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9
10 IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
11 OAKLAND DIVISION

13 **MARCIANO PLATA, et al.,**

14 Plaintiffs,

15 v.

17 **GAVIN NEWSOM, et al.,**

18 Defendants.

Case No. 4:01-cv-01351-JST

**DEFENDANTS’ REPLY IN SUPPORT
OF MOTION TO STAY SEPTEMBER
27, 2021 ORDER RE: MANDATORY
VACCINATIONS (ECF NO. 3684)
PENDING APPEAL, AND ORDERS
ISSUED IN FURTHERANCE OF
SEPTEMBER 27 ORDER**

**Date: November 17, 2021
Time: 2:00 p.m.
Dept: 6, 2nd Floor
Judge: The Honorable Jon S. Tigar
Action Filed: 4/5/2001**

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INTRODUCTION

Defendants have consistently argued that while they agreed with the Receiver’s public health findings regarding COVID-19, Defendants were clear that they “do not agree with the conclusions the Receiver drew from these findings, namely, that the ‘only method to ensure adequate protection and care for incarcerated persons is’ to vaccinate all prison staff.” ECF No. 3717, Joint CMC Stmt., Oct. 26, 2021, at 5:9-14, *quoting* ECF No. 3660 at 19:23-20:2. Indeed, recent public health studies and CDC guidance directly refute Plaintiffs’ and the Receiver’s conclusion that vaccinating staff is the best means of protecting incarcerated persons.

And yet, in their oppositions, Plaintiffs and the Receiver continue to repeat the falsehood that “Defendants [] do not dispute that no other measure [other than mandating staff vaccination] would be as effective at protecting both vaccinated and unvaccinated incarcerated people.” Pls.’ Opp’n to Defs.’ and CCPOA’s Mots. to Stay (“Pls.’ Opp’n”) at 5:5-6; *see also* Receiver’s Opp’n to Defs.’ and CCPOA’s Mots. to Stay (“Receiver’s Opp’n”) at 5:18. This distortion of Defendants’ position serves as the foundation for Plaintiffs’ and the Receiver’s assertions that Defendants will not succeed on the merits of their appeal, and that Defendants’ claims of irreparable harm are somehow “speculative.” But Plaintiffs’ and the Receiver’s misstatements as to Defendants’ position do not overcome Defendants’ showing that they are entitled to a stay.

Further, Plaintiffs and the Receiver fail to effectively refute Defendants’ showing of likelihood of success, where the Court applied an incorrect standard and overlooked the strict mandates of the Prison Litigation Reform Act. The Ninth Circuit’s recent decision in *Frailhat* is instructive here, notwithstanding Plaintiffs’ and the Receiver’s efforts to distinguish this on-point decision. Moreover, Plaintiffs’ and the Receiver’s efforts to diminish the harms Defendants would suffer in the absence of a stay are unpersuasive in light of Defendants’ ample evidence to the contrary. This Court should therefore grant a stay to preserve the status quo.

ARGUMENT

I. DEFENDANTS ARE LIKELY TO SUCCEED ON THE MERITS OF THEIR APPEAL.

Defendants have been strong, vocal proponents of vaccinations in the largest possible numbers in prisons since COVID-19 vaccines first became available nearly a year ago. That is

1 why Defendants implemented numerous measures to make COVID-19 vaccines widely available
 2 to CDCR's incarcerated population and staff, and encouraged voluntary acceptance of
 3 vaccinations. *See, e.g.*, ECF No. 3660 at 22-23, 25. Defendants have also long recognized the
 4 risks COVID-19 poses to those who live and work in CDCR's institutions, *id.* at 9, regardless of
 5 vaccination status, and that risk has prompted Defendants to implement comprehensive and
 6 continuously evolving public-health safety measures, *see, e.g., id.* at 12-17.

7 Based on these facts, a court that correctly applies the Eighth Amendment and the PLRA's
 8 needs-narrowness-intrusiveness standard—and fully considers Defendants' efforts in its
 9 analysis—can only reach one conclusion: this Court lacked the authority under the PLRA to order
 10 the vaccine mandates set forth in its September 27 and October 27, 2021 orders. Accordingly,
 11 Defendants are likely to succeed on the merits of their appeal.

12 **A. *Fraihat* is Instructive Here.**

13 The question is not whether this Court applied the same standard the Ninth Circuit did in
 14 *Fraihat*, as the Receiver asserts, but whether the Court properly analyzed the facts and drew the
 15 correct conclusions under the correct standard. Receiver's Opp'n at 15; *see also* ECF No. 3715-1
 16 at 5. The Eighth Amendment standard elaborated by *Fraihat* and *Farmer v. Brennan* demands
 17 *reasonableness*, not the exhaustion of every possible measure as the Receiver argues is
 18 appropriate. *Farmer*, 511 U.S. 825, 844 (1994); *Fraihat v. U.S. Immigration and Customs*
 19 *Enforcement*, 20-55634, 2021 WL 4890884, at *19 (9th Cir. Oct. 20, 2021).

20 Plaintiffs' opposition did not provide an Eighth Amendment analysis, and instead attempted
 21 to distinguish the Ninth Circuit's recent decision in *Fraihat* by referencing the specific factual
 22 circumstances there (pre-vaccine), but ignored the opinion's robust discussion of how the Eighth
 23 Amendment deliberate indifference standard must be applied. Pls.' Opp'n at 17. Plaintiffs'
 24 absurd rationale for distinguishing *Fraihat*—that it concerned a pre-vaccine period during the
 25 pandemic—would require the rejection of their own reliance on *Helling v. McKinney*, 509 U.S.
 26 25 (1993), a seminal case concerning an incarcerated person's exposure to cigarette smoke,
 27 because that case predated the COVID-19 pandemic and also “dealt with a pre-vaccine world.”
 28 Pls.' Opp'n at 17, 21.

1 In ordering a vaccine mandate, the Court found that Defendants' existing policy could have
 2 gone further. But as *Frailhat* explained, the fact that a court might believe a policy could be
 3 stronger does not convert a party's conduct to deliberate indifference. *Frailhat*, 20-55634, 2021
 4 WL 4890884 at *24. Thus, *Frailhat* is squarely on point.

5 **B. Defendants Have Reasonably Abated the Risk of Harm Due to COVID.**

6 The Eighth Amendment requires prison officials to *reasonably* abate a risk of harm, not to
 7 completely eliminate it, and Defendants have more than satisfied this reasonableness requirement.
 8 *Farmer*, 511 U.S. at 844. At the time of the hearing on the order to show cause, 79 percent of
 9 CDCR's incarcerated population of approximately 99,000 was fully vaccinated against COVID-
 10 19, 253 out of approximately 99,000 incarcerated people had COVID-19 infections, two were
 11 hospitalized for COVID-19-related reasons, and the total number of deaths resulting from a
 12 COVID-19 infection contracted after full vaccination was one out of approximately 78,000
 13 vaccinated incarcerated people. Tr. 20:7, 24:18-25:12, Sept. 24, 2021.

14 CDCR's COVID-19 tracker—a recent image of which Plaintiffs submitted into evidence—
 15 shows that COVID-19 case numbers have remained relatively low since March 2021. Decl.
 16 Bixby, ECF No. 3739-1 at 17. Compared to the spike in cases that existed in December 2020 and
 17 January 2021, the success of the State's efforts is undeniable.

18 **C. The Receiver's Legal Analysis Falls Short.**

19 As discussed above and in Defendants' stay motion, their responses to the order to show
 20 cause regarding mandatory vaccinations, and dozens of filings submitted to this Court during the
 21 COVID-19 pandemic, Defendants have implemented and continue to implement extensive
 22 public-health-based COVID-19 mitigation measures. *See, e.g.*, ECF No. 3660. These measures,
 23 many of which were initiated by the Receiver, are reasonable, consistent with current public
 24 health guidance, and continue to evolve with the science.

25 The Receiver attempts to equate Defendants' COVID-19 response with the facts in *Jones v.*
 26 *City & Cty. of San Francisco*, 976 F.Supp. 896 (N.D. Cal. 1997), a 24-year-old district court case
 27 in which jail officials violated the Eighth Amendment by failing to abate the risk of fire hazards,
 28 including by failing to install fire-rated doors and sprinklers. Receiver's Opp'n at 9-10. But the

1 present situation is easily distinguishable from *Jones*. Here, unlike in *Jones*, Defendants
 2 implemented a host of reasonable, evidence-based measures, including mass vaccinations, with
 3 success. Nearly 80 percent of incarcerated people and 65 percent of staff are vaccinated as a
 4 result of measures and CDCR's incarcerated population is experiencing very low infection,
 5 hospitalization, and mortality numbers.

6 The question of whether a water sprinkler should be installed to abate the risk of a fire is
 7 different and considerably less complex than deciding whether to require vaccinations of tens of
 8 thousands of employees as part of a multilayered public health initiative during a novel, global
 9 pandemic. This is particularly true when the evidence shows that new and existing measures,
 10 including a mass vaccination program, and the emerging availability of treatment options,
 11 including monoclonal antibodies and oral medication that reduces the risk of severe symptoms of
 12 COVID-19 among vulnerable populations by nearly 90%, are succeeding. *See* ECF No. 3660 at
 13 22-23 (listing recent mitigation measures); Robbins, Rebecca, "*Pfizer Says Its Antiviral Pill Is*
 14 *Highly Effective in Treating Covid*," Nov. 5, 2021,
 15 <https://www.nytimes.com/2021/11/05/health/pfizer-covid-pill.html>. Accordingly, *Jones* is not
 16 instructive.

17 Next, in response to Defendants' argument that the Court improperly disregarded relevant
 18 cases cited in their briefing, the Receiver contends the Court properly deemed one case—*Zatko v.*
 19 *Rowland*, 835 F.Supp. 1174 (N.D. Cal. 1993) (finding prison officials do not violate the Eighth
 20 Amendment when an incarcerated person refuses medical treatment)—irrelevant because
 21 "Defendants fail to consider that it is not only the unvaccinated population that is at substantial
 22 risk of serious harm from COVID-19, and that such risk would be present even if the entire
 23 incarcerated population was vaccinated." Receiver's Opp'n, ECF No. 3738 at 15 citing ECF No.
 24 3684 at 9. But in rejecting *Zatko*, the Court omitted analysis of Defendants' efforts to abate the
 25 risk of harm to vaccinated incarcerated people, which have been successful and cannot amount to
 26 an Eighth Amendment violation—as *Zatko* instructs, Defendants are not deliberately indifferent
 27 as a result of 20,000 incarcerated people's voluntary rejection of the best available protection
 28 against COVID-19. And relieving incarcerated people of personal responsibility by adopting a

1 “zero-COVID” strategy, as discussed below, and overlooking the science to label mandatory staff
 2 vaccination policy as the most effective protective measure for incarcerated people do not lead to
 3 the Receiver’s conclusion of an Eighth Amendment violation. Plaintiffs make a similar argument
 4 to the Receiver’s, suggesting that only unvaccinated staff can carry and spread the virus, when the
 5 Receiver’s own data, and new science discussed below, conclude otherwise. ECF No. 3638 at 22
 6 (two doses of the Pfizer vaccine are between 64 and 88 percent effective against symptomatic
 7 disease, and 94 percent effective against serious illness).

8 Like the Court, the Receiver and Plaintiffs ignore the salient portion of *Davis v. Allison*,
 9 No. 1:21-cv-00494-HBK, 2021 WL 3761216 at *6 (E.D. Cal. Aug. 25, 2021), *report and*
 10 *recommendation adopted*, 2021 WL 4262400 (E.D. Cal. Sept. 20, 2021), a case that conducted an
 11 in-depth analysis of CDCR’s pandemic response and concluded that “[t]he protocols challenged
 12 by Plaintiff fall far short of denying him his basic human needs.” ECF No. 3715-1 at 17-18.

13 Lastly, neither the Receiver nor Plaintiffs address Defendants’ argument regarding the
 14 Court’s incorrect conclusion that *Pride v. Correa*, 719 F.3d 1130 (9th Cir. 2013) required the
 15 rejection of the relevant cases Defendants cited because they concerned individual plaintiff
 16 claims. These cases and the cases cited in Defendants’ stay motion and response to the order to
 17 show cause remain instructive, and support Defendants’ position that they are likely to succeed on
 18 the merits of their appeal.

19 **D. CDCR’s Position Here Does Not Contradict its Position in *Davis*.**

20 The Receiver asserts there is a contradiction between Defendants’ position in the present
 21 case and a declaration submitted in *Davis v. Cal. Dep’t. Pub. Health, et al.*, No. BCV-21-102318
 22 (Kern County Sup. Ct.), a state court case in which certain CDCR employees challenged the
 23 implementation of the August 19 public health order¹ requiring vaccinations of certain
 24 correctional staff. Receiver’s Opp’n at 1, 6, 10, 14, 23. But this case did not involve the question
 25 of whether Defendants’ COVID-19 safety measures predating the Court’s vaccine mandate

26 ¹ The Receiver conflates Defendants’ implementation of the CDPH’s August 19 public health
 27 order with a concession “that mandatory vaccination of workers is a reasonable measure[.]”
 28 (Receiver’s Opp’n at 14.) The plan was implemented in furtherance of an executive order and
 made no concessions regarding the fact that this Court lacks the authority under the PLRA to
 order mandatory vaccinations. (ECF No. 3657.)₅

1 satisfied their obligations to the incarcerated population under the Eighth Amendment, and Dr.
 2 Reingold does not opine—like the Receiver—that mandatory vaccinations of all staff are the
 3 single most effective way to reduce the risk of harm from COVID-19 to the incarcerated
 4 population, or that such a mandate is required under the Eighth Amendment. Decl. Kreilkamp,
 5 ECF No. 3738-1 at 15, ¶ 25; ECF No. 3638 at 5. And because that declaration supported a case
 6 addressing a different issue, it did not assess the efficacy of Defendants’ additional COVID-19
 7 safety measures or high vaccination rates among incarcerated people in CDCR’s institutions.

