Fwd: Public Comment for 21-0878

1 message

Office of the City Clerk <cityclerk@lacity.org> Thu, Aug 26, 2021 at 4:19 PM
To: City Clerk Council and Public Services <clerk.cps@lacity.org>
Cc: Melinda Novoa <melinda.novoa@lacity.org>

--------- Forwarded message ---------
From: **Brian Planas** <brian.a.planas@gmail.com>
Date: Thu, Aug 26, 2021 at 4:06 PM
Subject: Public Comment for 21-0878
To: <CityClerk@lacity.org>

Helio,
I was having trouble submitting the public comment on the City website. May you please submit the comment below along with attached documents for public comment on 21-0878 of the special committee meeting?
Thanks!

Public Comment:

NOTICE OF LIABILITY:
PLEASE READ THOROUGHLY!

PLEASE support My Body My Choice! Health and safety for our families and community is a top priority, and so is preserving our Constitutional Rights.

Mandating Covid-19 "vaccines" in any way is ILLEGAL. It is against the Nuremberg Code, egregious, and inherently unconstitutional because "vaccines" are still being trialed for safety (see both EUA status and recent FDA approval of COMIRNATY requesting more studies) and therefore Covid "vaccines" are EXPERIMENTAL INJECTIONS.
- Has there been any true informed consent at all with those who have received these experimental injections?
- What would be the collateral damage of these DISCRIMINATORY mandates?
- What about the MILLIONS of people injured by vaccines?

All facts and evidence, including those being heavily censored and socially suppressed, must be deferentially reviewed (see EHT v. FCC 8/13/21 Appellate DC Supreme Court ruling), especially when we have clear RED FLAGS all over current data and global media (Japan rejects 1.6 Million viles, 32,000 vaccine deaths reported in Brazil, millions protest all over Europe and Australia against "Vaccine" Passports, etc.).
- How can these experimental injections be effective if the vaccinated are still getting Covid?
- What about the blood clotting issues, reproductive issues, and UNKNOWN long-term side-effects?
- What about the alternative treatments that have been well documented, yet suppressed and shamed?
- What about VAERS?

Making capricious mandates that would segregate the People and deeply affect them is ILLEGAL! Elected officials are liable - PLEASE do the research, look at the totality of information, and RISE above the fear-mongering.

The mainstream narrative is FRAUDULENT and has over-amplified the "pandemic."

It is grossly negligent to create both mainstream news and/or public policy based on FLAWED ASSUMPTIONS. Any statistics derived from PCR test results using Cycle Thresholds (Ct) above 33-35 are inherently INACCURATE (high likelihood of false readings).
- Exactly what Cycle Thresholds were used in PCR tests for Covid data throughout Los Angeles?

A "vaccine" mandate assumes that these EXPERIMENTAL INJECTIONS are safe, effective, and necessary - they are NOT!

- They are NOT SAFE (look at the VAERS data)
- They are NOT EFFECTIVE (numbers of vaccinated in hospitals?)
- They are NOT NECESSARY (there ARE alternative treatments and Covid numbers are SEVERELY inflated (what happened to the flu, pneumonia, etc.?))

PLEASE support My Body My Choice!

PLEASE uphold our Constitutional Rights!
PLEASE do not further create policy or mandates akin to the beginnings of Nazi Germany!

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4 attachments

Stanford-Mask-Study.pdf
420K

EHT v FCC Appellate Supreme Court Ruling 08 13 21.pdf
365K

SSRN-id3897733.pdf
1403K

COVID19-Dossier.pdf
4836K

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Facemasks in the COVID-19 era: A health hypothesis

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ABSTRACT

Many countries across the globe utilized medical and non-medical facemasks as non-pharmaceutical intervention for reducing the transmission and infectivity of coronavirus disease-2019 (COVID-19). Although, scientific evidence supporting facemasks' efficacy is lacking, adverse physiological, psychological and health effects are established. Is has been hypothesized that facemasks have compromised safety and efficacy profile and should be avoided from use. The current article comprehensively summarizes scientific evidences with respect to wearing facemasks in the COVID-19 era, providing prosper information for public health and decisions making.

Introduction

Facemasks are part of non-pharmaceutical interventions providing some breathing barrier to the mouth and nose that have been utilized for reducing the transmission of respiratory pathogens [1]. Facemasks can be medical and non-medical, where two types of the medical masks primarily used by healthcare workers [1,2]. The first type is National Institute for Occupational Safety and Health (NIOSH)-certified N95 mask, a filtering face-piece respirator, and the second type is a surgical mask [1]. The designed and intended uses of N95 and surgical masks are different in the type of protection they potentially provide. The N95s are typically composed of electret filter media and seal tightly to the face of the wearer, whereas surgical masks are generally loose fitting and may or may not contain electret-filtering media. The N95s are designed to reduce the wearer's inhalation exposure to infectious and harmful particles from the environment such as during extermination of insects. In contrast, surgical masks are designed to provide a barrier protection against splash, spittle and other body fluids to spray from the wearer (such as surgeon) to the sterile environment (patient during operation) for reducing the risk of contamination [1].

The third type of facemasks are the non-medical cloth or fabric masks. The non-medical facemasks are made from a variety of woven and non-woven materials such as Polypropylene, Cotton, Polyester, Cellulose, Gauze and Silk. Although non-medical cloth or fabric facemasks are neither a medical device nor personal protective equipment, some standards have been developed by the French Standardization Association (AFNOR Group) to define a minimum performance for filtration and breathability capacity [2]. The current article reviews the scientific evidences with respect to safety and efficacy of wearing facemasks, describing the physiological and psychological effects and the potential long-term consequences on health.

Hypothesis

On January 30, 2020, the World Health Organization (WHO) announced a global public health emergency of severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) causing illness of coronavirus disease-2019 (COVID-19) [3]. As of October 1, 2020, worldwide 34,166,633 cases were reported and 1,018,876 have died with virus diagnosis. Interestingly, 99% of the detected cases with SARS-CoV-2 are asymptomatic or have mild condition, which contradicts with the virus name (*severe* acute respiratory syndrome-coronavirus-2) [4]. Although infection fatality rate (number of death cases divided by number of reported cases) initially seems quite high 0.029 (2.9%) [4], this overestimation related to limited number of COVID-19 tests performed which biases towards higher rates. Given the fact that asymptomatic or minimally symptomatic cases is several times higher than the number of reported cases, the case fatality rate is considerably less than 1% [5]. This was confirmed by the head of National Institute of Allergy and Infectious Diseases from US stating, "the overall clinical consequences of COVID-19 are similar to those of severe seasonal influenza" [5], having a case fatality rate of approximately 0.1% [5–8]. In addition, data from hospitalized patients with COVID-19 and general public indicate that the majority of deaths were among older and chronically ill individuals, supporting the possibility that the virus may exacerbates existing conditions but rarely causes death by itself [9,10]. SARS-CoV-2 primarily

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affects respiratory system and can cause complications such as acute respiratory distress syndrome (ARDS), respiratory failure and death [3,9]. It is not clear however, what the scientific and clinical basis for wearing facemasks as protective strategy, given the fact that facemasks restrict breathing, causing hypoxemia and hypercapnia and increase the risk for respiratory complications, self-contamination and exacerbation of existing chronic conditions [2,11–14].

Of note, hyperoxia or oxygen supplementation (breathing air with high partial O_2 pressures that above the sea levels) has been well established as therapeutic and curative practice for variety acute and chronic conditions including respiratory complications [11,15]. It fact, the current standard of care practice for treating hospitalized patients with COVID-19 is breathing 100% oxygen [16–18]. Although several countries mandated wearing facemask in health care settings and public areas, scientific evidences are lacking supporting their efficacy for reducing morbidity or mortality associated with infectious or viral diseases [2,14,19]. Therefore, it has been hypothesized: 1) the practice of wearing facemasks has compromised safety and efficacy profile, 2) Both medical and non-medical facemasks are ineffective to reduce human-to-human transmission and infectivity of SARS-CoV-2 and COVID-19, 3) Wearing facemasks has adverse physiological and psychological effects, 4) Long-term consequences of wearing facemasks on health are detrimental.

Evolution of hypothesis

Breathing Physiology

Breathing is one of the most important physiological functions to sustain life and health. Human body requires a continuous and adequate oxygen (O_2) supply to all organs and cells for normal function and survival. Breathing is also an essential process for removing metabolic byproducts [carbon dioxide (CO_2)] occurring during cell respiration [12,13]. It is well established that acute significant deficit in O_2 (hypoxemia) and increased levels of CO_2 (hypercapnia) even for few minutes can be severely harmful and lethal, while chronic hypoxemia and hypercapnia cause health deterioration, exacerbation of existing conditions, morbidity and ultimately mortality [11,20–22]. Emergency medicine demonstrates that 5–6 min of severe hypoxemia during cardiac arrest will cause brain death with extremely poor survival rates [20–23]. On the other hand, chronic mild or moderate hypoxemia and hypercapnia such as from wearing facemasks resulting in shifting to higher contribution of anaerobic energy metabolism, decrease in pH levels and increase in cells and blood acidity, toxicity, oxidative stress, chronic inflammation, immunosuppression and health deterioration [11–13,24].

Efficacy of facemasks

The physical properties of medical and non-medical facemasks suggest that facemasks are ineffective to block viral particles due to their difference in scales [16,17,25]. According to the current knowledge, the virus SARS-CoV-2 has a diameter of 60 nm to 140 nm [nanometers (billionth of a meter)] [16,17], while medical and non-medical facemasks' thread diameter ranges from 55 μm to 440 μm [micrometers (one millionth of a meter), which is more than 1000 times larger [25]. Due to the difference in sizes between SARS-CoV-2 diameter and facemasks thread diameter (the virus is 1000 times smaller), SARS-CoV-2 can easily pass through any facemask [25]. In addition, the efficiency filtration rate of facemasks is poor, ranging from 0.7% in non-surgical, cotton-gauze woven mask to 26% in cotton sweeter material [2]. With respect to surgical and N95 medical facemasks, the efficiency filtration rate falls to 15% and 58%, respectively when even small gap between the mask and the face exists [25].

Clinical scientific evidence challenges further the efficacy of facemasks to block human-to-human transmission or infectivity. A randomized controlled trial (RCT) of 246 participants [123 (50%) symptomatic)] who were allocated to either wearing or not wearing surgical facemask, assessing viruses transmission including coronavirus [26]. The results of this study showed that among symptomatic individuals (those with fever, cough, sore throat, runny nose ect…) there was no difference between wearing and not wearing facemask for coronavirus droplets transmission of particles of >5 μm. Among asymptomatic individuals, there was no droplets or aerosols coronavirus detected from any participant with or without the mask, suggesting that asymptomatic individuals do not transmit or infect other people [26]. This was further supported by a study on infectivity where 445 asymptomatic individuals were exposed to asymptomatic SARS-CoV-2 carrier (been positive for SARS-CoV-2) using close contact (shared quarantine space) for a median of 4 to 5 days. The study found that none of the 445 individuals was infected with SARS-CoV-2 confirmed by real-time reverse transcription polymerase [27].

A *meta*-analysis among health care workers found that compared to no masks, surgical mask and N95 respirators were not effective against transmission of viral infections or influenza-like illness based on six RCTs [28]. Using separate analysis of 23 observational studies, this *meta*-analysis found no protective effect of medical mask or N95 respirators against SARS virus [28]. A recent systematic review of 39 studies including 33,867 participants in community settings (self-report illness), found no difference between N95 respirators versus surgical masks and surgical mask versus no masks in the risk for developing influenza or influenza-like illness, suggesting their ineffectiveness of blocking viral transmissions in community settings [29].

Another *meta*-analysis of 44 non-RCT studies (n = 25,697 participants) examining the potential risk reduction of facemasks against SARS, middle east respiratory syndrome (MERS) and COVID-19 transmissions [30]. The *meta*-analysis included four specific studies on COVID-19 transmission (5,929 participants, primarily health-care workers used N95 masks). Although the overall findings showed reduced risk of virus transmission with facemasks, the analysis had severe limitations to draw conclusions. One of the four COVID-19 studies had zero infected cases in both arms, and was excluded from *meta*-analytic calculation. Other two COVID-19 studies had unadjusted models, and were also excluded from the overall analysis. The *meta*-analytic results were based on only one COVID-19, one MERS and 8 SARS studies, resulting in high selection bias of the studies and contamination of the results between different viruses. Based on four COVID-19 studies, the *meta*-analysis failed to demonstrate risk reduction of facemasks for COVID-19 transmission, where the authors reported that the results of *meta*-analysis have low certainty and are inconclusive [30].

In early publication the WHO stated that "facemasks are not required, as no evidence is available on its usefulness to protect non-sick persons" [14]. In the same publication, the WHO declared that "cloth (e.g. cotton or gauze) masks are not recommended under any circumstance" [14]. Conversely, in later publication the WHO stated that the usage of fabric-made facemasks (Polypropylene, Cotton, Polyester, Cellulose, Gauze and Silk) is a general community practice for "preventing the infected wearer transmitting the virus to others and/or to offer protection to the healthy wearer against infection (prevention)" [2]. The same publication further conflicted itself by stating that due to the lower filtration, breathability and overall performance of fabric facemasks, the usage of woven fabric mask such as cloth, and/or non-woven fabrics, should only be considered for infected persons and not for prevention practice in asymptomatic individuals [2]. The Central for Disease Control and Prevention (CDC) made similar recommendation, stating that only symptomatic persons should consider wearing facemask, while for asymptomatic individuals this practice is not recommended [31]. Consistent with the CDC, clinical scientists from Departments of Infectious Diseases and Microbiology in Australia counsel against facemasks usage for health-care workers, arguing that there is no justification for such practice while normal caring relationship between patients and medical staff could be compromised [32].

Moreover, the WHO repeatedly announced that "at present, there is no direct evidence (from studies on COVID-19) on the effectiveness face masking of healthy people in the community to prevent infection of respiratory viruses, including COVID-19"[2]. Despite these controversies, the potential harms and risks of wearing facemasks were clearly acknowledged. These inciuding self-contamination due to hand practice or non-replaced when the mask is wet, soiled or damaged, development of facial skin lesions, irritant dermatitis or worsening acne and psychological discomfort. Vulnerable populations such as people with mental health disorders, developmental disabilities, hearing problems, those living in hot and humid environments, children and patients with respiratory conditions are at significant health risk for complications and harm [2].

