for public health surveillance. All participants provided informed consent for testing.

Results

A total of 869 samples, 500 from HYT and 369 from UeS, were included in the analysis. All analyzed samples from HYT were asymptomatic at the time of collection and 75% of the positive samples were from unvaccinated individuals (N=375). Positive samples from UeS were from both symptomatic (N=237) and asymptomatic individuals (N=132). The frequency of vaccine breakthroughs among the UeS samples (171 fully vaccinated, 198 unvaccinated) was greater than among the HYT samples reflecting the different types of populations sampled. The Delta variant was the predominant variant detected in both populations (Supplementary Table 1).

There were no statistically significant differences in mean Ct-values of vaccinated (UeS: 23.1; HYT: 25.5) vs. unvaccinated (UeS: 23.4; HYT: 25.4) samples. In both vaccinated and unvaccinated, there was great variation among individuals, with Ct-values of <15 to >30 in both UeS and HYT data (Fig. 1A, 1B). Similarly, no statistically significant differences were found in the mean Ct-values of asymptomatic (UeS: 24.3; HYT: 25.4) vs. symptomatic (UeS: 22.7) samples, overall or stratified by vaccine status (Fig. 1B). Similar Ct-values were also found among different age groups, between genders, and vaccine types (Supplemental Figure 1).

In all groups, there were individuals with low Ct-values indicative of high viral loads. A total of 69 fully vaccinated individuals had Ct-values <20. Of these, 24 were asymptomatic at the time of testing.

Discussion

In our study, mean viral loads as measured by Ct-value were similar for large numbers of asymptomatic and symptomatic individuals infected with SARS-Cov-2 during the Delta surge, regardless of vaccine status, age, or gender. This contrasts with a large ongoing UK community cohort in which the median Ct-value was higher for vaccinated individuals (27.6) than for unvaccinated individuals (23.1) [5]. Also, a study from San Francisco reported that 10 fully vaccinated asymptomatic individuals had significantly lower viral loads than 28 symptomatic, vaccinated individuals [6]. Our study is consistent with other recent reports showing similar viral loads among vaccinated and unvaccinated individuals in settings with transmission of the Delta variant. In a Wisconsin study, Ct-values were similar and culture positivity was not different in a subset of analyses between 11 vaccinated and 24 unvaccinated cases [4]. In both Massachusetts and Singapore, individuals with vaccination breakthroughs caused by the Delta variant had similar Ct-values as unvaccinated individuals [3, 10]. Our findings are supported by consistency across large sample sets using different assays from two distinct locations.

A substantial proportion of asymptomatic, fully vaccinated individuals in our study had low Ct-values, indicative of high viral loads. Given that low Ct-values are indicative of high levels of virus, culture positivity, and increased transmission [11], our detection of low Ct-values in asymptomatic, fully vaccinated individuals is consistent with the potential for transmission from breakthrough infections prior to any emergence of symptoms. Interestingly, the viral loads decreased more rapidly in vaccinated than unvaccinated individuals in Singapore [3], suggesting that vaccinated individuals may remain infectious for shorter periods of time.

Over 20% of positive, vaccinated individuals had low Ct-values (<20), a third of which were asymptomatic when tested. This highlights the need for additional studies of the immunological status of such vaccine escapes and how infectious they are. If such individuals

carry high loads of active virus, asymptomatic vaccinated individuals may increasingly contribute to the ongoing pandemic as the proportion of vaccinated individuals grows.

Ct-values in some children under 12 who are not yet eligible for vaccination were also low. Twenty out of 109 (18.3%) children under 12 years of age had Ct-values <20, of which 14 were asymptomatic at the time of testing. Low Ct indicates that the children had high viral loads and were likely infectious. This emphasizes the value of regular, rapid testing for school children to detect infection early and block chains of transmission in settings where the Delta variant is circulating.

The data gathered in this study during the surge of the Delta variant strongly support the notion that neither vaccine status nor the presence or absence of symptoms should influence the recommendation and implementation of good public health practices, including mask wearing, testing, social distancing, and other measures designed to mitigate the spread of SARS-CoV-2.