8 The Receiver touts this declaration as evidence of Defendants’ support of his public health
 9 findings, Receiver’s Opp’n at 14, but Defendants have not disagreed with the data cited in the
 10 Receiver’s policy at any stage of this litigation; rather, they disagree with the conclusions he drew
 11 from it. *See, e.g.*, Defs.’ Reply re: Order to Show Cause, ECF No. 3673 at 16. Finally, consistent
 12 with Defendants’ position, Dr. Reingold’s declaration highlights the dangers of remaining
 13 unvaccinated, explaining that “[a]s of July 31, 2021, ~97% of all hospitalizations for COVID-19
 14 in the U.S. are among unvaccinated individuals[,]” further supporting Defendants’ interpretation
 15 of the Receiver’s data and argument that incarcerated people will be safest if vaccinated
 16 themselves. Decl. Kreilkamp at 10, ¶ 15.

17 Accordingly, the Receiver’s conclusion that Dr. Reingold “fully agreed with the Receiver’s
 18 recommendation and this Court’s order” is inaccurate and drawn out of context.

19 **E. The Court’s Vaccine Mandate Does Not Satisfy the PLRA, and Plaintiffs**
 20 **and the Receiver Fail to Prove Otherwise.**

21 Plaintiffs and the Receiver fail to rebut Defendants’ showing that they are likely to succeed
 22 on their argument that the Court’s vaccine-mandate order did not satisfy the Prison Litigation
 23 Reform Act’s needs-narrowness-intrusiveness requirement. 18 U.S.C. § 3626(a)(1)(A).

24 First, a more narrowly tailored approach to reduce the risks associated with COVID-19 to
 25 class members would be to vaccinate all unvaccinated class members. The best way to protect
 26 individuals from the virus is to vaccinate *them*—not to vaccinate others. Neither Plaintiffs nor the
 27 Receiver refute this. Contrary to the Receiver’s assertion that “Defendants do not put forward
 28 evidence to show that vaccination of all incarcerated persons would correct the violation of the

1 Eighth Amendment[.]” Defendants’ evidence included public health science from the Centers for
 2 Disease Control and Prevention and the Receiver’s own policy.

3 The simple concept that the best way to protect people is to vaccinate them was again
 4 confirmed in a recent study in *The Lancet Infectious Diseases* medical journal entitled
 5 “Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in
 6 vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study”
 7 (“the Lancet Study”). RJN Exs. A & B. The yearlong study reached the following scientific
 8 conclusions concerning vaccination and the spread of the delta variant:

- 9 • People inoculated against COVID-19 are just as likely to spread the delta variant to
 10 contacts in their household as those who have not had a vaccination;
- 11 • The peak in viral load is similar regardless of vaccination status;
- 12 • Vaccination is not sufficient to prevent people from being infected with the delta variant
 13 and spreading it to others in household settings; and
- 14 • Direct protection of individuals via vaccination is key to protecting against serious
 15 illness and death. *Id.*

16 This study rejects Plaintiffs’ and the Receiver’s theory that vaccinating all staff will prevent
 17 COVID-19 from entering CDCR’s prisons. Zero-COVID strategies, like the one advocated by
 18 Plaintiffs and the Receiver, are being universally abandoned in favor of the notion that this virus
 19 will become endemic now that vaccines are widely available.² Consequently, the best way to
 20 protect class members is to vaccinate them so that when they are inevitably exposed to COVID-
 21 19, they are protected from serious illness. Thus, full class member vaccination is not only a
 22 more narrowly tailored measure, but also the most effective measure.

23 Approximately 20,000 class members remain unvaccinated and Plaintiffs’ have not refuted
 24 the fact that they would be safer if they themselves were vaccinated, or that vaccinating
 25 incarcerated people would be a more effective, narrowly tailored remedy to achieve the intended
 26 purpose of the Receiver’s policy. Pls.’ Opp’n. at 14. But such a policy has neither been
 27 submitted to the Court nor implemented, and no evidence in the record suggests that a similar

28 ² Ellyatt, Holly, ‘Zero Covid’ strategies are being abandoned as the highly infectious delta
 variant dominates, October 5, 2021, [https://www.cnbc.com/2021/10/05/zero-covid-strategies-
 abandoned-in-the-face-of-the-delta-variant.html](https://www.cnbc.com/2021/10/05/zero-covid-strategies-abandoned-in-the-face-of-the-delta-variant.html).⁷

1 policy has been implemented with those effects in the past. *See* ECF Nos. 3684 at 22:1-3, 3727 at
 2 15:21-16:3. Given that it would be a far more narrowly tailored and less intrusive method to
 3 reduce the risk of harm for class members, the court erred by not first mandating that the Receiver
 4 fully explore this option.

5 **II. PLAINTIFFS’ AND THE RECEIVER’S CHALLENGE TO DEFENDANTS’ CLAIMS OF**
 6 **IRREPARABLE HARM RING HOLLOW.**

7 Both Plaintiffs and the Receiver ask this Court to ignore Defendants’ claims of irreparable
 8 harm, arguing that Defendants’ claims are “speculative” in nature and that they should be ignored
 9 or discounted because they were not previously asserted in response to this Court’s Order to
 10 Show Cause or brought to this Court’s attention sooner. These arguments are repeated
 11 throughout both coordinated briefs, though neither filing is persuasive on these points.

12 **A. Defendants’ Claims of Irreparable Harm Are Supported by Ample**
 13 **Evidence.**

14 Plaintiffs and the Receiver claim that Defendants’ estimated noncompliance rates, which
 15 are drawn from actual data set forth in the declaration of CDCR’s Director of Adult Institutions,
 16 Connie Gipson, that neither Plaintiffs nor the Receiver have refuted, are “speculative.” Director
 17 Gipson explained in her declaration that rates of staff noncompliance at CHCF and CMF can
 18 serve as a barometer for staff compliance system-wide since an August 19 California Department
 19 of Public Health Order mandated that all staff at CHCF and CMF be vaccinated by October 14,
 20 2021. Director Gipson stated that as of October 25, 2021, 8.26 percent of CHCF correctional
 21 officers at CMF and 10.14 percent of correctional officers at CMF were neither vaccinated nor
 22 sought an exemption, and that noncompliance rates at those levels statewide “will cause a
 23 substantial increase in correctional-officer vacancies above current projections” with a
 24 “devastating [impact] to CDCR’s prison operations.” Decl. Gipson at 4:12-13, 5:1-2.

25 In response, the Receiver trivializes this data, arguing that “Defendants’ numbers do not
 26 actually demonstrate rates of noncompliance” because the deadline for compliance with the
 27 August 19 CDPH mandatory vaccination requirement was extended from October 14, 2021 to
 28 November 24, 2021. Receiver’s Opp’n at 21:10-12. But the Receiver ignores that the deadline

1 for compliance was extended on October 25, 2021—11 days *after* the deadline had already
 2 passed. Supp. Decl. Gipson, ¶ 2. As Director Gipson states, “[a]s of the morning of October 25,
 3 anyone who remained unvaccinated at CHCF or CMF would have understood that they remained
 4 noncompliant eleven days past the deadline for compliance.” *Id.* Therefore, the number of
 5 noncompliant staff as of the initial compliance deadline does indeed serve as a legitimate
 6 barometer for rates of noncompliance, and is not “speculative.” *See id.* And even taking into
 7 account the revised³ rate of noncompliance of 5.2% at CHCF, that level of noncompliance across
 8 the entire prison system would nonetheless have a “severe” impact on prison operations. *Id.*, ¶ 3.

9 The Receiver further argues that regardless, “it is not unusual for roughly 10% of staff to
 10 have failed to comply with a new policy shortly after the deadline for compliance,” and cites to
 11 Director Foss’s declaration in support. Receiver’s Opp’n at 21:14-15. But Director Foss’s
 12 declaration does not support this assertion. Instead, Director Foss states that a 10% non-
 13 compliance rate “*at or before* the deadline” is “not unusual.” Decl. Foss, ECF No. 3738-2, at ¶ 2,
 14 emphasis added.) Nothing in Director Foss’s declaration indicates that a 10 percent non-
 15 compliance rate 11 days *after* a deadline is commonplace.

16 Next, Plaintiffs and the Receiver argue that Defendants’ claims of harm are speculative
 17 because it does not appear that other jurisdictions that have implemented a vaccine mandate have
 18 suffered any harm. Of course, this argument is, ironically, speculative insofar as neither the
 19 Receiver nor Plaintiffs submit any evidence to suggest that an accurate comparison may be drawn
 20 between CDCR and these other jurisdictions. For instance, Plaintiffs allege that Defendants
 21 “downplay[ed] the fact that Washington’s Department of Corrections issued a statement saying
 22 there were no operational impacts suffered in response to the mandate.” Pls.’ Opp’n at 11:24-25.
 23 In making this argument, Plaintiffs ignore Director Gipson’s declaration which explicitly
 24 acknowledges that “Washington’s prisons were still sufficiently staffed to operate.” Decl. Gipson
 25 at 5:17. Nonetheless, as Director Gipson went on to explain, Washington’s Department of

26 ³ In her supplemental declaration, Ms. Gipson advises that since submitting her prior declaration
 27 in support of Defendants’ stay motion, her staff at CHCF and CMF discovered that CCHCS’s
 28 vaccine registry included incorrect noncompliance data. The correct data reflects noncompliance
 rates among correctional officers of 5.2% at CHCF and 2% at CMF as of November 9, 2021.
 (Supp. Decl. Gipson, ¶ 3.)

Corrections lost approximately 4.5% of its prison staff, and if CDCR were to lose a similar percentage of its staff, “the impact on prison operations would be severe, and normal operations would not be possible in all of CDCR’s prisons.” *Id.* at 5:17-19. Thus, the question isn’t whether the “many jurisdictions that have already established vaccine mandates” have suffered “serious problems[,]” Pls.’ Opp’n at 12:1-2, as Plaintiffs posit, but rather, whether CDCR could withstand losses similar to those other jurisdictions. Defendants submitted evidence that they cannot, and neither Plaintiffs nor the Receiver submitted evidence to the contrary. Supp. Decl. Gipson, ¶ 7; Decl. Gipson, ¶ 10. Indeed, Plaintiffs themselves amplify this point, stating that the “large numbers of [CDCR] staff on quarantine or isolation has caused significant backlogs in both primary care and specialty appointments.” Pls.’ Opp’n at 15:20-22.

B. Plaintiffs’ and the Receiver’s Claims of Irreparable Harm Are Baseless.

Plaintiffs and the Receiver argue that the Plaintiff class members will suffer irreparable harm if a stay is granted because a delay in implementation risks a new, more dangerous variant that would lead to additional preventable illness and deaths. Pls.’ Opp’n at 15:7-10; Receiver’s Opp’n at 26:13-14. Not only is this assertion entirely speculative, but it is also contradicted by the newly published Lancet Study, discussed *supra*. Req. Jud. Not. Supp. Defs.’ Reply (RJN), Exs. A & B. As the Lancet Study explains, “fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts.” *Id.* at 1. The Lancet Study further states that “[a]lthough vaccines remain highly effective at preventing severe disease and deaths from COVID-19, our findings suggest that *vaccination is not sufficient to prevent transmission of the delta variant in household settings with prolonged exposures.*” *Id.* at 2, emphasis added. In other words, the vaccine will not prevent staff from spreading the virus to incarcerated persons, and indeed, “breakthrough infections in fully vaccinated people can efficiently transmit infection in the household setting.” *Id.* at 10. Rather, the vaccine prevents incarcerated persons from suffering severe disease and death, but only when *incarcerated persons* themselves are vaccinated. This finding is consistent with Centers for Disease Control and Prevention guidance cited by Defendants in their response to the Court’s order to show cause. ECF No. 3660 at 19-20.

1 Yet, Plaintiffs and the Receiver continue to ignore this scientific reality.

2 Plaintiffs and the Receiver also discount Defendants' claims of irreparable harm,
3 claiming—without support—that staffing shortages can be addressed through other means. For
4 instance, the Receiver argues that CDCR can simply increase the number of correctional officers
5 to meet any shortfalls by offering bonuses or running additional academies. Receiver's Opp'n at
6 24:4-6. These claims ignore the facts presented in Director Gipson's declaration that there simply
7 are no correctional officers waiting to take the place of unvaccinated CDCR staff. Decl. Gipson,
8 ¶ 14. As Director Gipson stated previously, "CDCR's Correctional Officer Academy has been
9 generating fewer cadets during the pandemic than in previous years," and it is already challenging
10 to replace officers who retire or quit, vaccine mandate aside. *Id.*, ¶ 14. Additional academies will
11 not address the problem that there are insufficient numbers of cadets to fill those academies.
12 Moreover, many of the cadets in the academy are unvaccinated—only 24 percent of those who
13 graduated last month were vaccinated. *Id.* Thus, there is not a boundless supply of fresh,
14 vaccinated recruits to take the place of those officers who refuse vaccination.