Physiological effects of wearing facemasks

Wearing facemask mechanically restricts breathing by increasing the resistance of air movement during both inhalation and exhalation process [12,13]. Although, intermittent (several times a week) and repetitive (10–15 breaths for 2–4 sets) increase in respiration resistance may be adaptive for strengthening respiratory muscles [33,34], prolonged and continues effect of wearing facemask is maladaptive and could be detrimental for health [11–13]. In normal conditions at the sea level, air contains 20.93% O_2 and 0.03% CO_2, providing partial pressures of 100 mmHg and 40 mmHg for these gases in the arterial blood, respectively. These gas concentrations significantly altered when breathing occurs through facemask. A trapped air remaining between the mouth, nose and the facemask is rebreathed repeatedly in and out of the body, containing low O_2 and high CO_2 concentrations, causing hypoxemia and hypercapnia [11–13,35,36]. Severe hypoxemia may also provoke cardiopulmonary and neurological complications and is considered an important clinical sign in cardiopulmonary medicine [37–42]. Low oxygen content in the arterial blood can cause myocardial ischemia, serious arrhythmias, right or left ventricular dysfunction, dizziness, hypotension, syncope and pulmonary hypertension [43]. Chronic low-grade hypoxemia and hypercapnia as result of using facemask can cause exacerbation of existing cardiopulmonary, metabolic, vascular and neurological conditions [37–42]. Table 1 summarizes the physiological, psychological effects of wearing facemask and their potential long-term consequences for health.

In addition to hypoxia and hypercapnia, breathing through facemask residues bacterial and germs components on the inner and outside layer of the facemask. These toxic components are repeatedly rebreathed back into the body, causing self-contamination. Breathing through facemasks also increases temperature and humidity in the space between the mouth and the mask, resulting a release of toxic particles from the mask's materials [1,2,19,26,35,36]. A systematic literature review estimated that aerosol contamination levels of facemasks including 13 to 202,549 different viruses [1]. Rebreathing contaminated air with high bacterial and toxic particle concentrations along with low O_2 and high CO_2 levels continuously challenge the body homeostasis, causing self-toxicity and immunosuppression [1,2,19,26,35,36].

Table 1
Physiological and Psychological Effects of Wearing Facemask and Their Potential Health Consequences.

Physiological Effects	Psychological Effect	Health Consequences
• Hypoxemia • Hypercapnia • Shortness of breath • Increase lactate concentration • Decline in pH levels • Acidosis • Toxicity • Inflammation • Self-contamination • Increase in stress hormones level (adrenaline, noradrenaline and cortisol) • Increased muscle tension • Immunosuppression	• Activation of "fight or flight" stress response • Chronic stress condition • Fear • Mood disturbances • Insomnia • Fatigue • Compromised cognitive performance	• Increased predisposition for viral and infection illnesses • Headaches • Anxiety • Depression • Hypertension • Cardiovascular disease • Cancer • Diabetes • Alzheimer disease • Exacerbation of existing conditions and diseases • Accelerated aging process • Health deterioration • Premature mortality

A study on 39 patients with renal disease found that wearing N95 facemask during hemodialysis significantly reduced arterial partial oxygen pressure (from PaO_2 101.7 to 92.7 mm Hg), increased respiratory rate (from 16.8 to 18.8 breaths/min), and increased the occurrence of chest discomfort and respiratory distress [35]. Respiratory Protection Standards from Occupational Safety and Health Administration, US Department of Labor states that breathing air with O_2 concentration below 19.5% is considered oxygen-deficiency, causing physiological and health adverse effects. These include increased breathing frequency, accelerated heartrate and cognitive impairments related to thinking and coordination [36]. A chronic state of mild hypoxia and hypercapnia has been shown as primarily mechanism for developing cognitive dysfunction based on animal studies and studies in patients with chronic obstructive pulmonary disease [44].

The adverse physiological effects were confirmed in a study of 53 surgeons where surgical facemask were used during a major operation. After 60 min of facemask wearing the oxygen saturation dropped by more than 1% and heart rate increased by approximately five beats/min [45]. Another study among 158 health-care workers using protective personal equipment primarily N95 facemasks reported that 81% (128 workers) developed new headaches during their work shifts as these become mandatory due to COVID-19 outbreak. For those who used the N95 facemask greater than 4 h per day, the likelihood for developing a headache during the work shift was approximately four times higher [Odds ratio = 3.91, 95% CI (1.35–11.31) p = 0.012], while 82.2% of the N95 wearers developed the headache already within ≤10 to 50 min [46].

With respect to cloth facemask, a RCT using four weeks follow up compared the effect of cloth facemask to medical masks and to no masks on the incidence of clinical respiratory illness, influenza-like illness and laboratory-confirmed respiratory virus infections among 1607 participants from 14 hospitals [19]. The results showed that there were no difference between wearing cloth masks, medical masks and no masks for incidence of clinical respiratory illness and laboratory-confirmed respiratory virus infections. However, a large harmful effect with more than 13 times higher risk [Relative Risk = 13.25 95% CI (1.74 to 100.97) was observed for influenza-like illness among those who were wearing cloth masks [19]. The study concluded that cloth masks have significant health and safety issues including moisture retention, reuse, poor filtration and increased risk for infection, providing recommendation against the use of cloth masks [19].

Psychological effects of wearing facemasks

Psychologically, wearing facemask fundamentally has negative effects on the wearer and the nearby person. Basic human-to-human connectivity through face expression is compromised and self-identity is somewhat eliminated [47–49]. These dehumanizing movements partially delete the uniqueness and individuality of person who wearing the facemask as well as the connected person [49]. Social connections and relationships are basic human needs, which innately inherited in all people, whereas reduced human-to-human connections are associated with poor mental and physical health [50,51]. Despite escalation in technology and globalization that would presumably foster social connections, scientific findings show that people are becoming increasingly more socially isolated, and the prevalence of loneliness is increasing in last few decades [50,52]. Poor social connections are closely related to

isolation and loneliness, considered significant health related risk factors [50–53].

A *meta*-analysis of 91 studies of about 400,000 people showed a 13% increased morality risk among people with low compare to high contact frequency [53]. Another *meta*-analysis of 148 prospective studies (308,849 participants) found that poor social relationships was associated with 50% increased mortality risk. People who were socially isolated or fell lonely had 45% and 40% increased mortality risk, respectively. These findings were consistent across ages, sex, initial health status, cause of death and follow-up periods [52]. Importantly, the increased risk for mortality was found comparable to smoking and exceeding well-established risk factors such as obesity and physical inactivity [52]. An umbrella review of 40 systematic reviews including 10 *meta*-analyses demonstrated that compromised social relationships were associated with increased risk of all-cause mortality, depression, anxiety suicide, cancer and overall physical illness [51].

As described earlier, wearing facemasks causing hypoxic and hypercapnic state that constantly challenges the normal homeostasis, and activates "fight or flight" stress response, an important survival mechanism in the human body [11–13]. The acute stress response includes activation of nervous, endocrine, cardiovascular, and the immune systems [47,54–56]. These include activation of the limbic part of the brain, release stress hormones (adrenalin, neuro-adrenalin and cortisol), changes in blood flow distribution (vasodilation of peripheral blood vessels and vasoconstriction of visceral blood vessels) and activation of the immune system response (secretion of macrophages and natural killer cells) [47,48]. Encountering people who wearing facemasks activates innate stress-fear emotion, which is fundamental to all humans in danger or life threating situations, such as death or unknown, unpredictable outcome. While acute stress response (seconds to minutes) is adaptive reaction to challenges and part of the survival mechanism, chronic and prolonged state of stress-fear is maladaptive and has detrimental effects on physical and mental health. The repeatedly or continuously activated stress-fear response causes the body to operate on survival mode, having sustain increase in blood pressure, pro-inflammatory state and immunosuppression [47,48].

Long-Term health consequences of wearing facemasks

Long-term practice of wearing facemasks has strong potential for devastating health consequences. Prolonged hypoxic-hypercapnic state compromises normal physiological and psychological balance, deteriorating health and promotes the developing and progression of existing chronic diseases [11–13,23,38,39,43,47,48,57]. For instance, ischemic heart disease caused by hypoxic damage to the myocardium is the most common form of cardiovascular disease and is a number one cause of death worldwide (44% of all non-communicable diseases) with 17.9 million deaths occurred in 2016 [57]. Hypoxia also playing an important role in cancer burden [58]. Cellular hypoxia has strong mechanistic feature in promoting cancer initiation, progression, metastasis, predicting clinical outcomes and usually presents a poorer survival in patients with cancer. Most solid tumors present some degree of hypoxia, which is independent predictor of more aggressive disease, resistance to cancer therapies and poorer clinical outcomes [59,60]. Worth note, cancer is one of the leading causes of death worldwide, with an estimate of more than 18 million new diagnosed cases and 9.6 million cancer-related deaths occurred in 2018 [61].

With respect to mental health, global estimates showing that COVID-19 will cause a catastrophe due to collateral psychological damage such as quarantine, lockdowns, unemployment, economic collapse, social isolation, violence and suicides [62–64]. Chronic stress along with hypoxic and hypercapnic conditions knocks the body out of balance, and can cause headaches, fatigue, stomach issues, muscle tension, mood disturbances, insomnia and accelerated aging [47,48,65–67]. This state suppressing the immune system to protect the body from viruses and bacteria, decreasing cognitive function, promoting the developing and exacerbating the major health issues including hypertension, cardiovascular disease, diabetes, cancer, Alzheimer disease, rising anxiety and depression states, causes social isolation and loneliness and increasing the risk for prematurely mortality [47,48,51,56,66].

Conclusion

The existing scientific evidences challenge the safety and efficacy of wearing facemask as preventive intervention for COVID-19. The data suggest that both medical and non-medical facemasks are ineffective to block human-to-human transmission of viral and infectious disease such SARS-CoV-2 and COVID-19, supporting against the usage of facemasks. Wearing facemasks has been demonstrated to have substantial adverse physiological and psychological effects. These include hypoxia, hypercapnia, shortness of breath, increased acidity and toxicity, activation of fear and stress response, rise in stress hormones, immunosuppression, fatigue, headaches, decline in cognitive performance, predisposition for viral and infectious illnesses, chronic stress, anxiety and depression. Long-term consequences of wearing facemask can cause health deterioration, developing and progression of chronic diseases and premature death. Governments, policy makers and health organizations should utilize prosper and scientific evidence-based approach with respect to wearing facemasks, when the latter is considered as preventive intervention for public health.

CRediT authorship contribution statement

Baruch Vainshelboim: Conceptualization, Data curation, Writing - original draft.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued January 25, 2021 Decided August 13, 2021

No. 20-1025

ENVIRONMENTAL HEALTH TRUST, ET AL.,
PETITIONERS

v.

FEDERAL COMMUNICATIONS COMMISSION AND UNITED STATES OF AMERICA,
RESPONDENTS

Consolidated with 20-1138

On Petitions for Review of an Order
of the Federal Communications Commission

W. Scott McCollough argued the cause for petitioners. With him on the joint briefs were *Edward B. Myers* and *Robert F. Kennedy, Jr.*

Sharon Buccino was on the brief for *amici curiae* Natural Resources Defense Council and Local Elected Officials in support of petitioners.

Dan Kleiber and *Catherine Kleiber*, pro se, were on the brief for *amici curiae* Dan and Catherine Kleiber in support of peititioners.

James S. Turner was on the brief for *amicus curiae* Building Biology Institute in support of petitioners.

Stephen L. Goodman was on the brief for *amicus curiae* Joseph Sandri in support of petitioners.

Ashley S. Boizelle, Deputy General Counsel, Federal Communications Commission, argued the cause for respondents. With her on the brief were *Jonathan D. Brightbill*, Principal Deputy Assistant Attorney General at the time the brief was filed, U.S. Department of Justice, *Eric Grant*, Deputy Assistant Attorney General at the time the brief was filed, *Jeffrey Beelaert* and *Justin Heminger*, Attorneys, *Thomas M. Johnson, Jr.*, General Counsel at the time the brief was filed, Federal Communications Commission, *Jacob M. Lewis*, Associate General Counsel, and *William J. Scher* and *Rachel Proctor May*, Counsel. *Richard K. Welch*, Deputy Associate General Counsel, entered an appearance.

Before: HENDERSON, MILLETT and WILKINS, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* WILKINS.

Opinion dissenting in part filed by *Circuit Judge* HENDERSON.

WILKINS, *Circuit Judge*: Environmental Health Trust and several other groups and individuals petition for review of an order of the Federal Communications Commission ("the Commission") terminating a notice of inquiry regarding the

adequacy of the Commission's guidelines for exposure to radiofrequency radiation. The notice of inquiry requested comment on whether the Commission should initiate a rulemaking to modify its guidelines. The Commission concluded that no rulemaking was necessary. Petitioners argue that the Commission violated the requirements of the Administrative Procedure Act by failing to respond to significant comments. Petitioners also argue that the National Environmental Policy Act required the Commission to issue an environmental assessment or environmental impact statement regarding its decision to terminate its notice of inquiry.

We grant the petitions in part and remand to the Commission. The Commission failed to provide a reasoned explanation for its determination that its guidelines adequately protect against the harmful effects of exposure to radiofrequency radiation unrelated to cancer.

I.