Author Contribution Statement:

JD, RWM, DH, and MP conceived the project. DC, CM, SR, DH, and GP helped collect the data. CA, AM, CYW, and JL helped perform the tests, genotyping, and sequencing. CA, JH, LS, JD, AM, CYW, JS, and JL prepared the data for publication. RM, EG, DH, MP, DC, JS, and JD contributed to the writing of the manuscript. All authors read and approved the final manuscript.

Funding: This work was supported by the Chan Zuckerberg Biohub, Healthy Yolo Together, the University of California, San Francisco, the Chan Zuckerberg Initiative, and The University of California, Davis.

Acknowledgements: Many people were responsible for collecting the samples, running the tests, performing the genotyping and sequencing, and processing the data as listed in Supplementary Table 2.

Conflict of Interest: Dr. DeRisi reports being a scientific advisor to the Public Health Co. and a scientific advisor to Allen & Co. Dr. Havlir reports non-financial support from Abbott outside of the submitted work. The other authors declare no competing interests.

References

1. Abu-Raddad LJ, Chemaitelly H, Butt AA, National Study Group for C-V. Effectiveness of the BNT162b2 Covid-19 Vaccine against the B.1.1.7 and B.1.351 Variants. *N Engl J Med* 2021; 385: 187-9. DOI: 10.1056/NEJMc2104974.
2. Pouwels KB, Pritchard E, Matthews PC, et al. Impact of Delta on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK. Pre-print 2021 https://www.medrxiv.org/content/10.1101/2021.08.18.21262237v1
3. Chia PY, Ong SWX, Chiew CJ, et al. Virological and serological kinetics of SARS-CoV-2 Delta variant vaccine-breakthrough infections: a multi-center cohort study. Pre-print 2021. https://www.medrxiv.org/content/10.1101/2021.07.28.21261295v1
4. Riemersma KK, Grogan BE, Kita-Yarbro A, et al. Shedding of Infectious SARS-CoV-2 Despite Vaccination. Pre-Print 2021. https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v4
5. Elliott P, Haw D, Wang H, et al. REACT-1 round 13 final report: exponential growth, high prevalence of SARS-CoV-2 and vaccine effectiveness associated with Delta variant in England during May to July 2021. Pre-print 2021. https://spiral.imperial.ac.uk/bitstream/10044/1/90800/2/react1_r13_final_preprint_final.pdf
6. Servellita V, Morris MK, Sotomayor-Gonzalez A, et al. Predominance of antibody-resistant SARS-CoV-2 variants in vaccine breakthrough cases from the San Francisco Bay Area, California. Pre-print 2021. https://www.medrxiv.org/content/10.1101/2021.08.19.21262139v1

7. Pilarowski G, Lebel P, Sunshine S, et al. Performance Characteristics of a Rapid Severe Acute Respiratory Syndrome Coronavirus 2 Antigen Detection Assay at a Public Plaza Testing Site in San Francisco. *J Infect Dis* 2021; 223(7): 1139-1144. DOI: 10.1093/infdis/jiaa802.

8. Crawford E, Acosta I, Ahyong V, et al. Rapid deployment of SARS-CoV-2 testing: The CLIAHUB. *PLoS Pathog* 2020 16(10):e1008966. doi: 10.1371/journal.ppat.1008966.

9. Peng J, Liu J, Mann SA, et al. Estimation of secondary household attack rates for emergent spike L452R SARS-CoV-2 variants detected by genomic surveillance at a community-based testing site in San Francisco. *Clin Infect Dis* 2021; ciab283. DOI: 10.1093/cid/ciab283.

10. Brown CM, Vostok J, Johnson H, et al. Outbreak of SARS-CoV-2 infections, including COVID-19 vaccine breakthrough infections, associated with large public gatherings-Barnstable County, Massachusetts, July 2021. MMWR Morb Mortal Wkly Rep 2021; 70: 1059-1062. DOI: http://dx.doi.org/10.15585/mmwr.mm7031e2

11. Jefferson T, Spencer EA, Brassey J, Heneghan C. Viral cultures for COVID-19 infectious potential assessment – a systematic review. *Clin Infect Dis* 2020; ciaa1764. DOI: 10.1093/cid/ciaa1764