15 Similarly, Plaintiffs assert that even if shortages do occur, CDCR can address them by
16 expending more money to hire staff or reducing the prison population. Pls.' Opp'n at 16:5-8. But
17 Plaintiffs do not provide any evidence to suggest that bonuses would solve recruitment problems.
18 And even Director Foss acknowledges that correctional officers are provided "a good salary and
19 benefits." Decl. Foss, ¶ 9. The issue isn't compensation; law enforcement agencies nationwide
20 are struggling to recruit and retain officers.⁴ And as Defendants have stated in response to
21 Plaintiffs' repetitive calls for population reduction, CDCR's population was decreased by more
22 than 20% since mid-March 2020 through a variety of population reduction measures, including an
23 early-release program that took into account various public safety factors. *See* ECF No. 3579 at
24 11:2-6. Simply put, further large-scale population reductions would be unnecessarily detrimental
25 to public safety and are not warranted, particularly as the vaccine remains freely available to all

26
27 ⁴ *See, e.g.,* Stefanie Dazio, Jake Bleiberg & Kate Brumback, *Law enforcement struggles to recruit*
28 *since killing of Floyd*, AP News (June 11, 2021), <https://apnews.com/article/government-and-politics-george-floyd-racial-injustice-only-on-ap-coronavirus-pandemic-d434cc8023875ddb996abb7df0a7bc44>.

1 who are incarcerated.

2 The Receiver also claims that, even if CDCR is unable to recruit or retain staff in the face
3 of the mandatory vaccine order, contingency plans nonetheless exist and CDCR could operate on
4 reduced staffing levels. Receiver's Opp'n at 23:21-22. While it is true that the essential
5 functions of a prison can be maintained for some limited period of time even in the face of severe
6 staffing shortages, such shortages go hand-in-hand with a number of serious harms, including: (1)
7 adverse impacts on safety, security, and order within the prison; (2) officer fatigue and burnout;
8 (3) more staff injuries and requests for extended leave; (4) suspension of programming so that
9 staff can focus on providing essential services and maintaining critical prison operations; and (5)
10 increases in rates of attrition which can exacerbate staffing problems. Suppl. Decl. Gipson, ¶ 9.
11 Even Director Foss does not suggest that operating an entire system with severe staffing shortages
12 is a viable long-term solution. See Decl. Foss, ¶ 11.

13 Plaintiffs and the Receiver further argue that harm is months away, if at all, because the
14 progressive discipline process takes time. While it is true that the progressive discipline process,
15 by design, is incremental in nature, their conclusion that no harm will befall the State in the
16 interim is mistaken. As an initial matter, progressive discipline includes pay reductions, unpaid
17 suspension, and ultimately, termination. Suppl. Decl. Gipson, ¶ 6. When staff are suspended
18 without pay, staffing levels are impacted. Thus, Plaintiffs' assumption that noncompliant staff
19 will simply continue to work in the prisons indefinitely during the progressive discipline process
20 is incorrect. *Id.* Further, it is likely that, as in Washington, some percentage of staff will simply
21 choose to separate from CDCR, rather than wait to be terminated. Decl. Gipson, ¶ 10.

22 Finally, Plaintiffs argue that if there are harms related to staffing shortages in the future,
23 the court can simply "modify the implementation deadline, narrow the mandate, or otherwise
24 modify its order." Pls.' Opp'n at 7:17-19. Plaintiffs are mistaken. Once an appeal is filed, a
25 district court is divested of jurisdiction over the matters appealed. *Griggs v. Provident Consumer*
26 *Discount Co.*, 459 U.S. 56 (1982) (per curiam); *McClatchy Newspapers v. Central Valley*
27 *Typographical Union No. 46*, 686 F.2d 731, 734 (9th Cir. 1982). Because CDCR (and CCPOA)
28 have already appealed the September 27 and October 27 orders relating to mandatory

1 vaccination—*see* ECF Nos. 3693, 3714, 3730, 3736—this Court lacks jurisdiction to accept
 2 Plaintiffs’ invitation to modify these orders in any fashion that affects Defendants’ appeal. *Id.*
 3 Plaintiffs rely on *Hoffman v. Beer Drivers & Salesmens’ Local No. 888*, without any analysis, for
 4 the proposition that “where the court supervises a continuing course of conduct and where ...
 5 additional supervisory action by the court is required, an appeal from the supervisory order does
 6 not divest the district court of jurisdiction to continue its supervision, even though in the course of
 7 that supervision the court acts upon or modifies the order from which the appeal is taken.” 536
 8 F.2d 1268, 1276 (9th Cir. 1976); Pls.’ Opp’n at 8:3-8. But *Hoffman* is distinguishable from the
 9 facts here, where no additional supervision or action is anticipated with respect to the vaccine
 10 mandate, and the “maintenance of the status quo” does not require new action by the court, as it
 11 did in *Hoffman*. *See Hoffman*, 536 F.2d at 1276. Nor is an evidentiary hearing establishing “new
 12 facts” anticipated in this matter. *See id.* Accordingly, the maxim that an appeal divests the
 13 district court of jurisdiction over the matter appealed holds true.

14 **C. Defendants’ Stay Request Was Timely.**

15 Plaintiffs and the Receiver attempt to distract from their deficient arguments by claiming
 16 that Defendants demonstrated a lack of urgency in filing their stay motion, and therefore this
 17 Court need not order the requested relief. But in making this argument, Plaintiffs and the
 18 Receiver attempt to rewrite the history of events leading up to Defendants’ motion. Neither
 19 Plaintiffs nor the Receiver acknowledge that, prior to October 27, there was no court-ordered
 20 deadline for implementation. *See* ECF No. 3684. Defendants timely filed an implementation
 21 plan and noted a disagreement with the Receiver about implementation timelines in light of
 22 Defendants’ anticipated stay motion. ECF No. 3694 at 4, n. 3. Just three days later, on October
 23 15, 2021, Defendants advised the Court that “the deadlines set forth in the October 12, 2021 plan
 24 are no longer achievable and Defendants request clarification from this Court as to what
 25 deadlines, if any, now apply,” especially in light of the Kern County Superior Court’s issuance of
 26 a temporary restraining order that day. ECF No. 3703 at 2:12-14. This Court issued an order that
 27 same day—approaching three weeks after its September 27, 2021 order—confirming there was
 28 no clear implementation deadline and ordering Defendants to “meet and confer [with the

Receiver] to attempt to resolve” the dispute as to the timeline for implementation, with the expectation that Defendants would provide an update to the Court the following week. ECF No. 3705 at 1:27. Defendants and the Receiver met twice before the Receiver unilaterally abandoned negotiations and urged the Court to set an implementation deadline. ECF No. 3707; *see also* ECF No. 3710. Against this background, Defendants timely filed for a stay on October 25, 2021—before the Court had even set an implementation deadline. *See* ECF No. 3715.

Finally, Plaintiffs and the Receiver argue that Defendants are raising the issue of irreparable harm for the first time in their stay motion, and therefore these arguments somehow carry less weight. At the threshold, this argument is factually incorrect, as the operational concerns identified in the stay request are not being raised for the first time in the stay request. *See, e.g.*, ECF Nos. 3686 at 33:20-22, 3694 at 2 & 4. For instance, at the September 24 hearing on the Order to Show Cause, Defendants’ counsel specifically referenced “the unintended consequences” that had been discussed by CCPOA, and Defendants warned of their “serious reservations” about the impacts on staffing and operations if the plan were implemented. *See id.* Further, many of the events confirming Defendants’ concerns about irreparable operational harms post-dated the briefing period for the Court’s order to show cause, including the deadline for mandatory staff vaccination at CHCF and CMF. (*See supra*; Decl. Gipson, ¶ 11 (indicating that the number of religious accommodations requested “seems to indicate staff resistance to the vaccine-mandate order”).)

In any event, the “irreparable harm” inquiry is specific to a motion for stay and is irrelevant to a proper PLRA analysis, which must evaluate whether the relief contemplated by the court (and advocated for here by Plaintiffs and the Receiver) is necessary to remedy a constitutional violation, and whether that relief is narrowly drawn, extends no further than necessary, and is the least intrusive means of correcting the violation. 18 U.S.C. § 3626(a)(1)(A).

III. THE BALANCE OF THE HARDSHIPS TIP IN FAVOR OF GRANTING A STAY.

The final two factors in a stay analysis, the balance of equities and the public interest, merge when the State is a party. *Nken v. Holder*, 556 U.S. 418, 435 (2009). Plaintiffs and the Receiver fail to rebut Defendants’ showing that the balance of hardships tip in favor of a stay.

1 Plaintiffs argue that all incarcerated people stand to face “concrete hardship” if all staff are
 2 not vaccinated forthwith. Pls.’ Opp’n at 16. But this cannot be squared with public health
 3 guidance which unequivocally holds that vaccinated and unvaccinated staff alike can transmit the
 4 virus, and vaccination of incarcerated persons themselves is the most effective means of
 5 preventing severe illness or death. *See* discussion of Lancet Study, *infra*. Thus, incarcerated
 6 people can avert hardship themselves by simply accepting the vaccine. The Receiver’s
 7 speculative and unsupported argument that staff vaccinations in higher rates will reduce the
 8 spread of COVID-19 in the communities surrounding the prisons does not address the reality that
 9 unvaccinated incarcerated people remain at risk for serious illness from COVID-19 infections,
 10 which can be transmitted through vaccinated staff. Receiver’s Opp’n at 28; *see* RJN Exs. A & B.
 11 In short, the Receiver and Plaintiffs’ promotion of a zero-COVID policy is simply out of touch
 12 with current science.

13 Further, Plaintiffs’ and the Receiver’s claims that staffing shortages are speculative or
 14 avoidable are simply not supported by the evidence. Significant numbers of staff remained
 15 unvaccinated after the mandatory deadline at CHCF and CMF, and the impact to CDCR’s
 16 operations would be severe if those numbers were applied system-wide. Suppl. Decl. Gipson, ¶¶
 17 3, 5. Moreover, progressive discipline will not allow noncompliant staff to continue working
 18 indefinitely, thus, staffing shortages are imminent, and not the unlikely or distant occurrence as
 19 the Receiver and Plaintiffs suggest. *Id.*, ¶ 6. Where, as here, implementation of the order will not
 20 protect unvaccinated incarcerated persons and will instead result in severe and swift reductions in
 21 staffing, with impacts on institution security and access to programs, the balance of hardships tips
 22 decidedly in Defendants’ favor. *See Golden Gate Rest. Ass’n v. City & Cty. of San Francisco*,
 23 512 F.3d 1112, 1127 (9th Cir. 2008) (when faced with a “conflict between financial concerns and
 24 preventable human suffering . . . the balance of the equities tips decidedly in favor of the latter”).

25 CONCLUSION

26 A stay is necessary and warranted to maintain the status quo and ensure that the State is unharmed
 27 pending appeal, particularly where, as here, Defendants are likely to succeed and the balance of
 28 equities tips in their favor. The Receiver and Plaintiffs’ fail to persuade otherwise.

1 Dated: November 11, 2021

2 HANSON BRIDGETT LLP

3 /s/ Samantha Wolff

4 PAUL B. MELLO

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

MARCIANO PLATA, et al.,

Plaintiffs,

v.

GAVIN NEWSOM, et al.,

Defendants.

01-cv-01351-JST

**SUPPLEMENTAL DECLARATION OF
CONNIE GIPSON IN SUPPORT OF
DEFENDANTS’ REPLY FOR MOTION
TO STAY ORDER RE: MANDATORY
COVID-19 VACCINATIONS (ECF NO.
3684) PENDING APPEAL**

Date: November 17, 2021
Time: 2:00 p.m.
Courtroom: 6, 2nd Floor
Judge: The Honorable Jon S. Tigar
Action Filed: April 5, 2001

I, Connie Gipson, declare:

1. I have personal knowledge regarding the matters stated in this declaration, except for those statements made on information and belief. I am competent to testify to the matters set forth in this declaration and would do so if called upon to testify. I submit this declaration in support of Defendants’ reply supporting their motion to stay this Court’s vaccine-mandate orders.

2. I have reviewed Plaintiffs’ opposition to Defendants motion to stay and the

1 Declaration of Tammatha Foss in support. In her declaration, Ms. Foss asserts that
 2 noncompliance with the CDPH vaccine mandate at CCHCF and CMF as of October 25, 2021, has
 3 no bearing of the likelihood of noncompliance with the vaccine-mandate order going forward
 4 because the compliance deadline for the CDPH mandate is not until November 24, 2021. (Decl.
 5 Tammatha Foss, ECF No. 3738-2, Nov. 8, 2021, at ¶ 3 (“Because the deadline for compliance has
 6 not yet been reached, the number of correctional officers at CHCF and CMF who are not yet fully
 7 vaccinated is a particularly poor predictor of how many correctional officers will ultimately
 8 choose to leave CDCR employment rather than become vaccinated.”).) Ms. Foss is wrong. The
 9 CDPH deadline for compliance was October 14. As of the morning of October 25, anyone who
 10 remained unvaccinated at CHCF or CMF would have understood that they remained
 11 noncompliant eleven days past the deadline for compliance. The afternoon of October 25, the
 12 Wardens were notified that the deadline for compliance with the CDPH order would be extended
 13 to November 24, 2021. It is not clear how long it took for that information to make its way to all
 14 correctional staff, but it would have been sometime after the email notification was sent to the
 15 Wardens on October 25. Thus, my conclusion that rates of noncompliance with the CDPH order
 16 as of October 25 was the best available evidence of likely noncompliance rates going forward was
 17 sound.