The Federal Communications Commission regulates various facilities and devices that transmit radio waves and microwaves, including cell phones and facilities for radio, TV, and cell phone communications. 47 U.S.C. §§ 301, 302a(a); *see EMR Network v. FCC*, 391 F.3d 269, 271 (D.C. Cir. 2004). Radio waves and microwaves are forms of electromagnetic energy that are collectively described by the term "radiofrequency" ("RF"). Office of Eng'g & Tech., Fed. Commc'ns Comm'n, *OET Bulletin No. 56, Questions and Answers about Biological Effects and Potential Hazards of Radiofrequency Electromagnetic Fields* 1 (4th ed. Aug. 1999). The phenomenon of radio waves and microwaves moving through space is described as "RF radiation." *Id.*

We often associate the term "radiation" with the term "radioactivity." "Radioactivity," however, refers only to the

emission of radiation with enough energy to strip electrons from atoms. *Id.* at 5. That kind of radiation is called "ionizing radiation." *Id.* It can produce molecular changes and damage biological tissue and DNA. *Id.* Fortunately, RF radiation is "non-ionizing," meaning that it is not sufficiently energetic to strip electrons from atoms. *Id.* It can, however, heat certain kinds of materials, like food in your microwave oven or, at sufficiently high levels, human body tissue. *Id.* at 6–7. Biological effects that result from the heating of body tissue by RF energy are referred to as "thermal" effects, and are known to be harmful. *Id.* Exposure to lower levels of RF radiation might also cause other, "non-thermal" biological effects. *Id.* at 8. Whether it does, and whether such effects are harmful, are subjects of debate. *Id.*

The National Environmental Policy Act ("NEPA") and its implementing regulations require federal agencies to "establish procedures to account for the environmental effects of [their] proposed actions." *Am. Bird Conservancy, Inc. v. FCC*, 516 F.3d 1027, 1032 (D.C. Cir. 2008) (per curiam). If an agency proposes a "major Federal action[]" that stands to "significantly affect[] the quality of the human environment," the agency must prepare an environmental impact statement ("EIS") that examines the adverse environmental effects of the proposed action and potential alternatives. 42 U.S.C. § 4332(C). Not every agency action, however, requires the preparation of a full EIS. *Theodore Roosevelt Conservation P'ship v. Salazar*, 616 F.3d 497, 503 (D.C. Cir. 2010). If it is unclear whether a proposed action will "significantly affect[] the quality of the human environment," 42 U.S.C. § 4332(C), the responsible agency may prepare a more limited environmental assessment ("EA"). *See* 40 C.F.R. § 1501.5(a). An EA serves to "[b]riefly provide sufficient evidence and analysis for determining whether to prepare an [EIS] or a finding of no significant impact." 40 C.F.R. § 1501.5(c)(1).

Additionally, an agency may use "categorical exclusions" to "define categories of actions that normally do not have a significant effect on the human environment and therefore do not require preparation of an environmental impact statement." 40 C.F.R. § 1500.4(a); *see also* 40 C.F.R. § 1501.4(a).

To fulfill its obligations under NEPA, the Commission has promulgated guidelines for human exposure to RF radiation. *Cellular Phone Taskforce v. FCC*, 205 F.3d 82, 87 (2d Cir. 2000). The guidelines set limits for RF exposure. Before the Commission authorizes the construction or use of any wireless facility or device, the applicant for authorization must determine whether the facility or device is likely to expose people to RF radiation in excess of the limits set by the guidelines. 47 C.F.R. § 1.1307(b). If the answer is yes, the applicant must prepare an EA regarding the likely effects of the Commission's authorization of the facility or device. *Id.* Depending on the contents of the EA, the Commission may require the preparation of an EIS, and may subject approval of the application to a full vote by the Commission. Office of Eng'g & Tech., Fed. Commc'ns Comm'n, *OET Bulletin No. 65, Evaluating Compliance with FCC Guidelines for Human Exposure to Radiofrequency Electromagnetic Fields* 6 (ed. 97-01, Aug. 1997). If the answer is no, the applicant is generally not required to prepare an EA. 47 C.F.R. § 1.1306(a).

The Commission last updated its limits for RF exposure in 1996. *Resolution of Notice of Inquiry, Second Report and Order, Notice of Proposed Rulemaking, and Memorandum Opinion and Order*, 34 FCC Rcd. 11,687, 11,689–90 (2019) ("2019 Order"); *see also* Telecommunications Act of 1996, Pub. L. No. 104-104, § 704(b), 110 Stat. 56, 152 (directing the Commission to "prescribe and make effective rules regarding the environmental effects of radio frequency emissions" within 180 days). The limits are based on standards for RF exposure

issued by the American National Standards Institute Committee ("ANSI"), the Institute of Electrical and Electronic Engineers, Inc. ("IEEE"), and the National Council on Radiation Protection and Measurements ("NCRP"). *In re Guidelines for Evaluating the Environmental Effects of Radiofrequency Radiation*, 11 FCC Rcd. 15,123, 15,134–35, 15,146–47 (1996). The limits are designed to protect against "thermal effects" of exposure to RF radiation, but not "non-thermal" effects. *EMR Network*, 391 F.3d at 271.

In March 2013, the Commission issued a notice of inquiry regarding the adequacy of its 1996 guidelines. *See Reassessment of Radiofrequency Exposure Limits & Policies, Notice of Inquiry*, 28 FCC Rcd. 3,498 (2013) ("2013 Notice of Inquiry"). The Commission divided its notice of inquiry into five sections. In the first section, it sought comment on the propriety of its exposure limits for RF radiation, particularly as they relate to device use by children. *Id.* at 3,575–80. In the second section, the Commission sought comment on how to better provide information to consumers and the public about exposure to RF radiation and methods for reducing exposure. *Id.* at 3,580–82. In the third section, the Commission sought comment on whether it should impose additional precautionary restrictions on devices and facilities that are unlikely to expose people to RF radiation in excess of the limits set by the Commission's guidelines. *Id.* at 3,582–85. In the fourth and fifth sections, the Commission sought comment on whether it should change its methods for determining whether devices and facilities comply with the Commission's guidelines. *Id.* at 3,585–89.

The Commission explained that it was issuing the notice of inquiry in response to changes in the ubiquity of wireless devices and in scientific standards and research since 1996. *Id.* at 3,570. Specifically, the Commission noted that the IEEE had

"published a major revision to its RF exposure standard in 2006." *Id.* at 3,572. The Commission also noted that the International Commission on Non-Ionizing Radiation Protection had published RF exposure guidelines in 1998 that differed somewhat from the Commission's 1996 guidelines, and was likely to release a revision of those guidelines "in the near future." *Id.* at 3,573. And the Commission noted that the International Agency for Research on Cancer ("IARC") had classified RF radiation as possibly carcinogenic to humans, and was likely to release a detailed monograph regarding that classification prior to the resolution of the notice of inquiry. *Id.* at 3,575 & n.385. The Commission invited public comment on all of these developments, but underscored that it would "work closely with and rely heavily—but not exclusively—on the guidance of other federal agencies with expertise in the health field." *Id.* at 3,571.

In December 2019, the Commission issued a final order resolving its 2013 notice of inquiry by declining to undertake any of the changes contemplated in the notice of inquiry. *See 2019 Order*, 34 FCC Rcd. at 11,692–97.

In January 2020, Petitioners Environmental Health Trust, Consumers for Safe Cell Phones, Elizabeth Barris, and Theodora Scarato timely petitioned this Court for review of the Commission's 2019 final order. In February 2020, Petitioners Children's Health Defense, Michele Hertz, Petra Brokken, Dr. David O. Carpenter, Dr. Paul Dart, Dr. Toril H. Jelter, Dr. Ann Lee, Virginia Farver, Jennifer Baran, and Paul Stanley, M.Ed., timely petitioned the Ninth Circuit for review of the same order, and the Ninth Circuit transferred their petition to this Court pursuant to 28 U.S.C. § 2112. This Court consolidated the petitions. We have jurisdiction under 47 U.S.C. § 402(a) and 28 U.S.C. § 2342(1).

II.

Petitioners challenge the 2019 final order under NEPA and the Administrative Procedure Act ("APA"). We begin with the APA.

A.

Petitioners argue that the order is arbitrary and capricious and therefore must be set aside under 5 U.S.C. § 706(2)(A) for the following reasons: (1) the order fails to acknowledge evidence of negative health effects caused by exposure to RF radiation at levels below the limits set by the Commission's 1996 guidelines, including evidence of cancer, radiation sickness, and adverse effects on sleep, memory, learning, perception, motor abilities, prenatal and reproductive health, and children's health; (2) the order fails to respond to comments concerning environmental harm caused by RF radiation; (3) the order fails to discuss the implications of long-term exposure to RF radiation, exposure to RF pulsation or modulation (two methods of imbuing radio waves with information), and the implications of technological developments that have occurred since 1996, including the ubiquity of wireless devices and Wi-Fi, and the emergence of "5G" technology; (4) the order fails to adequately explain the Commission's refusal to modify its procedures for determining whether cell phones comply with its RF limits; and (5) the order fails to respond to various "additional legal considerations," Pet'rs' Br. at 84.

Before discussing these arguments, and the Commission's responses to them, we clarify our standard of review. The arbitrary and capricious standard of the Administrative Procedure Act "encompasses a range of levels of deference to the agency." *Am. Horse Prot. Ass'n v. Lyng*, 812 F.2d 1, 4 (D.C. Cir. 1987). We completely agree with the dissenting

opinion that the Commission's order is entitled to a high degree of deference, both because it is akin to a refusal to initiate a rulemaking, *see id.* at 4–5, and because it concerns highly technical determinations of the kind courts are ill-equipped to second-guess, *see Am. Radio Relay League, Inc., v. FCC*, 524 F.3d 227, 233 (D.C. Cir. 2008). So as to the governing law, the dissenting opinion and we are on the same page. Nevertheless, the Commission's decision to terminate its notice of inquiry must be "reasoned" if it is to survive arbitrary and capricious review. *See Am. Horse*, 812 F.2d at 5; *Am. Radio*, 524 F.3d at 241. As with other agency decisions not to engage in rulemaking, we will overturn the Commission's decision if there is "compelling cause, such as plain error of law or a fundamental change in the factual premises previously considered by the agency[.]" *Flyers Rights Educ. Fund, Inc. v. Fed. Aviation Admin.*, 864 F.3d 738, 743 (D.C. Cir. 2017) (quoting *WildEarth Guardians v. EPA*, 751 F.3d 649, 653 (D.C. Cir. 2014)). When an agency in the Commission's position is confronted with evidence that its current regulations are inadequate or the factual premises underlying its prior judgment have eroded, it must offer more to justify its decision to retain its regulations than mere conclusory statements. *See Am. Horse*, 812 F.2d at 6; *Am. Radio*, 524 F.3d at 241. Rather, the agency must provide "assurance that [it] considered the relevant factors," and it must provide analysis that follows "a discernable path to which the court may defer." *Am. Radio*, 524 F.3d at 241.

i.

Under this highly deferential standard of review, we find the Commission's order arbitrary and capricious in its failure to respond to record evidence that exposure to RF radiation at levels below the Commission's current limits may cause negative health effects unrelated to cancer. (As we explain

below, we find that the Commission offered an adequate explanation for its determination that exposure to RF radiation at levels below the Commission's current limits does not cause cancer.) That failure undermines the Commission's conclusions regarding the adequacy of its testing procedures, particularly as they relate to children, and its conclusions regarding the implications of long-term exposure to RF radiation, exposure to RF pulsation or modulation, and the implications of technological developments that have occurred since 1996, all of which depend on the premise that exposure to RF radiation at levels below its current limits causes no negative health effects. Accordingly, we find those conclusions arbitrary and capricious as well. Finally, we find the Commission's order arbitrary and capricious in its complete failure to respond to comments concerning environmental harm caused by RF radiation.

Petitioners point to multiple studies and reports, which were published after 1996 and are in the administrative record, purporting to show that RF radiation at levels below the Commission's current limits causes negative health effects unrelated to cancer, such as reproductive problems and neurological problems that span from effects on memory to motor abilities. *See, e.g.*, J.A. 3,068 (BIOINITIATIVE WORKING GROUP, BIOINITIATIVE REPORT (Cindy Sage & David O. Carpenter eds., 2012) (describing evidence that human sperm and their DNA are damaged by low levels of RF radiation)); J.A. 5,243 (Igor Yakymenko et al., *Oxidative Mechanisms of Biological Activity of Low-Intensity Radiofrequency Radiation*, ELECTROMAGNETIC BIOLOGY & MED., EARLY ONLINE, 1–16 (2015)); J.A. 5,259–69 (Henrietta Nittby et al., *Increased Blood-Brain Barrier Permeability in Mammalian Brian 7 Days After Exposure to the Radiation from a GSM-900 Mobile Phone*, 16 PATHOPHYSIOLOGY 103 (2009)); J.A. 5,320–68 (Henry Lai, *A Summary of Recent Literature on*

Neurobiological Effects of Radiofrequency Radiation, *in* MOBILE COMMUNICATIONS AND PUBLIC HEALTH 187–222 (M. Markov ed., 2018)); J.A. 5,994–6,007 (Milena Foerster et al., *A Prospective Cohort Study of Adolescents' Memory Performance and Individual Brain Dose of Microwave Radiation from Wireless Communication*, 126 ENV'T HEALTH PERSPS. 077007 (July 2018)). Petitioners also point to approximately 200 comments submitted by individuals who advised the Commission that either they or their family members suffer from radiation sickness, "a constellation of mainly neurological symptoms that manifest as a result of RF[] exposure." Pet'rs' Br. at 30–31, 30 n.99.

The Commission argues that its order adequately responded to this evidence by citing the Food and Drug Administration ("FDA")'s determination that exposure to RF radiation at levels below the Commission's current limits does not cause negative health effects. The order cites three statements from the FDA. First, the order cites an FDA webpage titled "Do cell phones pose a health hazard?" that, as of December 4, 2017, stated that "[t]he weight of scientific evidence has not linked cell phones with any health problems." *2019 Order*, 34 FCC Rcd. at 11,692–93, 11,693 n.31. Second, the order cites a February 2018 statement from the Director of the FDA's Center for Devices and Radiological Health advising the public that

> As part of our commitment to protecting the public health, the FDA has reviewed, and will continue to review, many sources of scientific and medical evidence related to the possibility of adverse health effects from radiofrequency energy exposure in both humans and animals and will continue to do so as new scientific data are published. Based on our ongoing evaluation

> of the issue, the totality of the available scientific evidence continues to not support adverse health effects in humans caused by exposures at or under the current radiofrequency energy exposure limits.

Id. at 11,695 n.42. Third, the order cites an April 2019 letter from the Director of the FDA's Center for Devices and Radiological Health that does not discuss non-cancer-related health effects but instead addresses a 2018 study by the National Toxicology Program that found that exposure to RF radiation emitted by cell phones may cause cancer in rodents. *2019 Order*, 34 FCC Rcd. at 11,692 & n.28. The letter explains that "[a]s a part of our ongoing monitoring activities, we have reviewed the results and conclusions of the recently published rodent study from the National Toxicology Program in the context of all available scientific information, including epidemiological studies, and concluded that no changes to the current standards are warranted at this time." Letter from Jeffrey Shuren, M.D., J.D., Dir., Ctr. for Devices & Radiological Health, Food & Drug Admin., Dep't of Health & Hum. Servs., to Julius Knapp, Chief, Off. Of Eng'g & Tech., FCC (April 24, 2019).