Figures

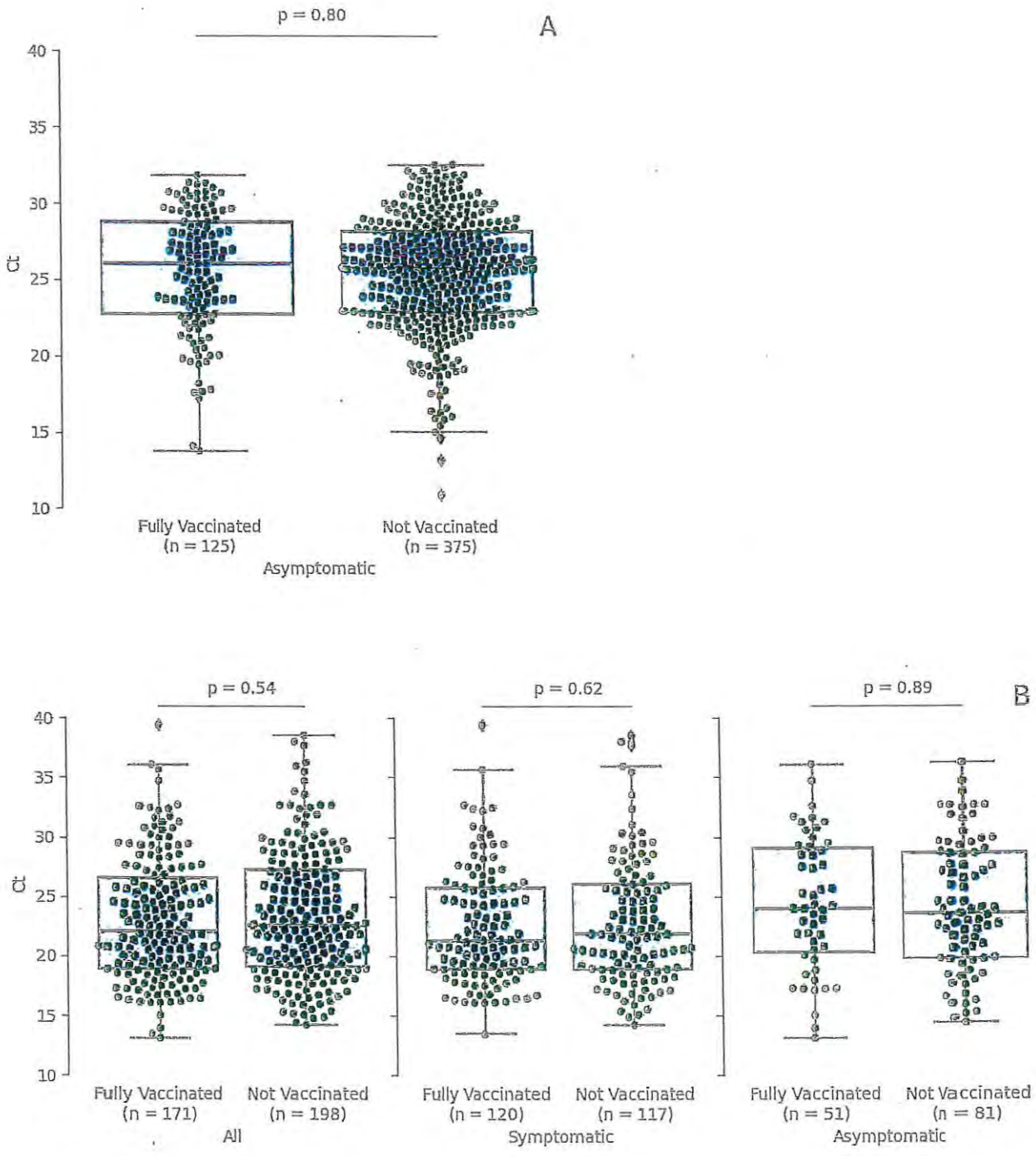

Figure 1. SARS-CoV-2 cycle threshold values in asymptomatic, symptomatic, vaccinated, and unvaccinated individuals in California. SARS-CoV-2 reverse transcription-polymerase chain reaction cycle threshold values for specimens from patients by vaccine status from Healthy

Yolo Together (City of Davis and Yolo County, California) (Panel A) and from specimens by vaccine and symptom status from Unidos en Salud (Mission District, San Francisco, California) (Panel B). Box plots show first quartile, median, and third quartiles in shaded region; diamonds indicate outliers beyond 1.5 times the interquartile range; p-values were calculated with two-sided t-tests.