18 3. In my previous declaration, I reported that about 8.26% of correctional officers at
 19 CHCF and 10.14% of correctional officers at CMF remained noncompliant with the CDPH order
 20 as of October 25. Since then, my staff at CHCF and CMF have discovered that CCHCS’s vaccine
 21 registry showed some correctional officers as noncompliant even though they had actually been
 22 vaccinated. Accordingly, my CHCF and CMF staff went through the entire list of noncompliant
 23 correctional officers at those two prisons and meticulously confirmed their vaccination status. In
 24 doing so, my staff discovered that several different issues resulted in the incorrect noncompliance
 25 data from CCHCS’s vaccine registry. My team has now provided me with corrected data for
 26 those two prisons. As of November 9, 2021, about 5.2% of correctional officers at CHCF and
 27 about 2% of correctional officers at CMF remain noncompliant with the CDPH vaccine mandate.
 28 My staff attribute most of the discrepancies in the numbers to the incorrect data in CCHCS’s

1 vaccine registry, but the levels of noncompliance have also gone down because some additional
2 correctional officers have been vaccinated or requested religious exemptions since October 25,
3 2021. CHCF's rate of noncompliance is still concerning to me because if, for example, 5.2% of
4 staff across the prison system were to refuse to comply with the Court's vaccine-mandate order,
5 the impact on prison operations would be severe.

6 4. The significant errors in the CCHCS vaccine registry are concerning. I have been
7 informed that CDCR has asked CCHCS look into the accuracy of the data, on which the Court
8 relied in its September 27, 2021 vaccine-mandate order. I also believe that Dr. Bick's declaration
9 in support of the Receiver's recommendation for a vaccine mandate and his declaration in support
10 of the Receiver's opposition to Defendants' stay motion heavily cited data from the vaccine
11 registry that was likely incorrect because, as CDCR staff have discovered, the vaccine registry
12 often does not contain accurate information about vaccinations that occurred in the community,
13 and frequently contains incorrect data concerning who works at particular prisons, among other
14 problems.

15 5. Although CHCF and CMF can serve as barometers for staff noncompliance they are
16 not representative of the levels of staff resistance to vaccination at all prisons. For example
17 prisons like High Desert State Prison and Pelican Bay State Prison, based on their low staff
18 vaccination rates, seem to be far more at risk of losing substantial numbers of staff as a result of
19 the vaccine-mandate order. And they are also prisons where it is especially difficult to recruit
20 staff to fill vacant positions given their remote location.

21 6. Plaintiffs seem to contend that noncompliant staff will be free to continue working in
22 the prisons indefinitely regardless of their noncompliance. This assumption is wrong. The
23 disciplinary process will begin on the first day after noncompliance with the vaccine-mandate
24 deadline and the hiring authorities have been directed to promptly initiate and expedite the
25 progressive-discipline process for staff who refuse to comply with the vaccine mandate. The
26 course of progressive discipline for individual staff members is variable depending on
27 aggravating and mitigating factors and individual disciplinary history. But on October 4, 2021,
28 CDCR issued a memorandum that provided guidance to address the noncompliance

1 accountability process for mandatory staff vaccinations under the CDPH order. That
2 memorandum provided the following hypothetical course of discipline, which was based on a
3 progressive discipline approach consistent with CDCR's disciplinary matrix: (1) letter of
4 instruction issued to noncompliant staff the day after the deadline for compliance; (2) if staff
5 continue to remain noncompliant seven to ten days later, a ten percent pay reduction for a set
6 period; (3) if staff continue to refuse to comply seven to ten days later, another ten percent pay
7 reduction for a longer period; (4) if staff continue to refuse to comply within seven to ten days, an
8 unpaid suspension for a set period; and (5) if staff continue to refuse to comply after an unpaid
9 suspension, termination. It is my understanding that the progressive-discipline memorandum for
10 noncompliance with the Court's vaccine mandate will be substantially similar to the October 4
11 memorandum. Further, under this disciplinary process, noncompliant staff will face salary
12 reductions consistent with the disciplinary matrix within a relatively short period—likely within 2
13 months after the compliance deadline. Thus, Plaintiffs' assumption that noncompliant staff will
14 simply continue to work in the prisons indefinitely during the progressive discipline process is
15 incorrect.

16 7. Plaintiffs seem to contend that because Washington's correctional department
17 asserted that it was able to absorb a 4.5% reduction in staff without an impact to prison
18 operations, CDCR should be able to do the same. Plaintiffs' assertion seems to be based on a
19 number of false assumptions, not the least of which is that Washington's prison system and
20 staffing levels are the same as CDCR's prison system and staffing levels. Regardless, based on
21 my knowledge about current staffing levels and my detailed understanding of CDCR's prison
22 operations, I am certain that a statewide 4.5% decrease in prison staff would have a substantial
23 adverse impact on prison operations, and would preclude a number of prisons from offering
24 regular programming.

25 8. I understand that Plaintiffs have asserted that Defendants' delay in bringing the
26 motion to stay demonstrates that there is no real concern about the harm that the vaccine-mandate
27 order may cause. My concern about staffing issues is real and not less urgent or important
28 because of the timing of Defendants' motion. I have always had concerns that if the Court

1 mandated staff vaccinations, we might face serious staffing challenges, but as the October 14,
2 2021 deadline for compliance with the CDPH's order approached, my concerns dramatically
3 increased when I realized that rates of noncompliance with the CDPH order were very high and
4 continued to be relatively high even after that initial deadline passed. And my concerns grew
5 again when I learned that 4.5% of Washington's correctional staff left Washington's Department
6 of Corrections in response to a vaccine mandate. These events unfolded in the weeks *after* the
7 Court's vaccine-mandate order issued. The district court's subsequent order setting a January 12,
8 2021 compliance deadline has also greatly increased my level of concern because the staffing
9 issues I identified are not likely to be ameliorated before that date.

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9. I understand that Plaintiffs cited a former declaration of mine from last year to support their contention that a prison could get by on severely reduced staffing levels. It is true that essential functions of a prison can be maintained for some limited period of time even in the face of severe staffing shortages. But as I discussed in my October 25 declaration, such severe staffing shortages go hand-in-hand with a number of serious harms, including: (1) adverse impacts on safety, security, and order within the prison; (2) officer fatigue and burnout; (3) more staff injuries and requests for extended leave; (4) suspension of programming so that staff can focus on providing essential services and maintaining critical prison operations; and (5) increases in rates of attrition which can exacerbate staffing problems. Additionally, as I explained in my October 25 declaration, one of the ways to mitigate a serious staffing shortage at a single prison is to redirect staff from other nearby prisons. But if the other nearby prisons are also contending with staffing shortages, this is not an option.

I declare under penalty of perjury that I have read this document, and its contents are true and correct to the best of my knowledge. Executed on November 11, 2021, in Sacramento, California.

/s/ CONNIE GIPSON

CONNIE GIPSON
Director of Adult Institutions
California Department of Corrections and
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IN THE UNITED STATES DISTRICT COURT
 FOR THE NORTHERN DISTRICT OF CALIFORNIA
 OAKLAND DIVISION

MARCIANO PLATA, et al.,

Plaintiffs,

v.

GAVIN NEWSOM, et al.,

Defendants.

01-cv-01351-JST

**Request for Judicial Notice in Support of
 Defendants’ Reply for Motion to Stay
 Order re: Mandatory Vaccinations (ECF
 No. 3684) Pending Appeal**

Date: November 17, 2021
 Time: 2:00 p.m.
 Courtroom: 6, 2nd Floor
 Judge: The Honorable Jon S. Tigar
 Action Filed: April 5, 2001

Defendants request that the Court, under Federal Rule of Evidence 201, take judicial notice of the documents attached as Exhibits A and B. Judicial notice is appropriate where the fact at issue is “not subject to reasonable dispute” because it “can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.” Fed. R. Evid. 201(b)(2). A court must take judicial notice “if a party requests it and the court is supplied with the necessary information.” Fed. R. Evid. 201(c)(2). A court may take judicial notice of undisputed matters of

1 public record. *See Reyn's Pasta Bella, LLC v. Visa USA, Inc.*, 442 F.3d 741, 746 (9th Cir. 2006)
 2 ("We may take judicial notice of court filings and other matters of public record.").

3 Defendants attach a as Exhibit A a true and correct copy of a news article published in
 4 Bloomberg and titled *Vaccinated People Also Spread the Delta Variant, Yearlong Study Shows*.
 5 This article, which was published on October 28, 2021, discusses a newly published scientific
 6 study concerning the spread of the delta variant by vaccinated individuals.

7 Defendants also attach as Exhibit B a true and correct copy of the scientific study referred
 8 to in Exhibit B, which was published in *The Lancet Infectious Diseases* medical journal on
 9 October 28, 2021.

10 Dated: November 11, 2021

HANSON BRIDGETT LLP

11
 12 /s/ *Samantha D. Wolff*

13 _____
 14 PAUL B. MELLO
 15 SAMANTHA D. WOLFF
 16 LAUREL O'CONNOR
 17 DAVID CASARRUBIAS
 18 *Attorneys for Defendants*

16 Dated: November 11, 2021

17 ROB BONTA
 18 Attorney General of California

19 /s/ *DAMON G. McCLAIN*

20 _____
 21 DAMON G. McCLAIN
 22 Supervising Deputy Attorney General
 23 IRAM HASAN
 24 Deputy Attorney General
 25 *Attorneys for Defendants*

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Exhibit A

Prognosis

Vaccinated People Also Spread the Delta Variant, Yearlong Study Shows

By [Suzi Ring](#) [+Sign Up](#)

October 28, 2021, 9 00 AM PDT

Study found similar peak viral load with or without shots

Immunized household contacts have a 25% chance of infection

People inoculated against Covid-19 are just as likely to spread the delta variant of the virus to contacts in their household as those who haven't had shots, according to new research.

In a yearlong study of 621 people in the U.K. with mild Covid 19, scientists found that their peak viral load was similar regardless of vaccination status, according to a [paper published Thursday](#) in [The Lancet Infectious Diseases](#) medical journal. The analysis also found that 25% of vaccinated household contacts still contracted the disease from an index case, while 38% of those who hadn't had shots became infected.

The results go some way toward explaining why the delta variant is so infectious even in nations with successful vaccine rollouts, and why the unvaccinated can't assume they are protected because others have had shots. Those who were inoculated cleared the virus more quickly and had milder cases, while unvaccinated household members were more likely to suffer from severe disease and hospitalization.

"Our findings show that vaccination alone is not enough to prevent people from being infected with the delta variant and spreading it in household settings," said [Ajit Lalvani](#), a professor of infectious diseases at Imperial College London who co-led the study. "The ongoing transmission

we are seeing between vaccinated people makes it essential for unvaccinated people to get vaccinated to protect themselves.”

Vaccination was found to reduce household transmission of the alpha variant -- first discovered in the U.K. in late 2020 -- by between 40% and 50%, and infected vaccinated individuals had a lower viral load in the upper respiratory tract than those who hadn't had shots. The delta variant has been the dominant strain globally for some time, however.

The research also showed that immunity from full vaccination waned in as little as three months. The authors said there wasn't enough data to advise on whether this should lead to a change in the U.K.'s booster policy, where third doses are currently being offered to older and more vulnerable people six months after their second shot.

Six months was an arbitrary time period chosen following early data from Israel on the effectiveness of boosters, but there is no reason to believe they would be less effective if given earlier, said Neil Ferguson, an epidemiologist at Imperial College London and investigator on the study, at a press briefing Thursday.

The booster program could help halt the virus, as extra shots or repeated infections tend to lead to longer immunological memory, potentially protecting people for up to a year, Lalvani said. More data are needed to confirm this, he said.

The authors didn't analyze infections based on the type of vaccines people had received. Maria Zambon, head of influenza and respiratory virology at the U.K. Health Security Agency, noted that there are still more than 300 vaccines in development, and said it's possible that future generations of shots may be better at preventing transmission.

Exhibit B

Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study



Anika Singanayagam*, Seran Hakki*, Jake Dunning*, Kieran J Madon, Michael A Crone, Aleksandra Koycheva, Nieves Derqui-Fernandez, Jack L Barnett, Michael G Whitfield, Robert Varro, Andre Charlett, Rhia Kundu, Joe Fenn, Jessica Cutajar, Valerie Quinn, Emily Conibear, Wendy Barclay, Paul S Freemont, Graham P Taylor, Shazaad Ahmad, Maria Zambon, Neil M Ferguson†, Ajit Lalvani†, on behalf of the ATACCC Study Investigators‡



Summary

Background The SARS-CoV-2 delta (B.1.617.2) variant is highly transmissible and spreading globally, including in populations with high vaccination rates. We aimed to investigate transmission and viral load kinetics in vaccinated and unvaccinated individuals with mild delta variant infection in the community.