We do not agree that these statements provide a reasoned explanation for the Commission's decision to terminate its notice of inquiry. Rather, we find them to be of the conclusory variety that we have previously rejected as insufficient to sustain an agency's refusal to initiate a rulemaking. In *American Horse*, this Court considered whether the Secretary of Agriculture had offered a satisfactory explanation under the APA of his refusal to institute rulemaking proceedings regarding the practice of deliberately injuring show horses by fastening heavy chains or similar equipment—referred to as "action devices"—to the horses' front limbs. 812 F.2d at 2. In

response to the argument that a certain study presented facts that merited a new rulemaking, the Secretary offered the following two-sentence explanation:

> 6. I have reviewed studies and other materials, relating to action devices, presented by humane groups, Walking Horse industry groups, and independent institutions, including the study referred to in the Complaint.
>
> 7. On the basis of this information, I believe that the most effective method of enforcing the Act is to continue the current regulations.

Id. at 5. This Court found these "two conclusory sentences . . . insufficient to assure a reviewing court that the agency's refusal to act was the product of reasoned decisionmaking." *Id.* at 6. *American Horse* explained that the study at issue "may or may not remove a 'significant factual predicate' of the original rules' gaps[,]" and remanded to the Secretary to make that determination. *Id.* at 7.

Similarly, in *American Radio*, this Court considered whether the Commission had offered a satisfactory explanation for its decision to retain in its regulations a particular "extrapolation factor"—an estimate of the projected rate at which radio frequency strength decreases from a radiation-emitting source—despite studies submitted in a petition for reconsideration indicating that a different extrapolation factor would be more appropriate. 524 F.3d at 240–41. The Commission explained its decision by asserting that "[n]o new information has been submitted that would provide a convincing argument for modifying the extrapolation factor . . . at this time." *Id.* (internal alterations omitted). We rejected that explanation as conclusory and unreasoned. *Id.*

The statements from the FDA on which the Commission's order relies are practically identical to the Secretary's statement in *American Horse* and the Commission's statement in *American Radio*. They explain that the FDA has reviewed certain information—here, "all," "the weight," or "the totality" of "scientific evidence." And they state the FDA's conclusion that, in light of that information, exposure to RF radiation at levels below the Commission's current limits does not cause harmful health effects. But they offer "no articulation of the factual . . . bases" for the FDA's conclusion. *Am. Horse*, 812 F.2d at 6 (internal quotation marks omitted). In other words, they do not explain why the FDA determined, despite the studies and comments that Petitioners cite, that exposure to RF radiation at levels below the Commission's current limits does not cause harmful health effects. Such conclusory statements "cannot substitute for a reasoned explanation," for they provide "neither assurance that the [FDA] considered the relevant factors nor [do they reveal] a discernable path to which the court may defer." *Am. Radio*, 524 F.3d at 241. They instead represent a failure by the FDA to address the implication of Petitioners' studies: The factual premise—the non-existence of non-thermal biological effects—underlying the current RF guidelines may no longer be accurate.

When repeated by the Commission, the FDA's conclusory statements still do not substitute for the reasoned explanation that the APA requires. It is the Commission's responsibility to regulate radio communications, 47 U.S.C. § 301, and devices that emit RF radiation and interfere with radio communications, *id.* § 302a(a), and to do so in the public interest, including in regard to public health, *Banzhaf v. FCC*, 405 F.2d 1082, 1096 (D.C. Cir. 1968). Even the Commission itself recognizes this. *See 2019 Order*, 34 FCC Rcd. at 11,689 ("The Commission has the responsibility to set standards for RF emissions"); *2013 Notice of Inquiry*, 28 FCC Rcd. at 3,571

(explaining that the Commission opened the notice of inquiry "to ensure [it] [was] meeting [its] regulatory responsibilities" and that it would "work closely with and rely heavily—*but not exclusively*—on the guidance of other federal agencies with expertise in the health field" in order to "fully discharge[] [its] regulatory responsibility") (emphasis added). And the APA requires that Commission's decisions concerning the regulation of radio communications and devices be reasoned. The Commission's purported reasoning in this case is that it chose to rely on the FDA's evaluation of the studies in the record. Absent explanation from the FDA as to how and why it reached its conclusions regarding those studies, however, we have no basis on which to review the reasonableness of the Commission's decision to adopt the FDA's conclusions. Ultimately, the Commission's order remains bereft of any explanation as to *why*, in light of the studies in the record, its guidelines remain adequate. The Commission may turn to the FDA to provide such an explanation, but if the FDA fails to do so, as it did in this case, the Commission must turn elsewhere or provide its own explanation. Were the APA to require less, our very deferential review would become nothing more than a rubber stamp.

The Commission also argues that its order provided a reasoned explanation for its decision to terminate the notice of inquiry, despite Petitioners' evidence, by observing that "no expert health agency expressed concern about the Commission's RF exposure limits," and that "no evidence has moved our sister health and safety agencies to issue substantive policy recommendations for strengthening RF exposure regulation." *2019 Order*, 34 FCC Rcd. at 11,692. The silence of other expert agencies, however, does not constitute a reasoned explanation for the Commission's decision to terminate its notice of inquiry for the same reason that the FDA's conclusory statements do not constitute a reasoned

explanation: silence does not indicate why the expert agencies determined, in light of evidence suggesting to the contrary, that exposure to RF radiation at levels below the Commission's current limits does not cause negative health effects unrelated to cancer. Silence does not even indicate whether the expert agencies made any such determination, or whether they considered any of the evidence in the record.

Our decision in *EMR Network* is not to the contrary. There, we rejected the argument that the Commission improperly delegated its NEPA duties by relying on input from other government agencies and non-governmental expert organizations in deciding whether to initiate a rulemaking to modify its RF radiation guidelines. 391 F.3d at 273. We found the Commission "not to have abdicated its responsibilities, but rather to have properly credited outside experts," and noted that "the FCC's decision not to leap in, at a time when the EPA (and other agencies) saw no compelling case for action, appears to represent the sort of priority-setting in the use of agency resources that is least subject to second-guessing by courts." *Id.* (citing *Am. Horse*, 812 F.2d at 4). We agree with the dissenting opinion that the Commission may credit outside experts in deciding whether to initiate a rulemaking to modify its RF radiation guidelines. To be sure, "[a]gencies can be expected to respect the views of such other agencies as to those problems for which those other agencies are more directly responsible and more competent." *City of Boston Delegation v. FERC*, 897 F.3d 241, 255 (D.C. Cir. 2018) (internal alteration and quotation marks omitted). What the Commission may not do, however, is rely on an outside expert's silence or conclusory statements in lieu of some reasoned explanation for its decision. And while it is certainly true that an agency's decision not to initiate a rulemaking at a time when other agencies see no compelling case for action may represent "the sort of priority-setting in the use of agency

resources that is least subject to second-guessing by courts," *EMR Network*, 391 F.3d at 273, the same is true of most agency decisions not to initiate a rulemaking, *see Am. Horse*, 812 F.2d at 4–5. Nevertheless, an agency's decision not to initiate a rulemaking must have some reasoned basis, and an agency cannot simply ignore evidence suggesting that a major factual predicate of its position may no longer be accurate. *Id.* at 5.

Nor does *Cellular Phone Taskforce* help the Commission. There, the Second Circuit rejected the argument that the Commission was required to consult with the Environmental Protection Agency ("EPA") or other outside agencies before declining to modify its RF radiation guidelines in the face of new evidence regarding non-thermal effects caused by RF radiation. 205 F.3d at 90–91. In so holding, the Second Circuit found that "[i]t was fully reasonable for the FCC to expect the agency with primacy in evaluating environmental impacts to monitor all relevant scientific input into the FCC's reconsideration, particularly because the EPA had been assigned the lead role in RF radiation health effects since 1970," and that the Commission was not required to "supply the new evidence to the other federal agencies with expertise in the area." *Id.* at 91. But the Second Circuit did not hold that the Commission could rely solely on the silence or unexplained conclusions of other federal agencies to justify its own inaction. It merely held that the Commission was not required to consult with outside agencies before declining to modify its RF radiation guidelines. No party before us today questions the propriety of that holding.

Finally, the Commission argues that the Commission itself addressed the major studies in the record in its order terminating the notice of inquiry. Specifically, the Commission points to its statement that "[t]he vast majority of filings were unscientific." *2019 Order*, 34 FCC Rcd. at 11,694.

Elsewhere, however, the order acknowledges that "the record include[d] some research information" and "filings that sought to present scientific evidence." *Id.* The order dismisses that research and evidence as "fail[ing] to make a persuasive case for revisiting our existing RF limits," *id.*, but again, such a conclusory statement cannot substitute for the minimal reasoning required at this stage, *Am. Radio*, 524 F.3d at 241. And while "[a]n agency is not obliged to respond to every comment, only those that can be thought to challenge a fundamental premise," *MCI WorldCom, Inc. v. FCC*, 209 F.3d 760, 765 (D.C. Cir. 2000), the studies in the record to which Petitioners point *do* challenge a fundamental premise of the Commission's decision to terminate its notice of inquiry—namely, the premise that exposure to RF radiation at levels below the Commission's current limits does not cause negative health effects. But the Commission said nothing at all in its order about any specific health effects unrelated to cancer.

The Commission also points to its statement that "the record [does not] include actionable alternatives or modifications to the current RF limits supported by scientifically rigorous data or analysis." *2019 Order*, 34 FCC Rcd. at 11,692; *see also id.* at 11,694. Had the notice of inquiry focused exclusively on whether the Commission should modify its RF exposure limits, we might agree that the failure of any commenter to propose actionable modifications to the RF limits would have justified the Commission's decision to terminate the notice of inquiry. But the notice of inquiry did not focus exclusively on whether the Commission should modify its RF exposure limits. Instead, it also sought comment on how to better provide information to consumers and the public about exposure to RF radiation and methods for reducing exposure, and whether the Commission should impose additional precautionary restrictions on devices and facilities that are unlikely to expose people to RF radiation in

excess of the Commission's limits. The Commission needed no actionable alternative to its current limits in order to provide additional information to the public or to impose precautionary restrictions in addition to its current limits. The failure of any commenter to propose actionable modifications to the Commission's RF exposure limits therefore does not justify the Commission's decision to terminate the notice of inquiry.

ii.

The Commission's failure to provide a reasoned explanation for its determination that exposure to RF radiation at levels below its current limits does not cause negative health effects unrelated to cancer renders the order arbitrary and capricious in three additional respects. First, it undermines the Commission's explanation for retaining its procedures for determining whether cell phones and other portable electronic devices comply with its RF limits. These procedures consist of testing the device against the head of a specialized mannequin, *2013 Notice of Inquiry*, 28 FCC Rcd. at 3,586 n.434, and no more than 2.5 centimeters away from the body of the mannequin, *id.* at 3,588 n.447. Petitioners claim that the testing is inaccurate because of the space between the device and the mannequin's body. On this point, the Commission's order cites the "large safety margin" incorporated in its existing RF exposure limits as a justification for its refusal to modify these procedures to include testing against the body. *2019 Order*, 34 FCC Rcd. at 11,696. Because the Commission's existing RF limits are overprotective, the order explains, the Commission need not worry about whether its testing procedures accurately detect devices that are likely to expose people to RF emissions in excess of the Commission's limits. *See id.* ("[E]ven if certified or otherwise authorized devices produce RF exposure levels in excess of Commission limits under normal use, such exposure would still be well below levels considered to be

dangerous, and therefore phones legally sold in the United States pose no health risks."). As the Commission itself recognizes, this explanation depends on the premise that RF radiation does not cause harmful effects at levels below its current limits. *See id.* at 11,696 n.49 ("We note that any claim as to the adequacy of the FCC required testing, certification, and authorization regime is no different than a challenge to the adequacy of the federal RF exposure limits themselves. Both types of claims would undermine the FCC's substantive policy determinations."). The Commission's failure to provide a reasoned explanation for its determination that exposure to RF radiation at levels below its current limits does not cause negative health effects therefore renders inadequate the Commission's explanation for its refusal to modify its testing procedures.

Second, the Commission equally failed to provide a reasoned explanation for brushing off record evidence addressing non-cancer-related health effects arising from the impact of RF radiation on children. Many commenters, including the American Academy of Pediatrics, urged the Commission to adopt limits that account for the use of RF-emitting devices by vulnerable children and pregnant women. *See, e.g.*, J.A. 4,533–34. In dismissing those concerns, the Commission again relied on a conclusory statement from the FDA that "[t]he scientific evidence does not show a danger to any users of cell phones from RF exposure, including children and teenagers." *2019 Order*, 34 FCC Rcd. at 11,696. But, as we have already explained, such a conclusory and unexplained statement is not the "reasoned" explanation required by the APA. In addition, the Commission noted that the testing to determine compliance with its limits "represents a conservative case" for both adults and children. *Id.* at 11,696 n.50. Whether the testing of compliance with existing limits was conservative is not the point. The unanswered question remains whether low

levels of RF radiation allowed by those existing limits cause negative health effects. So once again, the Commission's failure to provide a reasoned or even relevant explanation of its position that RF radiation below the current limits does not cause health problems unrelated to cancer renders its explanation as to the effect of RF radiation on children arbitrary and capricious.

Third, the Commission's failure to provide a reasoned explanation for its determination that exposure to RF radiation at levels below its current limits does not cause negative health effects unrelated to cancer renders inadequate the Commission's explanation for its failure to discuss the implications of long-term exposure to RF radiation, exposure to RF pulsation or modulation, or the implications of technological developments that have occurred since 1996, including the ubiquity of wireless devices and Wi-Fi, and the emergence of "5G" technology. In its brief, the Commission responds that it was not required to address these topics in its order because it "rationally concluded that the weight of scientific evidence does not support the existence of adverse health effects from radiofrequency exposure below the FCC's limits, regardless of the service or equipment at issue." Resp't's Br. at 45–46. (The Commission points out that "5G" cell towers, unlike traditional cell towers, are subject to its RF exposure limits.) Again, this explanation depends on the premise that RF radiation does not cause harmful health effects at levels below the Commission's current limits, and will not suffice absent a reasoned explanation for the Commission's determination that that premise is correct.

iii.