Methods Between Sept 13, 2020, and Sept 15, 2021, 602 community contacts (identified via the UK contract-tracing system) of 471 UK COVID-19 index cases were recruited to the Assessment of Transmission and Contagiousness of COVID-19 in Contacts cohort study and contributed 8145 upper respiratory tract samples from daily sampling for up to 20 days. Household and non-household exposed contacts aged 5 years or older were eligible for recruitment if they could provide informed consent and agree to self-swabbing of the upper respiratory tract. We analysed transmission risk by vaccination status for 231 contacts exposed to 162 epidemiologically linked delta variant-infected index cases. We compared viral load trajectories from fully vaccinated individuals with delta infection (n=29) with unvaccinated individuals with delta (n=16), alpha (B.1.1.7; n=39), and pre-alpha (n=49) infections. Primary outcomes for the epidemiological analysis were to assess the secondary attack rate (SAR) in household contacts stratified by contact vaccination status and the index cases' vaccination status. Primary outcomes for the viral load kinetics analysis were to detect differences in the peak viral load, viral growth rate, and viral decline rate between participants according to SARS-CoV-2 variant and vaccination status.

Findings The SAR in household contacts exposed to the delta variant was 25% (95% CI 18–33) for fully vaccinated individuals compared with 38% (24–53) in unvaccinated individuals. The median time between second vaccine dose and study recruitment in fully vaccinated contacts was longer for infected individuals (median 101 days [IQR 74–120]) than for uninfected individuals (64 days [32–97], $p=0.001$). SAR among household contacts exposed to fully vaccinated index cases was similar to household contacts exposed to unvaccinated index cases (25% [95% CI 15–35] for vaccinated vs 23% [15–31] for unvaccinated). 12 (39%) of 31 infections in fully vaccinated household contacts arose from fully vaccinated epidemiologically linked index cases, further confirmed by genomic and virological analysis in three index case–contact pairs. Although peak viral load did not differ by vaccination status or variant type, it increased modestly with age (difference of 0.39 [95% credible interval –0.03 to 0.79] in peak \log_{10} viral load per mL between those aged 10 years and 50 years). Fully vaccinated individuals with delta variant infection had a faster (posterior probability >0.84) mean rate of viral load decline (0.95 \log_{10} copies per mL per day) than did unvaccinated individuals with pre-alpha (0.69), alpha (0.82), or delta (0.79) variant infections. Within individuals, faster viral load growth was correlated with higher peak viral load (correlation 0.42 [95% credible interval 0.13 to 0.65]) and slower decline (–0.44 [–0.67 to –0.18]).

Interpretation Vaccination reduces the risk of delta variant infection and accelerates viral clearance. Nonetheless, fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts. Host–virus interactions early in infection may shape the entire viral trajectory.

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Introduction

While the primary aim of vaccination is to protect individuals against severe COVID-19 disease and its

consequences, the extent to which vaccines reduce onward transmission of SARS-CoV-2 is key to containing the pandemic. This outcome depends on the ability of

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Research in context

Evidence before this study

The SARS-CoV-2 delta variant is spreading globally, including in populations with high vaccination coverage. While vaccination remains highly effective at attenuating disease severity and preventing death, vaccine effectiveness against infection is reduced for delta. Determining the extent of transmission from vaccinated delta-infected individuals to their vaccinated contacts is a public health priority. Comparing the upper respiratory tract (URT) viral load kinetics of delta infections with those of other variants gives insight into potential mechanisms for its increased transmissibility. We searched PubMed and medRxiv for articles published between database inception and Sept 20, 2021, using search terms describing "SARS-CoV-2, delta variant, viral load, and transmission".

Two studies longitudinally sampled the URT in vaccinated and unvaccinated delta variant-infected individuals to compare viral load kinetics. In a retrospective study of a cohort of hospitalised patients in Singapore, more rapid viral load decline was found in vaccinated individuals than unvaccinated cases. However, the unvaccinated cases in this study had moderate-to-severe infection, which is known to be associated with prolonged shedding. The second study longitudinally sampled professional USA sports players. Again, clearance of delta viral RNA in vaccinated cases was faster than in unvaccinated cases, but only 8% of unvaccinated cases had delta variant infection, complicating interpretation. Lastly, a report of a single-source nosocomial outbreak of a distinct delta sub-lineage in Vietnamese health-care workers plotted viral load kinetics (without comparison with unvaccinated delta infections) and demonstrated transmission between fully vaccinated health-care workers in the nosocomial setting. The findings might therefore not be generalisable beyond the particular setting and distinct viral sub-lineage investigated.

Added value of this study

The majority of SARS-CoV-2 transmission occurs in households, but transmission between fully vaccinated individuals in this

setting has not been shown to date. To ascertain secondary transmission with high sensitivity, we longitudinally followed index cases and their contacts (regardless of symptoms) in the community early after exposure to the delta variant of SARS-CoV-2, performing daily quantitative RT-PCR on URT samples for 14–20 days. We found that the secondary attack rate in fully vaccinated household contacts was high at 25%, but this value was lower than that of unvaccinated contacts (38%). Risk of infection increased with time in the 2–3 months since the second dose of vaccine. The proportion of infected contacts was similar regardless of the index cases' vaccination status. We observed transmission of the delta variant between fully vaccinated index cases and their fully vaccinated contacts in several households, confirmed by whole-genome sequencing. Peak viral load did not differ by vaccination status or variant type but did increase modestly with age. Vaccinated delta cases experienced faster viral load decline than did unvaccinated alpha or delta cases. Across study participants, faster viral load growth was correlated with higher peak viral load and slower decline, suggesting that host–virus interactions early in infection shape the entire viral trajectory. Since our findings are derived from community household contacts in a real-life setting, they are probably generalisable to the general population.

Implications of all the available evidence

Although vaccines remain highly effective at preventing severe disease and deaths from COVID-19, our findings suggest that vaccination is not sufficient to prevent transmission of the delta variant in household settings with prolonged exposures. Our findings highlight the importance of community studies to characterise the epidemiological phenotype of new SARS-CoV-2 variants in increasingly highly vaccinated populations. Continued public health and social measures to curb transmission of the delta variant remain important, even in vaccinated individuals.

vaccines to protect against infection and the extent to which vaccination reduces the infectiousness of breakthrough infections.

Vaccination was found to be effective in reducing household transmission of the alpha variant (B.1.1.7) by 40–50%,¹ and infected, vaccinated individuals had lower viral load in the upper respiratory tract (URT) than infections in unvaccinated individuals,² which is indicative of reduced infectiousness.^{3,4} However, the delta variant (B.1.617.2), which is more transmissible than the alpha variant,^{5,6} is now the dominant strain worldwide. After a large outbreak in India, the UK was one of the first countries to report a sharp rise in delta variant infection. Current vaccines remain highly effective at preventing admission to hospital and death from delta infection.⁷ However, vaccine effectiveness against infection is reduced for delta, compared with alpha,^{8,9} and the delta variant

continues to cause a high burden of cases even in countries with high vaccination coverage. Data are scarce on the risk of community transmission of delta from vaccinated individuals with mild infections.

Here, we report data from a UK community-based study, the Assessment of Transmission and Contagiousness of COVID-19 in Contacts (ATACCC) study, in which ambulatory close contacts of confirmed COVID-19 cases underwent daily, longitudinal URT sampling, with collection of associated clinical and epidemiological data. We aimed to quantify household transmission of the delta variant and assess the effect of vaccination status on contacts' risk of infection and index cases' infectiousness, including (1) households with unvaccinated contacts and index cases and (2) households with fully vaccinated contacts and fully vaccinated index cases. We also compared sequentially sampled

URT viral RNA trajectories from individuals with non-severe delta, alpha, and pre-alpha SARS-CoV-2 infections to infer the effects of SARS-CoV-2 variant status—and, for delta infections, vaccination status—on transmission potential.

Methods

Study design and participants

ATACCC is an observational longitudinal cohort study of community contacts of SARS-CoV-2 cases. Contacts of symptomatic PCR-confirmed index cases notified to the UK contact-tracing system (National Health Service Test and Trace) were asked if they would be willing to be contacted by Public Health England to discuss participation in the study. All contacts notified within 5 days of index case symptom onset were selected to be contacted within our recruitment capacity. Household and non-household contacts aged 5 years or older were eligible for recruitment if they could provide written informed consent and agree to self-swabbing of the URT. Further details on URT sampling are given in the appendix (p 13).

The ATACCC study is separated into two study arms, ATACCC1 and ATACCC2, which were designed to capture different waves of the SARS-CoV-2 pandemic. In ATACCC1, which investigated alpha variant and pre-alpha cases in Greater London, only contacts were recruited between Sept 13, 2020, and March 13, 2021. ATACCC1 included a pre-alpha wave (September to November, 2020) and an alpha wave (December, 2020, to March, 2021). In ATACCC2, the study was relaunched specifically to investigate delta variant cases in Greater London and Bolton, and both index cases and contacts were recruited between May 25, and Sept 15, 2021. Early recruitment was focused in West London and Bolton because UK incidence of the delta variant was highest in these areas.¹⁰ Based on national and regional surveillance data, community transmission was moderate-to-high throughout most of our recruitment period.

This study was approved by the Health Research Authority. Written informed consent was obtained from all participants before enrolment. Parents and caregivers gave consent for children.

Data collection

Demographic information was collected by the study team on enrolment. The date of exposure for non-household contacts was obtained from Public Health England. COVID-19 vaccination history was determined from the UK National Immunisation Management System, general practitioner records, and self-reporting by study participants. We defined a participant as unvaccinated if they had not received a single dose of a COVID-19 vaccine at least 7 days before enrolment, partially vaccinated if they had received one vaccine dose at least 7 days before study enrolment, and fully vaccinated if they had received two doses of a COVID-19 vaccine at least 7 days before

study enrolment. Previous literature was used to determine the 7-day threshold for defining vaccination status.^{11–13} We also did sensitivity analyses using a 14-day threshold. The time interval between vaccination and study recruitment was calculated. We used WHO criteria¹⁴ to define symptomatic status up to the day of study recruitment. Symptomatic status for incident cases—participants who were PCR-negative at enrolment and subsequently tested positive—was defined from the day of the first PCR-positive result.

Laboratory procedures

SARS-CoV-2 quantitative RT-PCR, conversion of ORF1ab and envelope (E-gene) cycle threshold values to viral genome copies, whole-genome sequencing, and lineage assignments are described in the appendix (pp 13–14).

Outcomes

Primary outcomes for the epidemiological analysis were to assess the secondary attack rate (SAR) in household contacts stratified by contact vaccination status and the index cases' vaccination status. Primary outcomes for the viral load kinetics analysis were to detect differences in the peak viral load, viral growth rate, and viral decline rate between participants infected with pre-alpha versus alpha versus delta variants and between unvaccinated delta-infected participants and vaccinated delta-infected participants.

We assessed vaccine effectiveness and susceptibility to SARS-CoV-2 infection stratified by time elapsed since receipt of second vaccination as exploratory analyses.

Statistical analysis

To model viral kinetics, we used a simple phenomenological model of viral titre¹⁵ during disease pathogenesis. Viral kinetic parameters were estimated on a participant-specific basis using a Bayesian hierarchical model to fit this model to the entire dataset of sequential cycle threshold values measured for all participants. For the 19 participants who were non-household contacts of index cases and had a unique date of exposure, the cycle threshold data were supplemented by a pseudo-absence data point (ie, undetectable virus) on the date of exposure. Test accuracy and model misspecification were modelled with a mixture model by assuming there was a probability p of a test giving an observation drawn from a (normal) error distribution and probability $1-p$ of it being drawn from the true distribution.

The hierarchical structure was represented by grouping participants based on the infecting variant and their vaccination status. A single-group model was fitted, which implicitly assumes that viral kinetic parameters vary by individual but not by variant or vaccination status. A four-group model was also explored, where groups 1, 2, 3, and 4 represent pre-alpha, alpha, unvaccinated delta, and fully vaccinated delta, respectively. We fitted a correlation matrix between

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Articles

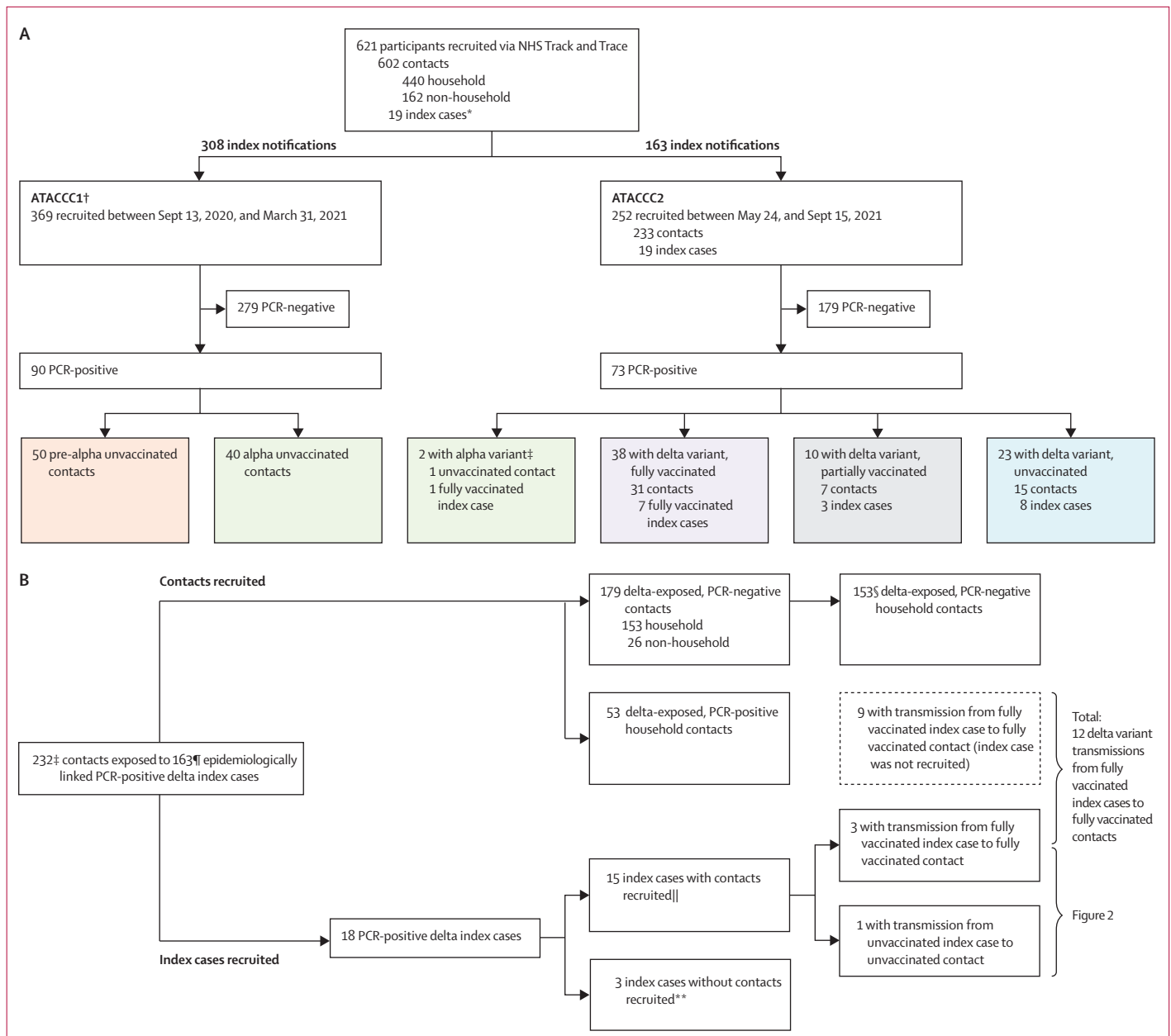


Figure 1: Recruitment, SARS-CoV-2 infection, variant status, and vaccination history for ATACCC study participants

(A) Study recruitment and variant status confirmed by whole-genome sequencing (ATACCC1 and ATACCC2 combined). (B) ATACCC2: delta-exposed contacts included in secondary attack rate calculation (table 1) and transmission assessment (table 2). NHS=National Health Service. * All index cases were from ATACCC2. † All contacts. ‡ The two earliest PCR-positive cases from the ATACCC2 cohort (one index case and one contact) were confirmed as having the alpha variant on whole-genome sequencing (recruited on May 28, 2021). This alpha variant-exposed, PCR-positive contact is excluded from figure 1B. § One PCR-negative contact had no vaccination status data available and one PCR-negative contact's index case had no vaccination data available. ¶ Vaccination data were available for 138 index cases of 163. || The contacts of these 15 index cases are included within the 232 total contacts. ** These three index cases without contacts are only included in the viral load kinetics analysis (figure 3) and are not included in tables 1 and 2.

participant-specific kinetic parameters to allow us to examine whether there is within-group correlation between peak viral titre, viral growth rate, and viral decline rate. Our initial model selection, using leave-one-out cross-validation, selected a four-group hierarchical model with fitted correlation coefficients between individual-level parameters determining peak viral load

and viral load growth and decline rates (appendix p 5). However, resulting participant-specific estimates of peak viral load (but not growth and decline rates) showed a marked and significant correlation with age in the exploratory analysis, which motivated examination of models where mean peak viral load could vary with age. The most predictive model overall allowed mean viral

load growth and decline rates to vary across the four groups, with mean peak viral load common to all groups but assumed to vary linearly with the logarithm of age (appendix p 5). We present peak viral loads for the reference age of 50 years with 95% credible intervals (95% CrIs). 50 years was chosen as the reference age as it is typical of the ages of the cases in the whole dataset and the choice of reference age made no difference in the model fits or judgment of differences between the groups.

We computed group-level population means and within-sample group means of log peak viral titre, viral growth rate, and viral decline rate. Since posterior estimates of each of these variables are correlated across groups, overlap in the credible intervals of an estimate for one group with that for another group does not necessarily indicate no significant difference between those groups. We, therefore, computed posterior probabilities, pp , that these variables were larger for one group than another. For our model, Bayes factors can be computed as $pp/(1-pp)$. We only report population (group-level) posterior probabilities greater than 0.75 (corresponding to Bayes factors >3) as indicating at least moderate evidence of a difference.

For vaccine effectiveness, we defined the estimated effectiveness at preventing infection, regardless of symptoms, with delta in the household setting as $1 - \text{SAR (fully vaccinated)} / \text{SAR (unvaccinated)}$.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Sept 13, 2020, and Sept 15, 2021, 621 community-based participants (602 contacts and 19 index cases) from 471 index notifications were prospectively enrolled in the ATACCC1 and ATACCC2 studies, and contributed 8145 URT samples. Of these, ATACCC1 enrolled 369 contacts (arising from 308 index notifications), and ATACCC2 enrolled 233 contacts (arising from 163 index notifications) and 19 index cases. SARS-CoV-2 RNA was detected in 163 (26%) of the 621 participants. Whole-genome sequencing of PCR-positive cases confirmed that 71 participants had delta variant infection (18 index cases and 53 contacts), 42 had alpha variant infection (one index case and 41 contacts), and 50 had pre-alpha variant infection (all contacts; figure 1A).

Of 163 PCR-positive participants, 89 (55%) were female and 133 (82%) were White. Median age was 36 years (IQR 26–50). Sex, age, ethnicity, body-mass index (BMI) distribution, and the frequency of comorbidities were similar among those with delta, alpha, and pre-alpha infection, and for vaccinated and unvaccinated delta-infected participants, except for age and sex (appendix pp 2–3). There were fewer unvaccinated

	Total	PCR positive	PCR negative	SAR (95% CI)	p value
Contacts					
All	231	53	178	23 (18–29)	NA
Fully vaccinated	140	31	109	22 (16–30)	0.16
Unvaccinated	44	15	29	34 (22–49)	..
Partially vaccinated	47	7	40	15 (7–28)	NA
Household contacts					
All	205	53	152	26 (20–32)	NA
Fully vaccinated	126	31	95	25 (18–33)	0.17
Unvaccinated	40	15	25	38 (24–53)	..
Partially vaccinated	39	7	32	18 (9–33)	NA

χ^2 test was performed to calculate p values for differences in SAR between fully vaccinated and unvaccinated cases. One PCR-negative contact who withdrew from the study without vaccination status information was excluded. NA=not applicable. SAR=secondary attack rate.

Table 1: SAR in contacts of delta-exposed index cases recruited to the ATACCC2 study

females than males ($p=0.04$) and, as expected from the age-prioritisation of the UK vaccine roll-out, unvaccinated participants infected with the delta variant were significantly younger ($p<0.001$; appendix p 3). Median time between exposure to the index case and study enrolment was 4 days (IQR 4–5). All participants had non-severe ambulatory illness or were asymptomatic. The proportion of asymptomatic cases did not differ among fully vaccinated, partially vaccinated, and unvaccinated delta groups (appendix p 3).

No pre-alpha-infected and only one alpha-infected participant had received a COVID-19 vaccine before study enrolment. Of 71 delta-infected participants (of whom 18 were index cases), 23 (32%) were unvaccinated, ten (14%) were partially vaccinated, and 38 (54%) were fully vaccinated (figure 1A; appendix p 3). Of the 38 fully vaccinated delta-infected participants, 14 had received the BNT162b2 mRNA vaccine (Pfizer–BioNTech), 23 the ChAdOx1 nCoV-19 adenovirus vector vaccine (Oxford–AstraZeneca), and one the CoronaVac inactivated whole-virion vaccine (Sinovac).

It is highly probable that all but one of the 233 ATACCC2 contacts were exposed to the delta variant because they were recruited when the regional prevalence of delta was at least 90%, and mostly 95–99% (figure 1B).¹⁰ Of these, 206 (89%) were household contacts (in 127 households), and 26 (11%) were non-household contacts. Distributions of age, ethnicity, BMI, smoking status, and comorbidities were similar between PCR-positive and PCR-negative contacts (appendix p 4). The median time between second vaccine dose and study recruitment in fully vaccinated contacts with delta variant infection was 74 days (IQR 35–105; range 16–201), and this was significantly longer in PCR-positive contacts than in PCR-negative contacts (101 days [IQR 74–120] vs 64 days [32–97], respectively, $p=0.001$; appendix p 4). All 53 PCR-positive contacts were exposed in household settings and the SAR for all delta variant-exposed household contacts was 26% (95% CI 20–32). SAR was

	All household contacts (n=204)*	Fully vaccinated contacts (n=125)		Partially vaccinated contacts (n=39)		Unvaccinated contacts (n=40)	
		PCR positive (n=31)	PCR negative (n=94)	PCR positive (n=7)	PCR negative (n=32)	PCR positive (n=15)	PCR negative (n=25)
Fully vaccinated index cases (n=50)	69	12	31	1	8	4	13
Partially vaccinated index cases (n=25)	35	7	12	3	10	3	0
Unvaccinated index cases (n=63)	100	12	51	3	14	8	12

Non-household exposed contacts (n=24, all PCR negative) were excluded. One PCR-negative household contact who withdrew from the study without vaccination status information was excluded. One PCR-negative household contact who could not be linked to their index case was also excluded. *The rows below show the number of contacts exposed to each category of index case.

Table 2: Comparison of vaccination status of the 138 epidemiologically linked PCR-positive index cases for 204 delta variant-exposed household contacts

not significantly higher in unvaccinated (38%, 95% CI 24–53) than fully vaccinated (25%, 18–33) household contacts (table 1). We estimated vaccine effectiveness at preventing infection (regardless of symptoms) with delta in the household setting to be 34% (bootstrap 95% CI –15 to 60). Sensitivity analyses using a 14 day threshold for time since second vaccination to study recruitment to denote fully vaccinated did not materially affect our estimates of vaccine effectiveness or SAR (data not shown). Although precision is restricted by the small sample size, this estimate is broadly consistent with vaccine effectiveness estimates for delta variant infection based on larger datasets.^{9,16,17}

The vaccination status of 138 epidemiologically linked index cases of 204 delta variant-exposed household contacts was available (figure 1B, table 2). The SAR in household contacts exposed to fully vaccinated index cases was 25% (95% CI 15–35; 17 of 69), which is similar to the SAR in household contacts exposed to unvaccinated index cases (23% [15–31]; 23 of 100; table 2). The 53 PCR-positive contacts arose from household exposure to 39 PCR-positive index cases. Of these index cases who gave rise to secondary transmission, the proportion who were fully vaccinated (15 [38%] of 39) was similar to the proportion who were unvaccinated (16 [41%] of 39). The median number of days from the index cases' second vaccination to the day of recruitment for their respective contacts was 73 days (IQR 38–116). Time interval did not differ between index cases who transmitted infection to their contacts and those who did not (94 days [IQR 62–112] and 63 days [35–117], respectively; $p=0.43$).

18 of the 163 delta variant-infected index cases that led to contact enrolment were themselves recruited to ATACCC2 and serial URT samples were collected from them, allowing for more detailed virology and genome analyses. For 15 of these, their contacts were also recruited (13 household contacts and two non-household contacts). A corresponding PCR-positive household contact was identified for four of these 15 index cases (figure 1B). Genomic analysis showed that index–contact pairs were infected with the same delta variant sub-lineage in these instances, with one exception (figure 2A). In one household (number 4), an unvaccinated index case transmitted the delta variant to an unvaccinated contact,

while another partially vaccinated contact was infected with a different delta sub-lineage (which was probably acquired outside the household). In the other three households (numbers 1–3), fully vaccinated index cases transmitted the delta variant to fully vaccinated household contacts, with high viral load in all cases, and temporal relationships between the viral load kinetics that were consistent with transmission from the index cases to their respective contacts (figure 2B).

Inclusion criteria for the modelling analysis selected 133 participant's viral load RNA trajectories from 163 PCR-positive participants (49 with the pre-alpha variant, 39 alpha, and 45 delta; appendix p 14). Of the 45 delta cases, 29 were fully vaccinated and 16 were unvaccinated; partially vaccinated cases were excluded. Of the 133 included cases, 29 (22%) were incident (ie, PCR negative at enrolment converting to PCR positive subsequently) and 104 (78%) were prevalent (ie, already PCR positive at enrolment). 15 of the prevalent cases had a clearly resolvable peak viral load. Figure 3 shows modelled viral RNA (ORF1ab) trajectories together with the viral RNA copy numbers measured for individual participants. The E-gene equivalent is shown in the appendix (p 2). Estimates derived from E-gene cycle threshold value data (appendix pp 5, 7, 9, 11) were similar to those for ORF1ab.