In addition to the Commission's inadequate response to the non-cancer-related effects of RF radiation on human health,

the Commission also completely failed even to acknowledge, let alone respond to, comments concerning the impact of RF radiation on the environment. That utter lack of a response does not meet the Commission's obligation to provide a reasoned explanation for terminating the notice of inquiry. The record contains substantive evidence of potential environmental harms. Most relevantly, the record included a letter from the Department of the Interior voicing concern about the impact of RF radiation from communication towers on migratory birds, *see* J.A. 8,379, 8,383–86. In the Department of the Interior's expert view, the Commission's RF radiation limits "continue to be based on thermal heating, a criterion now nearly 30 years out of date and inapplicable today." J.A. 8,383. "The [current environmental] problem," according to the Department of the Interior, "appears to focus on very low-level, non-thermal electromagnetic radiation." *Id.* Although the Commission has repeatedly claimed that it considered "inputs from [its] sister federal agencies[,]" *2019 Order*, 34 FCC Rcd. at 11,689, the Commission entirely failed to address the environmental harm concerns raised by the Department of the Interior. To be sure, the Commission could conclude that the link between RF radiation and environmental harms is too weak to warrant an amendment to its RF radiation limits. All we hold now is that the Commission should have said something about its sister agency's view rather than ignore it altogether. That lack of any reasoned explanation as to environmental harms does not satisfy the requirements of the APA.

iv.

The dissenting opinion portrays this case as about the Commission's disregard of just five articles and one Department of Interior letter. Not so. The record contained substantial information and material from, for example, the

American Academy of Pediatrics, J.A. 4,533; the Council of Europe, J.A. 4,242–44, 4,247–57; the Cities of Boston and Philadelphia, J.A. 4,592–99; medical associations, *see, e.g.*, J.A. 4,536–40 (California Medical Association); thousands of physicians and scientists from around the world, *see, e.g.*, J.A. 4,197–4,206 (letter to United Nations); J.A. 4,208–17 (letter to European Union); J.A. 5,173–86 (Frieburger Appeal by over one thousand German physicians); and hundreds of people who were themselves or who had loved ones suffering from the alleged effects of RF radiation, *see, e.g.*, J.A. 8,774–9,940; *see also* J.A. 4,218–39 (collecting statements from physicians and health organizations expressing concern about health effects of RF radiation).

The dissenting opinion then offers its own explanation as to why those select sources were not worth being addressed by the agency. This in-the-weeds assessment of scientific studies and assessments falls "outside our bailiwick[,]" Dissenting Op. at 10. More to the point, the Commission said none of what the dissenting opinion does. If it had and if those six sources fairly represented the credible record evidence seeking a change in Commission policy, that discussion likely would have sufficed. But just as *post hoc* rationales offered by counsel cannot fill in the holes left by an agency in its decision, neither can a dissenting opinion. *See Grace v. Barr*, 965 F.3d 883, 903 (D.C. Cir. 2020) ("[W]hen 'assessing the reasonableness of [an agency's action], we look only to what the agency said at the time of the [action]—not to its lawyers' post-hoc rationalizations.'") (second and third alterations in original) (quoting *Good Fortune Shipping SA v. Commissioner*, 897 F.3d 256, 263 (D.C. Cir. 2018)).

Instead, the Commission chose to hitch its wagon to the FDA's unexplained disinterest in some similar information. Importantly, the dissenting opinion does not dispute that the

FDA's conclusory dismissal of that evidence ran afoul of our precedent in *American Horse* and *American Radio*. It just says that the deficiency in the FDA's analysis cannot be imputed to a second agency, and so the dissenting opinion would hold dispositive "the fact that the Commission and the FDA are, to state the obvious, distinct agencies." Dissenting Op. at 5.

They certainly are. But that does not amount to a legal difference here. While imitation may be the highest form of flattery, it does not meet even the low threshold of reasoned analysis required by the APA under the deferential standard of review that governs here. One agency's unexplained adoption of an unreasoned analysis just compounds rather than vitiates the analytical void. Said another way, two wrongs do not make a right. *Compare City of Tacoma v. FERC*, 460 F.3d 53, 76 (D.C. Cir. 2006) ("[T]he action agency must not blindly adopt the conclusions of the consultant agency, citing that agency's expertise. Rather, the ultimate responsibility for compliance with the [Endangered Species Act] falls on the action agency."), *and Ergon-West Virginia, Inc. v. EPA*, 896 F.3d 600, 612 (4th Cir. 2018) ("Although the EPA is statutorily required to consider the [Department of Energy]'s recommendation, it may not turn a blind eye to errors and omissions apparent on the face of the report, which [petitioner] pointed out and the EPA did not address in any meaningful way. In doing so, the EPA 'ignore[d] important aspects of the problem.'") (internal citations omitted), *with Bellion Spirits, LLC v. United States*, No. 19-5252, slip op. at 13–14 (D.C. Cir. Aug. 6, 2021) (approving consultation by the Alcohol and Tobacco Tax and Trade Bureau ("TTB") with the FDA where the TTB "did not rubberstamp FDA's analysis of the scientific evidence or delegate final decisionmaking authority to FDA," but instead "systematically evaluated and explained its reasons for agreeing with FDA's analysis of each scientific study" and "then made its own determinations" about the claims at hand).

B.

Petitioners' remaining challenges under the APA are unavailing.

Petitioners first argue that the Commission failed to respond to record evidence that exposure to RF radiation at levels below the Commission's current limits may cause cancer. Specifically, Petitioners argue the Commission failed to mention the IARC's classification of RF radiation as possibly carcinogenic to humans, and its 2013 monograph regarding that classification, on which the Commission's notice of inquiry specifically sought comment. Petitioners also argue that the Commission failed to adequately respond to two 2018 studies—the National Toxicology Program ("NTP") study and the Ramazzini Institute study—that found increases in the incidences of certain types of cancer in rodents exposed to RF radiation. Had these 2018 studies been available prior to the IARC's publication of its monograph, Petitioners assert, the IARC would have likely classified RF radiation as "probably carcinogenic," rather than "possibly carcinogenic." This is so, according to Petitioners, because the IARC will classify an agent as "possibly carcinogenic" if there is "limited evidence" that it causes cancer in humans and animals, and as "probably carcinogenic" if there is "limited evidence" that it causes cancer in humans and "sufficient evidence" that it causes cancer in animals. In its 2013 monograph, the IARC found "limited evidence" that RF radiation causes cancer in humans and animals, and therefore classified RF radiation as "possibly carcinogenic." Int'l Agency for Rsch. on Cancer, *Non-Ionizing Radiation, Part 2: Radiofrequency Electromagnetic Fields*, 102 IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS 419 (2013) (emphases omitted). Petitioners assert that the NTP and Ramazzini Institute studies provide "sufficient evidence" that RF radiation

causes cancer in animals. Therefore, according to Petitioners, had those studies been available prior to the IARC's publication of its monograph, the IARC would have found "limited evidence" that RF radiation causes cancer in humans and "sufficient evidence" that it causes cancer in animals, and would have accordingly classified RF radiation as "probably carcinogenic."

Although the Commission's failure to make any mention of the IARC monograph does not epitomize reasoned decision making, we find that the Commission's order adequately responds to the record evidence that exposure to RF radiation at levels below the Commission's current limits may cause cancer. In contrast to its silence regarding non-cancerous effects, the order provides a reasoned response to the NTP and Ramazzini Institute studies. It explains that the results of the NTP study "cannot be extrapolated to humans because (1) the rats and mice received RF radiation across their whole bodies; (2) the exposure levels were higher than what people receive under the current rules; (3) the duration of exposure was longer than what people receive; and (4) the studies were based on 2G and 3G phones and did not study WiFi or 5G." *2019 Order*, 34 FCC Rcd. at 11,693 n.33. And the order cites a response to both studies published by the International Commission on Non-Ionizing Radiation Protection that provides a detailed explanation of various inconsistencies and limitations in the studies and concludes that "consideration of their findings does not provide evidence that radiofrequency EMF is carcinogenic." INT'L COMM'N ON NON-IONIZING RADIATION PROT., ICNIRP NOTE ON RECENT ANIMAL CARCINOGENESIS STUDIES 6 (2018), https://www.icnirp.org/cms/upload/publications/ICNIRPnote2018.pdf; *see also 2019 Order*, 34 FCC Rcd. at 11,693 n.34. Petitioners' contention that the IARC would have classified RF radiation as "probably carcinogenic" had the NTP and Ramazzini Institute studies

been published earlier is speculative, particularly in light of the International Commission on Non-Ionizing Radiation Protection's evaluation of those studies. And the IARC monograph's classification of RF radiation as "possibly carcinogenic" is not so contrary to the Commission's determination that exposure to RF radiation at levels below its current limits does not cause cancer as to render that determination arbitrary or capricious.

Petitioners also argue that the Commission's order impermissibly fails to respond to various "additional legal considerations." Specifically, Petitioners argue that the order (i) ignores "express invocations of constitutional, statutory and common law based individual rights," including property rights and the rights of "bodily autonomy and informed consent"; (ii) fails to explain whether FCC regulation preempts rights and remedies under the Americans with Disabilities Act and the Fair Housing Act; (iii) does not assess the costs and benefits associated with maintaining the Commission's current limits; (iv) does not resolve the question of whether "those advocating more protective limits have to prove the existing limits are inadequate," or whether the Commission carries the burden of proving that its existing limits are adequate; and (v) overlooks that the Supreme Court's decision in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), "flatly requires that the Commission allow for some remedy for those who suffer from exposure." Pet'rs' Br. at 84–101.

These arguments are not properly before us. The Communications Act provides that a petition for reconsideration is a "condition precedent to judicial review" of "questions of fact or law upon which the Commission . . . has been afforded no opportunity to pass." 47 U.S.C. § 405(a). We will accordingly only consider a question raised before us if "a reasonable Commission *necessarily* would have seen the

question . . . as part of the case presented to it." *NTCH, Inc. v. FCC*, 841 F.3d 497, 508 (D.C. Cir. 2016) (quoting *Time Warner Ent. Co. v. FCC*, 144 F.3d 75, 81 (D.C. Cir. 1998)). Petitioners did not submit a petition for reconsideration to the Commission, and they point to no comments raising their "additional legal considerations" in such a manner as to necessarily indicate to the Commission that they were part of the case presented to it.

Although Petitioners assert that the "Cities of Boston and Philadelphia specifically flagged [the issue of whether FCC regulation preempts rights and remedies under the Americans with Disabilities Act and the Fair Housing Act] and sought clarification," Pet'rs' Br. at 86, they are incorrect. The Cities of Boston and Philadelphia merely observed that the Second Circuit's decision in *Cellular Phone Taskforce* did not address whether "'electrosensitivity' [is] a cognizable disability under the Americans with Disabilities Act," J.A. 4,598. And the Cities noted that "the FCC and its sister regulatory agencies share responsibility for adherence to the ADA," J.A. 4,598–99, and urged the Commission to "lead in advice to electrosensitive persons about prudent avoidance," J.A. 4,599. This did not put the Commission on notice that the question whether FCC regulation preempts rights and remedies under the Americans with Disabilities Act and the Fair Housing Act was part of the case presented to it. Nor did a comment asserting that "[t]he telecommunications Act should not be interpreted to injure an identifiable segment of the population, exile them from their homes and their city, leave them no place where they can survive, and allow them no remedy under City, State or Federal laws or constitutions." J.A. 10,190. And Petitioners point to no comments that did a better job of flagging their other "additional legal considerations" for the Commission. The Commission therefore did not have an opportunity to pass on

these arguments, so we may not review them. 47 U.S.C. § 405(a).

C.

Petitioners also argue that NEPA required the Commission to issue an EA or EIS regarding its decision to terminate its notice of inquiry.

Petitioners are wrong. The Commission was not required to issue an EA or EIS because there was no ongoing federal action regarding its RF limits. The Commission already published an assessment of its existing RF limits that "'functionally' satisfied NEPA's requirements 'in form and substance.'" *EMR Network*, 391 F.3d at 272 (quoting *Cellular Phone Taskforce*, 205 F.3d at 94–95). NEPA obligations attach only to "proposals" for major federal action. *See* 42 U.S.C. § 4332(c); *see also* 40 C.F.R. § 1502.5. Once an agency has satisfied NEPA's requirements, it is only required to issue a supplemental assessment when "there remains major federal action to occur." *W. Org. of Res. Councils v. Zinke*, 892 F.3d 1234, 1242 (D.C. Cir. 2018) (internal quotation marks omitted) (quoting *Marsh v. Ore. Nat'l Res. Council*, 490 U.S. 360, 374 (1989)). An agency's promulgation of regulations constitutes a final agency action that is not ongoing. *Id.* at 1243. Once an agency promulgates a regulation and complies with NEPA's requirements regarding that regulation, it is not required to conduct any supplemental environmental assessment, *even if* its original assessment is outdated. *Id.* at 1242. Such is the case here. As we explained in *EMR Network* in response to the argument that new data required the Commission to issue a supplemental environmental assessment of its RF guidelines under NEPA, "the regulations having been adopted, there is at the moment no ongoing federal action, and no duty to

supplement the agency's prior environmental inquiries." 391 F.3d at 272 (internal quotation marks and citation omitted).

That the Commission voluntarily initiated an inquiry to "determine whether there is a need for reassessment of the Commission radiofrequency (RF) exposure limits and policies" does not change the analysis. *2013 Notice of Inquiry*, 28 FCC Rcd. at 3,501. As the Supreme Court explained long ago, "the mere contemplation of certain action is not sufficient to require an impact statement" under NEPA, *Kleppe v. Sierra Club*, 427 U.S. 390, 404 (1976) (internal quotation marks omitted), because, as in this case, "the contemplation of a project and the accompanying study thereof do not necessarily result in a proposal for major federal action," *id.* at 406. *See also Pub. Citizen v. Off. of U.S. Trade Representatives*, 970 F.2d 916, 920 (D.C. Cir. 1992) ("In accord with *Kleppe*, courts routinely dismiss NEPA claims in cases where agencies are merely contemplating a particular course of action but have not actually taken any final action at the time of suit.") (collecting cases). Were the Commission to propose revising its RF exposure guidelines, it might be required to prepare NEPA documentation. But since the Commission for now has not proposed to alter its guidelines, it need not yet conduct any new environmental review.

III.

For the reasons given above, we grant the petitions in part and remand to the Commission to provide a reasoned explanation for its determination that its guidelines adequately protect against harmful effects of exposure to radiofrequency radiation unrelated to cancer. It must, in particular, (i) provide a reasoned explanation for its decision to retain its testing procedures for determining whether cell phones and other portable electronic devices comply with its guidelines, (ii)

address the impacts of RF radiation on children, the health implications of long-term exposure to RF radiation, the ubiquity of wireless devices, and other technological developments that have occurred since the Commission last updated its guidelines, and (iii) address the impacts of RF radiation on the evironment. To be clear, we take no position in the scientific debate regarding the health and environmental effects of RF radiation—we merely conclude that the Commission's cursory analysis of material record evidence was insufficient as a matter of law. As the dissenting opinion indicates, there may be good reasons why the various studies in the record, only some of which we have cited here, do not warrant changes to the Commission's guidelines. But we cannot supply reasoning in the agency's stead, *see SEC v. Chenery Corp.*, 318 U.S. 80, 87–88 (1943), and here the Commission has failed to provide any reasoning to which we may defer.

So ordered.

KAREN LECRAFT HENDERSON, *Circuit Judge*, dissenting in part: "[A] court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). We thus must "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Id.* (quoting *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974)). I believe my colleagues' limited remand contravenes these first principles of administrative law. Because I would deny the petitions in full, I respectfully dissent from Part II.A.i.–iv. and Part III of the majority opinion.

I.

It is important to emphasize how deferential our standard of review is here—where, first, an agency's decision to terminate a notice of inquiry without initiating a rulemaking occurred after the agency opened the inquiry on its own and, second, the inquiry involves a highly technical subject matter at the frontier of science. As the majority recognizes, "[t]he arbitrary and capricious standard of the Administrative Procedure Act 'encompasses a range of levels of deference to the agency.'" Maj. Op. 8 (quoting *Am. Horse Prot. Ass'n v. Lyng*, 812 F.2d 1, 4 (D.C. Cir. 1987)). The majority further acknowledges that the Federal Communications Commission's (Commission or FCC) "order is entitled to a high degree of deference." *Id.* at 9. And our precedent also makes plain that "[i]t is only in the rarest and most compelling of circumstances that this court has acted to overturn an agency judgment not to institute rulemaking." *WWHT, Inc. v. FCC*, 656 F.2d 807, 818 (D.C. Cir. 1981); *see also Cellnet Commc'n, Inc. v. FCC*, 965 F.2d 1106, 1111 (D.C. Cir. 1992) ("an agency's refusal to initiate a rulemaking is evaluated with a deference so broad as to make the process akin to non-reviewability"). For the reasons that follow, I believe the Commission's order does not fit those rarest and most compelling circumstances.

A.

We have held that research articles containing tentative conclusions do not provide a basis for disturbing an agency's decision not to initiate rulemaking. *See EMR Network v. FCC*, 391 F.3d 269, 274 (D.C. Cir. 2004). Nevertheless, the majority rejects reaching the same conclusion here regarding the petitioners' assertion that radiofrequency (RF) radiation exposure below the Commission's limits can cause negative health effects unrelated to cancer. To do so, it relies on five research articles in an over 10,500-page record. *See* Maj. Op. at 10–11.[1]

A close inspection of the five research articles confirms that they also "are nothing if not tentative." *EMR Network*, 391 F.3d at 274. The Foerster article concludes "[o]ur findings *do not provide conclusive evidence* of causal effects and should be *interpreted with caution* until confirmed in other populations." Joint Appendix (J.A.) 6,006 (Milena Foerster et al., *A Prospective Cohort Study of Adolescents' Memory Performance and Individual Brain Dose of Microwave Radiation from Wireless Communication*, 126 ENV'T HEALTH PERSPS. 077007 (July 2018)) (emphases added).[2] The Lai

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[1] "The record in an informal rulemaking proceeding is 'a less than fertile ground for judicial review' and has been described as a 'sump in which the parties have deposited a sundry mass of materials.'" *Pro. Drivers Council v. Bureau of Motor Carrier Safety*, 706 F.2d 1216, 1220–21 (D.C. Cir. 1983) (quoting *Nat'l Res. Def. Council, Inc. v. SEC*, 606 F.2d 1031, 1052 (D.C. Cir. 1979)).

[2] *See also* J.A. 5,995 ("[T]he health effects of [exposure to radiofrequency electromagnetic fields (RF-EMFs)] are still unknown. . . . [T]o date studies addressing this topic have produced inconsistent results."); J.A. 6,005 ("Although we found decreases in figural memory, some experimental and epidemiological studies on

article provides a similarly murky picture of the current science. *See* J.A. 5,320–68 (Henry Lai, *A Summary of Recent Literature (2007–2017) on Neurological Effects of Radiofrequency Radiation*, *in* MOBILE COMMC'NS & PUB. HEALTH 187–222 (M. Markov ed., 2018)). In summarizing the results of human studies on the behavioral effects of RF radiation, the Lai article lists 31 studies that showed *no significant* behavioral effects compared to 20 studies that showed behavioral effects. *See* J.A. 5,327–32. Moreover, of the 20 studies that showed a behavioral effect, at least four found behavioral *improvements*, not negative health effects.

Even the Yakymenko article, which asserts that 93 of 100 peer-reviewed studies found low-intensity RF radiation induces oxidative effects in biological systems, fails to address the critical issue—whether RF radiation below the Commission's current limits can cause negative health effects. *See* J.A. 5,243–58 (Igor Yakymenko et al., *Oxidative Mechanisms of Biological Activity of Low-Intensity Radiofrequency Radiation*, ELECTROMAGNETIC BIOLOGY & MED., EARLY ONLINE, 1–16 (2015)). Specifically, the Yakymenko article discusses the International Commission on Non-Ionizing Radiation Protection's (ICNIRP) recommended RF exposure limit—a specific absorption rate of 2 W/kg. *See* J.A. 5,243–44. But the ICNIRP's recommended RF exposure limit is significantly higher than the Commission's current limit—0.08 W/kg averaged over the whole body and a peak spatial-average of 1.6 W/kg over any 1 gram of tissue. *See* 47 C.F.R. § 1.1310(c). Accordingly, it is uncertain how many, if

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RF-EMF found *improvements* in working memory performance.") (emphasis added).

any, of the referenced peer-reviewed studies were conducted at RF radiation levels below the Commission's current limits.[3]

Given this record, I believe we should have arrived at the same conclusion we did in *EMR Network*—"nothing in th[e]se studies so strongly evidenc[es] risk as to call into question the Commission's decision to maintain a stance of what appears to be watchful waiting." *EMR Network*, 391 F.3d at 274. "An agency is not obliged to respond to every comment, only those that can be thought to challenge a fundamental premise." *MCI WorldCom, Inc. v. FCC*, 209 F.3d 760, 765 (D.C. Cir. 2000). A review of the five articles on which the majority opinion relies makes plain that the articles do not challenge a fundamental premise of the Commission's order. Instead, it "cherry-pick[s] the factual record to reach [its] conclusion." *Ortiz-Diaz v. U.S. Dep't of Hous. & Urb. Dev.*, 867 F.3d 70, 79 (D.C. Cir. 2017) (Henderson, J., concurring in the judgment).

My colleagues assert that "[t]he dissenting opinion portrays this case as about the Commission's disregard of just five articles." Maj. Op. 22. But their attempt to "turn the tables" plainly fails. It is they who chose the five articles, *see* Maj. Op. 10–11, to rely on as the basis for their remand, *see id.* at 15 ("the Commission's order remains bereft of any explanation as to why, *in light of the studies in the record*, its guidelines remain adequate") (emphasis altered); *id.* at 18 ("*the studies in the record* to which Petitioners point *do* challenge a fundamental premise of the Commission's decision to terminate its notice of inquiry") (first emphasis added). I discuss the five articles *only* to demonstrate that the studies "are nothing if not tentative." *EMR Network*, 391 F.3d at 274. Because the studies on which the majority relies plainly are

[3] The BioInitiative Report the majority opinion cites is hardly worth discussing because the self-published report has been widely discredited as a biased review of the science.

tentative, they do not challenge a fundamental premise of the Commission's decision and therefore cannot provide the basis for the majority's limited remand under our precedent.[4]

B.

I reach the same conclusion regarding the majority's remand of the petitioners' environmental harm argument. *See* Maj. Op. 21–22. The majority relies on a 2014 letter from the U.S. Department of the Interior (Interior) to the U.S. Department of Commerce about, *inter alia*, the impact of communications towers on migratory birds. But the Interior letter itself concedes that "[t]o date, no independent, third-party field studies have been conducted in North America on impacts of tower electromagnetic radiation on migratory birds." J.A. 8,383.

Moreover, the petitioners did not raise the Interior letter in the environmental harm section of their briefs. "We apply forfeiture to unarticulated [legal and] evidentiary theories not only because judges are not like pigs, hunting for truffles buried in briefs or the record, but also because such a rule ensures fairness to both parties." *Jones v. Kirchner*, 835 F.3d 74, 83 (D.C. Cir. 2016) (alteration in original) (citation omitted). And finally, the environmental harm studies on which

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[4] The majority's hand wave to other record information, *see* Maj. Op. 22–23, does not carry the day. Rather than provide "substantial information," *id.* at 22, the cited material consists primarily of letters expressing generalized concerns about RF limits worldwide.

the petitioners *did* rely "are nothing if not tentative." *EMR Network*, 391 F.3d at 274.[5]

C.

More importantly, the majority's limited remand runs afoul of our precedent on this precise subject matter. In *EMR Network*, the petitioner asked "the Commission to initiate an inquiry on the need to revise [its] regulations to address the non-thermal effects" of RF radiation. 391 F.3d at 271. In denying the petition, we concluded "the [Commission]'s decision not to leap in, at a time when the [Environmental Protection Agency (EPA)] (and other agencies) saw no compelling case for action, appears to represent the sort of priority-setting in the use of agency resources that is least subject to second-guessing by courts." *Id.* at 273.

This time around, the majority faults the Commission for the U.S. Food and Drug Administration's (FDA) allegedly "conclusory statements" in response to the Commission's 2013 notice of inquiry. *See* Maj. Op. 14. The crux of the majority's position is that "[t]he statements from the FDA on which the Commission's order relies are practically identical to the Secretary's statement in *American Horse* and the

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[5] *See, e.g.*, J.A. 5,231 (Albert Manville, II, *A Briefing Memorandum: What We Know, Can Infer, and Don't Yet Know about Impacts from Thermal and Non-Thermal Non-Ionizing Radiation to Birds and Other Wildlife* 2 (2016)) ("the direct relationship between electromagnetic radiation and wildlife health continues to be complicated and in cases involving non-thermal effects, still unclear"); J.A. 6,174 (Ministry of Env't & Forest, Gov't of India, *Report on Possible Impacts of Communication Towers on Wildlife Including Birds and Bees* 4 (2011)) ("exact correlation between radiation of communication towers and wildlife, are not yet very well established").

Commission's statement in *American Radio*." *Id.*[6] But the analogy to *American Horse* and *American Radio* does not hold water. The majority's Achilles' heel is the fact that the Commission and the FDA are, to state the obvious, distinct agencies.

In *American Horse*, the appellant relied on the results of a study commissioned by the U.S. Department of Agriculture (Agriculture) to support its request for revised Agriculture regulations. *Am. Horse*, 812 F.2d at 2–3. The study found that devices Agriculture had declined to prohibit caused effects falling within the statutory definition of the condition known as "sore";[7] and the Congress had charged Agriculture to eliminate the practice of soring show horses. *Am. Horse*, 812 F.2d at 2–3. Against this backdrop, we found the Agriculture Secretary's "two conclusory sentences [dismissing the need to revise agency regulations] . . . insufficient to assure a reviewing court that the agency's refusal to act was the product of reasoned decisionmaking." *Id.* at 6. But an agency head's terse dismissal of his own agency's study is not the case here. First, as noted *supra*, there is no conclusive study in the record, much less one commissioned by the agency whose regulations are being considered for revision. Instead, the record contains dozens of highly technical studies from various sources—the credibility and findings of which we are ill-equipped to evaluate. And crucially, unlike in *American Horse*, the Commission requested the opinion of the FDA—the agency charged with "establish[ing] and carry[ing] out an electronic

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[6] *See Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227 (D.C. Cir. 2008).

[7] *See* 15 U.S.C. § 1821(3) ("The term 'sore' when used to describe a horse means that [as a result of any substance or device used on a horse's limb] such horse suffers, or can reasonably be expected to suffer, physical pain or distress, inflammation, or lameness when walking, trotting, or otherwise moving . . . .").

product radiation control program," 21 U.S.C. § 360ii(a)—studied that opinion and explained why it relied thereon in making its decision.

Similarly, in *American Radio*, the studies summarily dismissed by the FCC were studies the FCC sought to evaluate *itself*; we remanded for the FCC to explain why it failed to do so. *See Am. Radio*, 524 F.3d at 241. Moreover, *American Radio* addressed the reasoning underlying the FCC's *promulgation* of a rule, an action subjected to far less deference than an agency's decision not to initiate a rulemaking.[8]

I believe the Commission reasonably relied on the conclusions of the FDA, the agency statutorily charged with protecting the public from RF radiation. *See* 21 U.S.C. § 360ii(a) (FDA "shall establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation").[9] Our precedent is well-settled that "[a]gencies can be expected to 'respect [the] views of such other agencies as to those

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[8] *See, e.g.*, *ITT World Commc'ns, Inc. v. FCC*, 699 F.2d 1219, 1245–46 (D.C. Cir. 1983), *rev'd on other grounds*, 466 U.S. 463 (1984) ("Where an agency promulgates rules, our standard of review is diffident and deferential, but nevertheless requires a searching and careful examination of the administrative record to ensure that the agency has fairly considered the issues and arrived at a rational result. Where, as here, an agency chooses *not* to engage in rulemaking, our level of scrutiny is even more deferential . . ." (emphasis in original) (footnotes and internal quotations omitted)).