Although viral kinetics appear visually similar for all four groups of cases, we found quantitative differences in estimated viral growth rates and decline rates (tables 3, 4). Population (group-level) estimates of mean viral load decline rates based on ORF1ab cycle threshold value data varied in the range of 0.69–0.95 log₁₀ units per mL per daxes 4; appendix p 10), indicating that a typical 10-day period was required for viral load to decline from peak to undetectable. A faster decline was seen in the alpha ($pp=0.93$), unvaccinated delta ($pp=0.79$), and fully vaccinated delta ($pp=0.99$) groups than in the pre-alpha group. The mean viral load decline rate of the fully vaccinated delta group was also faster than those of the alpha group ($pp=0.84$) and the unvaccinated delta group ($pp=0.85$). The differences in decline rates translate into a difference of about 3 days in the mean duration of the decline phase between the pre-alpha and delta vaccinated groups.

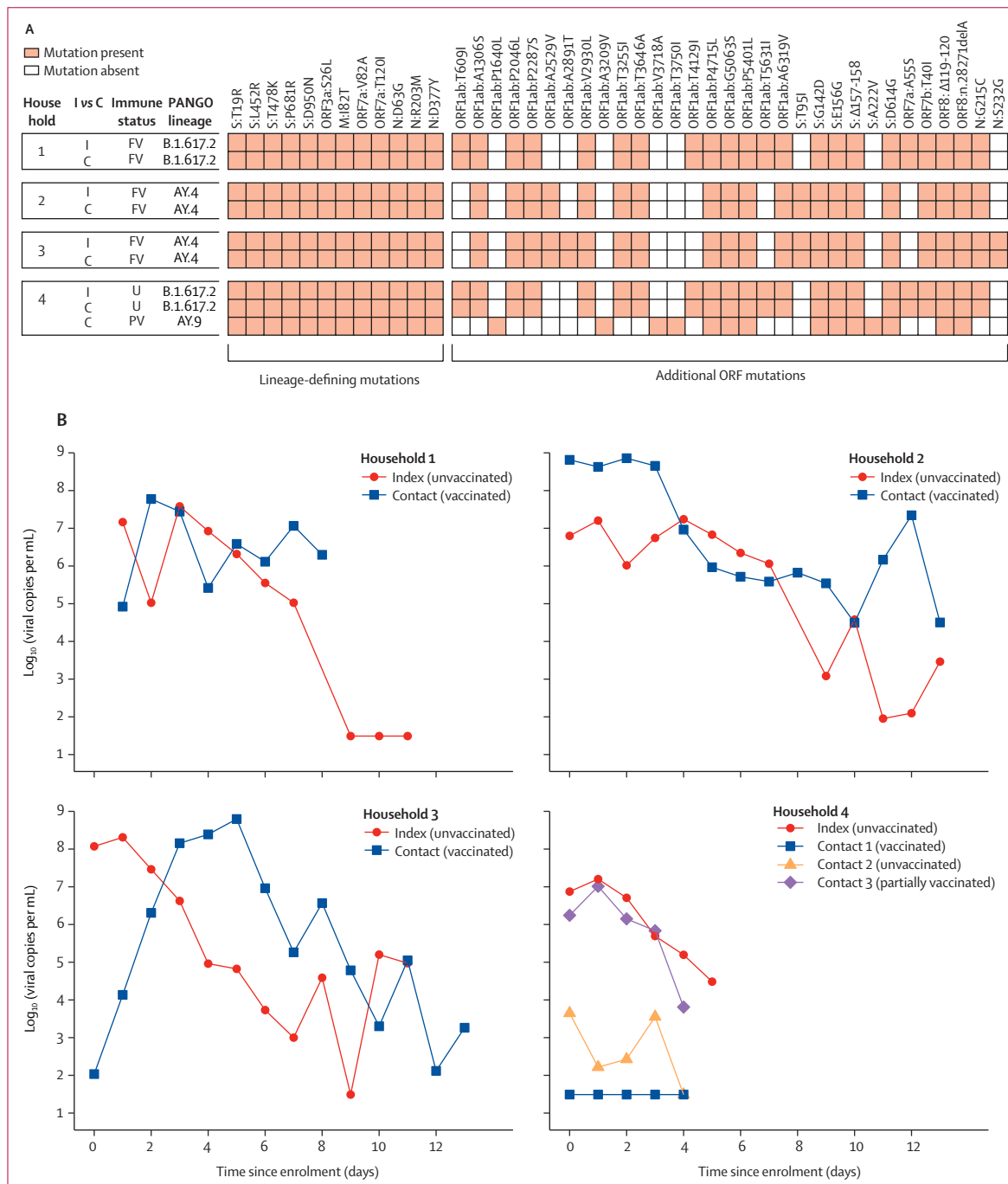
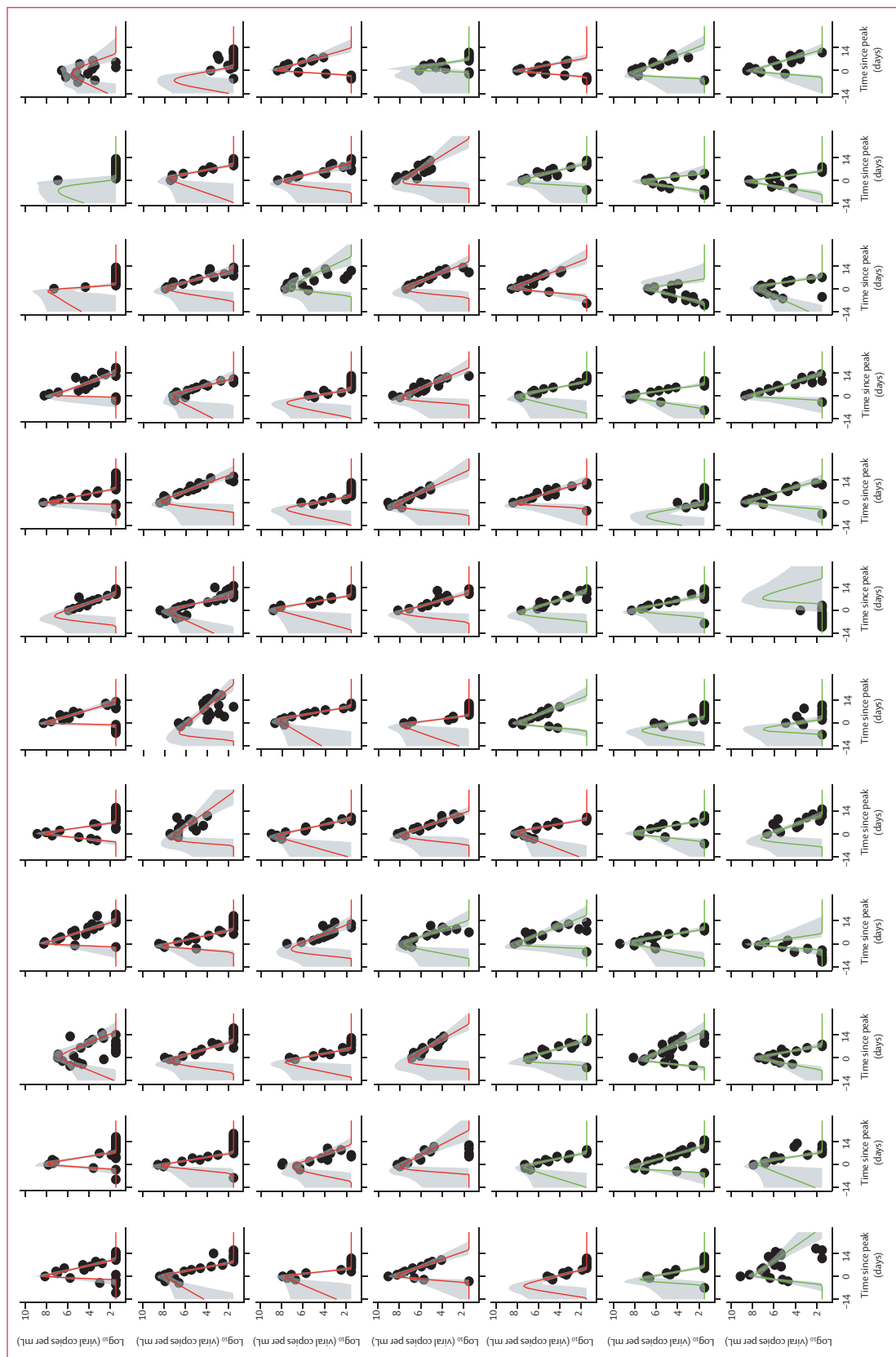


Figure 2: Virological, epidemiological, and genomic evidence for transmission of the SARS-CoV-2 delta variant (B.1.617.2) in households

(A) Genomic analysis of the four households with lineage-defining mutations for delta¹⁸ and additional mutations within ORFs displayed to give insight into whether strains from individuals within the household are closely related. Lineages AY.4 and AY.9 are sub-lineages of delta. (B) Viral trajectories and vaccination status of the four index cases infected with the delta variant for whom infection was detected in their epidemiologically linked household contacts. All individuals had non-severe disease. Each plot shows an index case and their household contacts. Undetectable viral load measurements are plotted at the limit of detection ($10^{1.49}$). C=contact. I=index case. FV=fully vaccinated. ORF=open reading frame. PV=partially vaccinated. U=unvaccinated.

Viral load growth rates were substantially faster than decline rates, varying in the range of 2.69–3.24 log₁₀ units per mL per day between groups, indicating that a typical 3-day period was required for viral load to

grow from undetectable to peak. Our power to infer differences in growth rates between groups was more restricted than for viral decline, but there was moderate evidence ($pp=0.79$) that growth rates were lower for



(Figure 3 continues on next page)

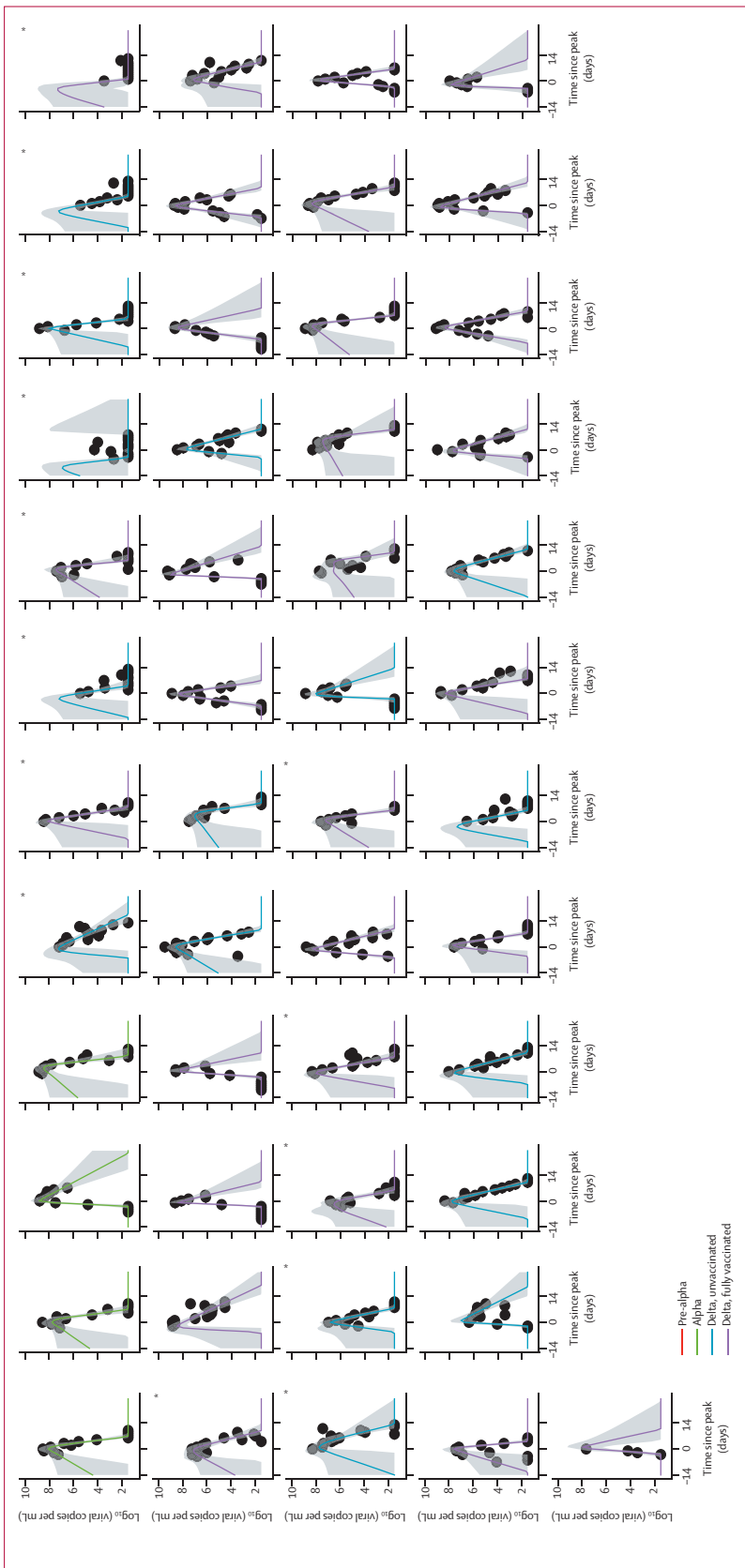


Figure 3: ORF1ab viral load trajectories from 14 days before to 28 days after peak for 133 participants infected with pre-alpha or alpha variants (unvaccinated), or the delta variant (vaccinated and unvaccinated) variants
 Black circles are measured values, with the first datapoint for each participant being taken to the day of enrolment. Plots are rooted on the day of peak viral load for each participant, denoted as day 0 on the x-axis. Curves show the model posterior median estimate, with a 95% credible interval shading. 133 infected participants, comprising 114 contacts and 19 index cases. *Index cases.