[9] *See also In re Guidelines for Evaluating the Env't Effects of Radiofrequency Radiation*, 11 FCC Rcd. 15,123, 15,130 ¶ 18 (1996) ("The FDA has general jurisdiction for protecting the public from potentially harmful radiation from consumer and industrial devices and in that capacity is expert in RF exposures that would result from consumer or industrial use of hand-held devices such as cellular telephones.").

problems' for which those 'other agencies are more directly responsible and more competent.'" *City of Bos. Delegation v. FERC*, 897 F.3d 241, 255 (D.C. Cir. 2018) (second alteration in original) (quoting *City of Pittsburgh v. Fed. Power Comm'n*, 237 F.2d 741, 754 (D.C. Cir. 1956)). That is precisely what the Commission did here.

The Commission's *2013 Notice of Inquiry* explained that the Commission intended to rely on, *inter alia*, the FDA to determine whether to reassess its own RF exposure limits. *See In re Reassessment of Fed. Commc'ns Comm'n Radiofrequency Exposure Limits & Policies*, 28 FCC Rcd. 3,498, 3,501 ¶ 6 (2013) (*2013 Notice of Inquiry*) ("Since the Commission is not a health and safety agency, we defer to other organizations and agencies with respect to interpreting the biological research necessary to determine what [RF radiation] levels are safe."). And the Commission has consistently deferred to expert health and safety agencies in this context. *See id.* at 3,572 ¶ 211 (RF exposure limits adopted in 1996 "followed recommendations received from the [EPA], the [FDA], and other federal health and safety agencies").[10]

The Commission was true to its word. On March 22, 2019, it asked the FDA if changes to the RF exposure limits were

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[10] *See also In re Guidelines for Evaluating the Env't Effects of Radiofrequency Radiation*, 12 FCC Rcd. 13,494, 13,505 ¶ 31 (1997) ("It would be impracticable for us to independently evaluate the significance of studies purporting to show biological effects, determine if such effects constitute a safety hazard, and then adopt stricter standards that [sic] those advocated by federal health and safety agencies. This is especially true for such controversial issues as non-thermal effects and whether certain individuals might be 'hypersensitive' or 'electrosensitive.'").

warranted by the current scientific research.[11] On April 24, 2019, the FDA responded:

> FDA is responsible for the collection and analysis of scientific information that may relate to the safety of cellphones and other electronic products. . . . As we have stated publicly, . . . the available scientific evidence to date does not support adverse health effects in humans due to exposures at or under the current limits, and . . . the FDA is committed to protecting public health and continues its review of the many sources of scientific literature on this topic.

J.A. 8,187 (Letter from Jeffrey Shuren, M.D., J.D., Dir., Ctr. for Devices and Radiological Health, U.S. Food & Drug Admin., Dep't of Health & Hum. Servs., to Julius Knapp, Chief, Off. of Eng'g & Tech., U.S. Fed. Commc'ns Comm'n (April 24, 2019)).[12] In my view, the Commission, relying on

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[11] *See* J.A. 8,184 (Letter from Julius Knapp, Chief, Off. of Eng'g & Tech., U.S. Fed. Commc'ns Comm'n, to Jeffrey Shuren, M.D., J.D., Dir., Ctr. for Devices and Radiological Health, U.S. Food & Drug Admin. (March 22, 2019)) ("Given that existing studies are continually being evaluated as new research is published, and that the work of key organizations such as [the Institute of Electrical and Electronics Engineers] and ICNIRP is continuing, we ask FDA's guidance as to whether any changes to the standards are appropriate at this time.").

[12] *See also Statement from Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health on the recent National Toxicology Program draft report on radiofrequency energy exposure*, FOOD & DRUG ADMIN. (Feb. 2, 2018), https://www.fda.gov/news-events/press-announcements/statement-jeffrey-shuren-md-jd-director-fdas-center-devices-and-radiological-health-recent-national (Since 1999, "there have been hundreds of

the FDA, reasonably concluded no changes to the current RF exposure limits were warranted at the time. *See In re Reassessment of Fed. Commc'ns Comm'n Radiofrequency Exposure Limits & Policies*, 34 FCC Rcd. 11,687, 11,691 ¶ 10 (2019) (*2019 Order*).

Simply put, the Commission's reliance on the FDA is reasonable "[i]n the face of conflicting evidence at the frontiers of science." *See Cellular Phone Taskforce v. FCC*, 205 F.3d 82, 90 (2d Cir. 2000). The majority takes issue with what it categorizes as "conclusory statements." Maj. Op. 14. But the Supreme Court's "*State Farm* [decision] does not require a word count; a short explanation can be a reasoned explanation." *Am. Radio*, 524 F.3d at 247 (Kavanaugh, J., dissenting in part). Brevity is even more understandable if the agency whose rationale is challenged relies on the agency the Congress has charged with regulating the matter.

Granted, "[w]hen an agency in the Commission's position is confronted with evidence that its current regulations are inadequate or the factual premises underlying its prior judgment have eroded, it must offer more to justify its decision to retain its regulations than mere conclusory statements." Maj.

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studies from which to draw a wealth of information about these technologies which have come to play an important role in our everyday lives. Taken together, all of this research provides a more complete picture regarding radiofrequency energy exposure that has informed the FDA's assessment of this important public health issue, and given us the confidence that the current safety limits for cell phone radiation remain acceptable for protecting the public health. . . . I want to underscore that based on our ongoing evaluation of this issue and taking into account all available scientific evidence we have received, we have not found sufficient evidence that there are adverse health effects in humans caused by exposures at or under the current radiofrequency energy exposure limits.").

Op. 9. But the majority opinion rests on an inaccurate premise—the Commission was not confronted with evidence that its regulations are inadequate nor have the factual premises underlying its RF exposure limits eroded. Sifting through the record's technical complexity is outside our bailiwick. If the record here establishes one point, however, it is that there is no scientific consensus regarding the "non-thermal" effects, if any, of RF radiation on humans. More importantly, the FDA, not the Commission, made the allegedly "conclusory statements" with which the majority takes issue and I believe the Commission adequately explained why it relied on the FDA's expertise.[13]

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[13] The majority asserts that "[o]ne agency's unexplained adoption of an unreasoned analysis just compounds rather than vitiates the analytical void." Maj. Op. 24. As set out *supra*, however, the Commission adequately explained its reliance—for the past 25 years—on the FDA's RF exposure expertise. Plus, after a review of "hundreds of studies," the FDA's conclusion is far from unreasoned. *See supra* note 12. And the two cases to which the majority points are inapposite. *See* Maj. Op. 24 (citing *City of Tacoma v. FERC*, 460 F.3d 53, 76 (D.C. Cir. 2006), and *Ergon-West Virginia, Inc. v. EPA*, 896 F.3d 600, 612 (4th Cir. 2018)). Importantly, unlike these petitions, neither case involves a decision not to initiate a rulemaking. As noted, inaction is reviewed under an especially deferential standard. It would be inappropriate to apply precedent using a less deferential standard to modify the standard applicable here. And finally, the Commission did not "blindly adopt the conclusions" of the FDA. *See City of Tacoma*, 460 F.3d at 76. Nor did it "turn a blind eye to errors and omissions apparent on the face of" the FDA's conclusions. *See Ergon-West Virginia*, 896 F.3d at 612.

The majority's citation to *Bellion Spirits, LLC v. United States*, No. 19-5252 (D.C. Cir. Aug. 6, 2021), is even further afield. First, *Bellion Spirits* addressed a "statutory authority" question—it did not apply arbitrary and capricious review, much less the especially

As in *EMR Network*, the record does not "call into question the Commission's decision to maintain a stance of what appears to be watchful waiting." 391 F.3d at 274. To hold otherwise begs the question: what was the Commission supposed to do? It has no authority over the level of detail the FDA provides in response to the Commission's inquiry. It admits that it does not have the expertise "to interpret[] the biological research necessary to determine what [RF radiation] levels are safe." *2013 Notice of Inquiry*, 28 FCC Rcd. at 3,501 ¶ 6. The Commission opened the *2013 Notice of Inquiry* "as a matter of good government" despite its "continue[d] . . . confidence in the current [RF] exposure limits." *Id.* at 3,570 ¶ 205. If it *had* reached a conclusion contrary to the FDA's, it most likely would have been attacked as *ultra vires*. For us to require the Commission to, in effect, "nudge" the FDA stretches both our jurisdiction as well as its authority beyond recognized limits.

Accordingly, I respectfully dissent from the limited remand set forth in Part II.A.i.–iv. and Part III of the majority opinion.[14]

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deferential standard applicable to a decision not to initiate a rulemaking. *See Bellion Spirits*, slip op. at 13. Second, to the extent *Bellion Spirits* is remotely relevant, I believe it supports my position. There, the Alcohol and Tobacco Tax and Trade Bureau "consulted with [the] FDA on a matter implicating [the] FDA's expertise and then considered that expertise in reaching its own final decision." *Id.* at 14. Again, in my view, the Commission did the same thing.

[14] Although I join Part II.B. of the majority opinion, I do not agree with the majority's aside, contrasting the Commission's purported silence regarding non-cancerous effects and its otherwise reasoned response. *See* Maj. Op. 26. As explained *supra*, I believe the Commission reasonably relied on the FDA's conclusion that RF radiation exposure below the Commission's limits does not cause negative health effects—cancerous or non-cancerous.

Transmission of SARS-CoV-2 Delta variant among vaccinated healthcare workers, Vietnam

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ABSTRACT

Background: Data on breakthrough SARS-CoV-2 Delta variant infections are limited.

Methods: We studied breakthrough infections among healthcare workers of a major infectious diseases hospital in Vietnam. We collected demographics, vaccination history and results of PCR diagnosis alongside clinical data. We measured SARS-CoV-2 (neutralizing) antibodies at diagnosis, and at week 1, 2 and 3 after diagnosis. We sequenced the viruses using ARTIC protocol.

Findings: Between 11th–25th June 2021 (week 7–8 after dose 2), 69 healthcare workers were tested positive for SARS-CoV-2. 62 participated in the clinical study. 49 were (pre)symptomatic with one requiring oxygen supplementation. All recovered uneventfully. 23 complete-genome sequences were obtained. They all belonged to the Delta variant, and were phylogenetically distinct from the contemporary Delta variant sequences obtained from community transmission cases, suggestive of ongoing transmission between the workers. Viral loads of breakthrough Delta variant infection cases were 251 times higher than those of cases infected with old strains detected between March-April 2020. Time from diagnosis to PCR negative was 8–33 days (median: 21). Neutralizing antibody levels after vaccination and at diagnosis of the cases were lower than those in the matched uninfected controls. There was no correlation between vaccine-induced neutralizing antibody levels and viral loads or the development of symptoms.

Interpretation: Breakthrough Delta variant infections are associated with high viral loads, prolonged PCR positivity, and low levels of vaccine-induced neutralizing antibodies, explaining the transmission between the vaccinated people. Physical distancing measures remain critical to reduce SARS-CoV-2 Delta variant transmission.

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RESEARCH IN CONTEXT

Evidence before this study

We conducted a literature search of PubMed Central for studies or reports of SARS-CoV-2 breakthrough infections up to 1st August 2021. We used the terms "breakthrough Delta variant infection", "Delta variant breakthrough infection" and "SARS-CoV-2 breakthrough infections" without language restriction. We identified 14 relevant scientific papers including one published in medRxiv. Of these, only the medRxiv paper described 6 cases of breakthrough Delta variant infections. Of the remaining 12, 10 described breakthrough infections associated with non-Delta variants of concerns (Alpha, Beta and Gama variants).

None of the above mentioned studies described the transmission between vaccinated people, while one study reported the transmission between vaccinated people and household members. Likewise, there was only one paper comparing the viral loads between fully vaccinated and partially vaccinated individuals with breakthrough Alpha variant infection and found no difference between the two group. And there was one paper comparing the viral load between vaccinated and unvaccinated people infected with the Alpha variant but found no difference in viral load between the two groups. Only one paper had follow-up data on PCR testing after infection and found low viral loads and short duration of viral shedding (2-7 days) in cases of breakthrough infections without information about the causal variant. Most recently, a study in Israel identified a correlation between neutralizing antibody titers after the second dose and at diagnosis and break through infection. The causal variant was the Alpha variant.

Added value of this study

We studied 62 breakthrough cases among healthcare workers of a major hospital for infectious diseases in Ho Chi Minh City (HCMC), Vietnam between 11th-25 June 2021. We captured the infected cases at a very early phase of the infection and carefully followed them up during hospitalization to assess the kinetic of viral loads and neutralizing antibodies, and the development of clinical symptoms. To dissect the epidemiological link and the transmission potential between the vaccinated healthcare workers, we conducted whole genome sequencing of SARS-CoV-2.

49/62 case patients were (pre)symtomatic) and all recovered uneventfully. A total of 23 complete genome sequences were obtained from the breakthrough cases. The obtained sequences were all belonged to the Delta variant, but distinct from contemporary sequences obtained from cases of community transmission in HCMC, suggesting that the ongoing transmission had occurred between vaccinated healthcare workers. Viral loads peaked at around 2-3 days before and after the development of clinical symptoms with prolonged PCR positivity of up to 33 days. Viral loads were 251 times higher than those in cases infected with old SARS-CoV-2 strains detected in Vietnam between March and April 2020. Vaccine-induced neutralizing antibodies after the second dose and at diagnosis were lower than those in the matched uninfected controls. There was no correlation between vaccine-induced neutralizing antibody levels and viral loads (i.e. infectivity) or the development of symptoms during the course of infection.

Implications of all the available evidence

Our study provided strong evidence demonstrating for the first time the transmission between vaccine breakthrough cases infected with the Delta variant. High viral loads coupled with prolonged PCR positivity and poorly ventilated indoor setting without in-

94 office mask wearing might have facilitated the transmission between vaccinated healthcare
95 workers. The absence of correlation between neutralizing antibody levels and peak viral
96 loads suggested that vaccine might not lower the infectivity of breakthrough cases. Given
97 the rapid spread of the Delta variant worldwide, physical distancing measures remain
98 critical to reduce the transmission of SARS-CoV-2 Delta variant, event in countries where
99 vaccination coverage is high.