	VL growth rate (95% CrI), log ₁₀ units per day	Posterior probability estimate is less than pre-alpha	Posterior probability estimate is less than alpha	Posterior probability estimate is less than delta (unvaccinated)	Posterior probability estimate is less than delta (fully vaccinated)
Pre-alpha (n=49)	3.24 (1.78–6.14)	..	0.44	0.27	0.21
Alpha (n=39)	3.13 (1.76–5.94)	0.56	..	0.32	0.25
Delta, unvaccinated (n=16)	2.81 (1.47–5.47)	0.73	0.68	..	0.44
Delta, fully vaccinated (n=29)	2.69 (1.51–5.17)	0.79	0.75	0.56	..

VL growth rates are shown as within-sample posterior mean estimates. Remaining columns show population (group-level) posterior probabilities that the estimate on that row is less than an estimate for a different group. Posterior probabilities are derived from 20 000 posterior samples and have sampling errors of <0.01. VL=viral load. CrI=credible interval.

Table 3: Estimates of VL growth rates for pre-alpha, alpha, and delta (unvaccinated and fully vaccinated) cases, derived from ORF1ab cycle threshold data

	VL decline rate (95% CrI), log ₁₀ units per day	Posterior probability estimate is larger than pre-alpha	Posterior probability estimate is larger than alpha	Posterior probability estimate is larger than delta (unvaccinated)	Posterior probability estimate is larger than delta (fully vaccinated)
Pre-alpha (n=49)	0.69 (0.58–0.81)	..	0.07	0.21	0.01
Alpha (n=39)	0.82 (0.67–1.01)	0.93	..	0.60	0.16
Delta, unvaccinated (n=16)	0.79 (0.59–1.04)	0.79	0.40	..	0.15
Delta, fully vaccinated (n=29)	0.95 (0.76–1.18)	0.99	0.84	0.85	..

VL decline rates are shown as within-sample posterior mean estimates. Remaining columns show population (group-level) posterior probabilities that the estimate on that row is less than an estimate for a different group. Posterior probabilities are derived from 20 000 posterior samples and have sampling errors of <0.01. VL=viral load. CrI=credible interval.

Table 4: Estimates of VL decline rates for pre-alpha, alpha, and delta (unvaccinated and fully vaccinated) cases, derived from ORF1ab cycle threshold data

those in the vaccinated delta group than in the pre-alpha group.

We estimated mean peak viral load for 50-year-old adults to be 8.14 (95% CrI 7.95 to 8.32) log₁₀ copies per mL, but peak viral load did not differ by variant or vaccination status. However, we estimated that peak viral load increases with age ($pp=0.96$ that the slope of peak viral load with log[age] was >0), with an estimated slope of 0.24 (95% CrI -0.02 to 0.49) log₁₀ copies per mL per unit change in log(age). This estimate translates to a difference of 0.39 (-0.03 to 0.79) in mean peak log₁₀ copies per mL between those aged 10 years and 50 years.

Within-group individual participant estimates of viral load growth rate were positively correlated with peak viral load, with a correlation coefficient estimate of 0.42 (95% CrI 0.13 to 0.65; appendix p 8). Hence, individuals with faster viral load growth tend to have higher peak viral load. The decline rate of viral load was also negatively correlated with viral load growth rate, with a correlation coefficient estimate of -0.44 (95% CrI -0.67 to -0.18), illustrating that individuals with faster viral load growth tend to experience slower viral load decline.

Discussion

Households are the site of most SARS-CoV-2 transmission globally.¹⁹ In our cohort of densely sampled household contacts exposed to the delta variant, SAR was 38% in unvaccinated contacts and 25% in fully vaccinated contacts. This finding is consistent with the known protective effect of COVID-19 vaccination against

infection.^{8,9} Notwithstanding, these findings indicate continued risk of infection in household contacts despite vaccination. Our estimate of SAR is higher than that reported in fully vaccinated household contacts exposed before the emergence of the delta variant.^{1,20,21} The time interval between vaccination and study recruitment was significantly higher in fully vaccinated PCR-positive contacts than fully vaccinated PCR-negative contacts, suggesting that susceptibility to infection increases with time as soon as 2–3 months after vaccination—consistent with waning protective immunity. This potentially important observation is consistent with recent large-scale data and requires further investigation.¹⁷ Household SAR for delta infection, regardless of vaccination status, was 26% (95% CI 20–32), which is higher than estimates of UK national surveillance data (10.8% [10.7–10.9]).¹⁰ However, we sampled contacts daily, regardless of symptomatology, to actively identify infection with high sensitivity. By contrast, symptom-based, single-timepoint surveillance testing probably underestimates the true SAR, and potentially also overestimates vaccine effectiveness against infection.

We identified similar SAR (25%) in household contacts exposed to fully vaccinated index cases as in those exposed to unvaccinated index cases (23%). This finding indicates that breakthrough infections in fully vaccinated people can efficiently transmit infection in the household setting. We identified 12 household transmission events between fully vaccinated index case–contact pairs; for three of these, genomic sequencing confirmed that the index case and

contact were infected by the same delta variant sub-lineage, thus substantiating epidemiological data and temporal relationships of viral load kinetics to provide definitive evidence for secondary transmission. To our knowledge, one other study has reported that transmission of the delta variant between fully vaccinated people was a point-source nosocomial outbreak—a single health-care worker with a particular delta variant sub-lineage in Vietnam.²²

Daily longitudinal sampling of cases from early (median 4 days) after exposure for up to 20 days allowed us to generate high-resolution trajectories of URT viral load over the course of infection. To date, two studies have sequentially sampled community cases of mild SARS-CoV-2 infection, and these were from highly specific population groups identified through asymptomatic screening programmes (eg, for university staff and students²³ and for professional athletes²⁴).

Our most predictive model of viral load kinetics estimated mean peak log₁₀ viral load per mL of 8.14 (95% CrI 7.95–8.32) for adults aged 50 years, which is very similar to the estimate from a 2021 study using routine surveillance data.²⁵ We found no evidence of variation in peak viral load by variant or vaccination status, but we report some evidence of modest but significant ($pp=0.95$) increases in peak viral load with age. Previous studies of viral load in children and adults^{4,25,26} have not used such dense sequential sampling of viral load and have, therefore, been restricted in their power to resolve age-related differences; the largest such study²⁵ reported a similar difference between children and adults to the one we estimated. We found the rate of viral load decline was faster for vaccinated individuals with delta infection than all other groups, and was faster for individuals in the alpha and unvaccinated delta groups than those with pre-alpha infection.

For all variant vaccination groups, the variation between participants seen in viral load kinetic parameter estimates was substantially larger than the variation in mean parameters estimated between groups. The modest scale of differences in viral kinetics between fully vaccinated and unvaccinated individuals with delta infection might explain the relatively high rates of transmission seen from vaccinated delta index cases in our study. We found no evidence of lower SARs from fully vaccinated delta index cases than from unvaccinated ones. However, given that index cases were identified through routine symptomatic surveillance, there might have been a selection bias towards identifying untypically symptomatic vaccine breakthrough index cases.

The differences in viral kinetics we found between the pre-alpha, alpha, and delta variant groups suggest some incremental, but potentially adaptive, changes in viral dynamics associated with the evolution of SARS-CoV-2 towards more rapid viral clearance. Our study provides the first evidence that, within each variant or vaccination group, viral growth rate is positively correlated with peak viral load, but is negatively correlated with viral decline

rate. This finding suggests that individual infections during which viral replication is initially fastest generate the highest peak viral load and see the slowest viral clearance, with the latter not just being due to the higher peak. Mechanistically, these data suggest that the host and viral factors determining the initial growth rate of SARS-CoV-2 have a fundamental effect on the trajectory throughout infection, with faster replication being more difficult (in terms of both peak viral load and the subsequent decline of viral load) for the immune response to control. Analysis of sequentially sampled immune markers during infection might give insight into the immune correlates of these early differences in infection kinetics. It is also possible that individuals with the fastest viral load growth and highest peaks contribute disproportionately to community transmission, a hypothesis that should be tested in future studies.

Several population-level, single-timepoint sampling studies using routinely available data have found no major differences in cycle threshold values between vaccinated and unvaccinated individuals with delta variant infection.^{10,27,28} However, as the timepoint of sampling in the viral trajectory is unknown, this restricts the interpretation of such results. Two other studies longitudinally sampled vaccinated and unvaccinated individuals with delta variant infection.^{23,29} A retrospective cohort of hospitalised patients in Singapore²⁹ also described a faster rate of viral decline in vaccinated versus unvaccinated individuals with delta variant, reporting somewhat larger differences in decline rates than we estimated here. However, this disparity might be accounted for by the higher severity of illness in unvaccinated individuals in the Singaporean study (almost two-thirds having pneumonia, one-third requiring COVID-19 treatment, and a fifth needing oxygen) than in our study, given that longer viral shedding has been reported in patients with more severe illness.³⁰ A longitudinal sampling study in the USA reported that pre-alpha, alpha, and delta variant infections had similar viral trajectories.²⁴ The study also compared trajectories in vaccinated and unvaccinated individuals, reporting similar proliferation phases and peak cycle threshold values, but more rapid clearance of virus in vaccinated individuals. However, this study in the USA stratified by vaccination status and variant separately, rather than jointly, meaning vaccinated individuals with delta infection were being compared with, predominantly, unvaccinated individuals with pre-alpha and alpha infection. Moreover, sampling was done as part of a professional sports player occupational health screening programme, making the results not necessarily representative of typical community infections.

Our study has limitations. First, we recruited only contacts of symptomatic index cases as our study recruitment is derived from routine contact-tracing notifications. Second, index cases were defined as the first household member to have a PCR-positive swab, but we cannot exclude the possibility that another household member might already have been infected and transmitted

to the index case. Third, recording of viral load trajectories is subject to left censoring, where the growth phase in prevalent contacts (already PCR-positive at enrolment) was missed for a proportion of participants. However, we captured 29 incident cases and 15 additional cases on the upslope of the viral trajectory, providing valuable, informative data on viral growth rates and peak viral load in a subset of participants. Fourth, owing to the age-stratified rollout of the UK vaccination programme, the age of the unvaccinated, delta variant-infected participants was lower than that of vaccinated participants. Thus, age might be a confounding factor in our results and, as discussed, peak viral load was associated with age. However, it is unlikely that the higher SAR observed in the unvaccinated contacts would have been driven by younger age rather than the absence of vaccination and, to our knowledge, there is no published evidence showing increased susceptibility to SARS-CoV-2 infection with decreasing age.³¹ Finally, although we did not perform viral culture here—which is a better proxy for infectiousness than RT-PCR—two other studies^{27,32} have shown cultivable virus from around two-thirds of vaccinated individuals infected with the delta variant, consistent with our conclusions that vaccinated individuals still have the potential to infect others, particularly early after infection when viral loads are high and most transmission is thought to occur.³⁰

Our findings help to explain how and why the delta variant is being transmitted so effectively in populations with high vaccine coverage. Although current vaccines remain effective at preventing severe disease and deaths from COVID-19, our findings suggest that vaccination alone is not sufficient to prevent all transmission of the delta variant in the household setting, where exposure is close and prolonged. Increasing population immunity via booster programmes and vaccination of teenagers will help to increase the currently limited effect of vaccination on transmission, but our analysis suggests that direct protection of individuals at risk of severe outcomes, via vaccination and non-pharmacological interventions, will remain central to containing the burden of disease caused by the delta variant.

Contributors

AS, JD, MZ, NMF, WB, and ALal conceptualised the study. AS, SH, JD, KJM, AK, JLB, MGW, ND-F, RV, RK, JF, CT, AVK, JC, VQ, EC, JSN, SH, EM, TP, HH, CL, JS, SB, JP, CA, SA, and NMF were responsible for data curation and investigation. AS, SH, KJM, JLB, AC, NMF, and ALal did the formal data analysis. MAC, AB, DJ, SM, JE, PSF, SD, and ALac did the laboratory work. RV, RK, JF, CT, AVK, JC, VQ, EC, JSN, SH, EM, and SE oversaw the project. AS, SH, JD, KJM, JLB, NMF, and ALal accessed and verified the data. JD, MZ, and ALal acquired funding. NMF sourced and oversaw the software. AS and ALal wrote the initial draft of the manuscript. AS, JD, GPT, MZ, NMF, SH, and ALal reviewed and edited the manuscript. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

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Declaration of interests

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Data sharing

An anonymised, de-identified version of the dataset can be made available upon request to allow all results to be reproduced. Modelling code will also be made publicly available on the GitHub repository.

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