INTRODUCTION

SARS-CoV-2 Delta variant is approximately 60% more transmissible than the Alpha (B.1.1.7) variant, and has rapidly spread worldwide[1], posing a significant threat to global COVID-19 control. The Delta variant possesses mutations in the spike protein (including L452R and T478K) that makes the virus less susceptible to neutralizing antibodies generated by current vaccines or natural infection.[2,3] This has raised concern about vaccine escape potential.

Data on vaccine breakthrough infections, especially those caused by the Delta variant, are limited.[4] Likewise, it remains unknown regarding the transmission potential of vaccine breakthrough infection cases, especially those infected with the Delta variant. These data however are critical to informing the development and deployment of COVID-19 vaccine, and the implementation of infection control measures. Here, we investigate breakthrough SARS-CoV-2 Delta variant infections among double-vaccinated healthcare workers of a major infectious diseases hospital in Ho Chi Minh City (HCMC), Vietnam.

MATERIALS AND METHODS

Setting

The study was conducted at the Hospital for Tropical Diseases (HTD) in HCMC. HTD is a 550-bed tertiary referral hospital for patients with infectious diseases in southern Vietnam.[5] The hospital has around 900 members of staff and 34 departments. All offices, except one, one are equipped with air conditioners that recirculate the air without mechanical ventilation (Supplementary Figure 1).

HTD staff members were amongst the first people in Vietnam to be offered the Oxford-AstraZeneca COVID-19 vaccine. The first doses were given on 8th March 2021; the second doses were given in the last two weeks of April 2021.[6]

Data collection

We collected demographics, vaccination history and clinical data alongside the results of SARS-CoV-2 PCR diagnosis from the study participants. For SARS-CoV-2 antibody measurement, we obtained 2ml of EDTA plasma from each study participants at diagnosis and at week 1, 2 and 3 after admission.

Nasopharyngeal-throat swab collection, PCR testing and viral load conversion

Nasopharyngeal swabs were collected and placed in 1mL of viral transport medium, and 200uL was used for viral RNA extraction using the MagNApure 96 platform (Roche Diagnostics, Germany), according to the manufacturer's instructions. For SARS-CoV-2 RNA detection, we used real-time RT-PCR assay with primers and probe targeted at the envelope protein-coding gene (TIB MOLBIOL)[7]. PCR Ct values were converted to RNA loads using an in-house established formula ($y = -0.3092x + 12.553$, $R^2 = 0.9963$, where y is viral load and x is Ct value) based on 10-fold dilution series of in-vitro transcribed RNA[7,8].

Whole genome sequencing and sequence analysis

Whole-genome sequences of SARS-CoV-2 were directly obtained from leftover RNA after PCR testing using ARTIC protocol and Illunina reagents on a MiSeq platform with the inclusion of a negative control in every sequencing run. The obtained reads from individual samples were mapped to a SARS-CoV-2 reference genome (GISIAD sequence ID: EPI_ISL_1942165) to generate the consensuses using Geneious software (Biomatter, New

Zealand). SARS-CoV-2 variant assignment was carried out using Pangolin.[9] Detection of amino acid changes as compared to the original Wuhan strain was done using COV-GLUE.[10] Maximum likelihood phylogenetic tree was reconstructed using IQ-TREE.[11]

SARS-CoV-2 antibody measurement

We measured antibodies against SARS-CoV-2 nucleocapsid (N) protein using Elecsys Anti-SARS-CoV-2 assay (Diagnostics, Germany), and SARS-CoV-2 neutralizing antibodies using SARS-CoV-2 Surrogate Virus Neutralization Test (sVNT) (GenScript, USA).[12] The experiments were carried according to the manufacturers' instructions.

Additional data for analysis

Because the breakthrough infections coincided with the sampling schedule at month 3 after dose 1 (week 7 after the second dose) of the vaccine study,[6] we used available data on neutralizing antibodies of the vaccine study for case-control analyses. We matched cases with the controls for age and gender with a matching ratio of 1:3 (when data of the controls are available) or 1:1 (when data of the controls are limited).

For viral load comparison, we used previously reported data of SARS-CoV-2 infected cases detected in Vietnam during the early phase of the pandemic in Vietnam between March and April 2020.[5]

Data analysis

Data analysis was carried in Graphpad Prims 9.0.2. For comparisons between groups, we used the Fisher exact test or the Mann-Whitney U test. We performed linear regression analysis to assess the correlation between neutralizing antibody levels at diagnosis and peak viral loads.

Ethics

The study was approved by the Institutional Review Board of HTD and the Oxford Tropical Research Ethics Committee, University of Oxford, UK. Written informed consents were obtained from all the participants.

RESULTS

The outbreak and initial investigations

On 11th June 2021 (week 7 after the second dose), a 41-year old member of HTD staff (patient 1) complained of body pain and tiredness. Because community transmission of SARS-CoV-2 has been increasing in HCMC since May 2021, he was tested that day and found to be positive for SARS-CoV-2 (PCR Ct value: 18.5 (equivalent to $\log_{10}$ viral load of 8.5 copies per mL)). PCR screening for SARS-CoV-2 was then expanded to all hospital staff and was completed by the end of 12th June 2021. A total of 52 additional members were found positive, including all 6 members sharing an office with patient 1 (Figure 1 and Supplementary Figure 1).

Following Vietnamese Government recommendations, HTD was locked down for two weeks (12th-26th June 2021), with no one allowed to enter or leave the hospital. Further PCR testing of all staff during this period identified 16 additional positive cases, totaling 69 infected members from 19/34 departments (Figure 1 and Supplementary Table 1). Serological testing for SARS-CoV-2 N protein antibodies was carried out on 683 members (including those stayed in the HTD during the lockdown and the infected cases) between 14th and 16th June 2021, but none was positive.

Demographics and clinical features

All the 69 members of HTD staff infected with SARS-CoV-2 were isolated for clinical follow up and management at HTD. Apart from patient 1, one additional member

190 presented with symptoms at diagnosis (15th June 2021). Thus only 1 out of the first 53
191 members tested positive between 11th and 12th June 2021 was symptomatic at diagnosis.
192 Sixty-two consented to have their demographics and clinical features reported. Of these,
193 two received one dose, and 60 (including patient 1) were fully vaccinated. The infected
194 cases (29 females and 33 males) were aged between 24-60 years (median 41.5 years).
195 Forty-seven developed respiratory symptoms between 1-15 days (median: 4) after
196 diagnosis. Three had pneumonia on chest x-ray examination. Of these, one required
197 oxygen supplementation for three days. Otherwise, they all were either asymptomatic or
198 mildly symptomatic (Table 1). All those with symptoms recovered uneventfully.

199 **Viral loads**

200 At diagnosis, median PCR Ct value was 31.7 (range: 37.6–14.0), equivalent to $\log_{10}$ copies
201 per mL of 4.5 (range: 2.6–9.9); eleven (20.8%) of the first 53 cases from 5 different
202 departments had high viral loads, median Ct value (range): 17.9 (14.0–22.6), equivalent to
203 $\log_{10}$ copies per mL of 8.7 (range: 7.3–9.9), including patient 1 and 4/6 members sharing
204 the office with him.

205 The viral loads of the 49 (pre)symptomatic cases peaked within 2-3 days before and after
206 symptom onset, with a median Ct value (range) of 16.8 (13.1–36.9), corresponding to $\log_{10}$
207 copies per mL of 9.1 (range: 2.8–10.2) (Figure 2A). During the course of infection, peaks
208 of viral loads measured at any time point of the symptomatic cases were higher than that of
209 asymptomatic cases; 16.5 (13.6–32) vs. 30.8 (13.1–36.9), equivalent to median $\log_{10}$ viral
210 load of 9.2 copies per mL (range: 4.3–10.1) vs. 4.7 copies per mL (range: 2.8–10.2),
211 p=0.005, respectively (Supplementary Figure 2). The median time from diagnosis to PCR
212 negative prior discharge was 21 days (range: 8–33).

213 Compared with peak viral loads of cases infected with old SARS-CoV-2 strains detected in
214 Vietnam between March and April 2020, peak viral loads of breakthrough cases were
215 significantly higher, median log10 viral load in copies per mL (range): 9.1 (range: 2.8–
216 10.2) vs. 6.7 (1.9–9.5), equivalent to 251 times higher for median viral loads. The
217 differences were more profound among symptomatic cases while there was no difference
218 in viral loads among asymptomatic cases between the two groups (Figure 2B).

219 **Whole genome sequencing**

220 A total of 23 whole genome sequences of SARS-CoV-2 were obtained from 35 samples
221 with sufficient viral loads. The obtained sequences were derived from 23 members
222 (including patient 1) of 10 different departments of HTD (Supplementary Table 1). All
223 were assigned to SARS-CoV-2 Delta variant. They were either identical or different from
224 each other by only 1 to 7 nucleotides, but no novel amino acid changes were identified
225 among them. Phylogenetically, the 23 sequences clustered tightly together but were
226 separated from the contemporary Delta variant sequences obtained from cases of
227 community transmission in HCMC (Figure 3), suggestive of ongoing transmission between
228 the vaccinated people.

229 **Antibody development and case-control analyses**

230 A total of 209 plasma samples were collected from the 62 study participants; 61 at
231 diagnosis and week 1, and 57 at week 2 and 31 at week 3 after admission. At diagnosis, all
232 but three had detectable neutralizing antibodies, with comparable levels between
233 (pre)symptomatic and asymptomatic cases (Supplementary Figure 3). Likewise, there was
234 no correlation between neutralizing antibodies at diagnosis and peak viral loads during the
235 course of infection (Figure 4).

236 At week 2 and 3 after diagnosis, neutralizing antibody levels of the case patients
237 significantly increased, and were higher than neutralizing antibody levels measured at
238 week 2 after the second dose of the 62 matched uninfected controls (Supplementary Figure
239 3).

240 Ten patients had data on neutralizing antibodies measured at both two weeks after the
241 second dose and at diagnosis. Neutralizing antibody levels measured at these two time
242 points of the 10 case patients were significantly lower than those in the 30 matched
243 uninfected controls, median % of inhibition (range): 69.4 (13.7-96.3) vs. 91.3 (57.5-97.6),
244 p=0.012 and 59.4 (12.5-95.0) vs. 91.1 (20.9-97.0), p=0.001, respectively (Figure 5).
245 Similarly, the 62 case patients had lower levels of neutralizing antibodies measured at
246 diagnosis than those in the 62 matched uninfected controls, median % of inhibition
247 (range): 68.6 (12.5-97.0) vs. 82.3 (19.3-96.7), p=0.002.

248 The seroconversion rates for antibodies against N protein steadily increased from 0% at
249 baseline to 65% (20/31) at week 3. Asymptomatic patients had slightly lower
250 seroconversion rates than symptomatic patients (Supplementary Figure 4). There was no
251 difference in neutralizing antibodies between the N protein antibody negative and positive
252 groups (data not shown).

253 **DISCUSSION**

254 We studied Oxford-AstraZeneca vaccine breakthrough infections associated with SARS-
255 CoV-2 Delta variant among healthcare workers of a major hospital for infectious diseases
256 in HCMC, Vietnam between 11th and 25th June 2021 (week 7 and 8 after the second dose).
257 62/69 infected cases participated in the clinical study. One required cannula oxygen
258 supplementation for three days but all made full recovery in line with recent reports

regarding the vaccine effectiveness in protecting against severe disease.[13-15] However, we found strong evidence demonstrating for the first time that fully vaccinated healthcare workers could still pass the virus between each other.

Indeed, the 23 whole-genome sequences of SARS-CoV-2 obtained from the infected cases clustered tightly on the phylogenetic tree, but separately from the contemporary Delta variant genomes obtained from cases of community transmission in HCMC. This strongly suggested that these individuals likely caught the virus from a single introduction into the hospital. Additionally, because only 1 out of the first 53 infected cases of the outbreak were symptomatic at diagnosis, presymptomatic and/or asymptomatic transmission had occurred between the vaccinated members of staff of HTD. This was likely attributed to several factors. Firstly, high viral loads, >7 $\log_{10}$ copies per mL, which was strongly correlated with positive culture (i.e. infectiousness),[8,16] was recorded in 11 of the first 53 positive cases of the outbreak at diagnosis. Second, HTD offices are typically equipped with air conditioners without mechanical ventilation systems, a well-known indoor setting that could facilitate the transmission of SARS-CoV-2.[17] Third, mask wearing in the office was not mandatory at the time.

Lower levels of neutralizing antibodies after vaccination and at diagnosis were associated with breakthrough infections in a recent report from Israel,[18] supporting findings of the present study. However, we found no correlation between vaccine-induced neutralizing antibody levels at diagnosis and the development of respiratory symptoms or viral loads (i.e. infectivity). Thus, while neutralizing antibodies might be a surrogate of protection, especially against severe diseases as a whole,[19] they might not be good indicators of disease progression and infectiousness for breakthrough Delta variant infection. The rapid

increase in neutralizing antibodies after infection among cases of the present study in turn suggested that a third dose may improve the immunity and potentially the protection.

At the beginning of the outbreak, none of the HTD members of staff (including the PCR confirmed cases) were tested positive for N-protein antibodies, which only develop in response to whole-virus based vaccine and natural infection. Additionally, between 12th and 14th May 2021, all members of HTD staff were subjected to a periodic testing for SARS-CoV-2 by PCR, but none was positive. The data thus suggested that the infected cases were captured at an early phase of the infection. Therefore, by carefully following up the patients during hospitalization, we have also provided new insights into the natural history of breakthrough Delta variant infections. We found viral loads of breakthrough Delta variant infection cases peaked around 2-3 days before and after the development of symptoms, and were 251 times higher than those of the infected cases detected during the early phase of the pandemic in 2020.[5] Additionally, there has been only one report showing that 9/11 cases of vaccine breakthrough infection had no detectable RNA when retested within 2–7 days after diagnosis.[20] Yet, we found prolonged PCR positivity was up to 33 days in our study participants. These factors might explain the current rapid expansion of the Delta variant, even in the countries with high vaccination coverage.

In summary, we report the transmission SARS-CoV-2 Delta variant among vaccinated health care workers. Breakthrough Delta variant infections are associated with high viral loads, prolonged PCR positivity, and low levels of neutralizing antibodies after vaccination and at diagnosis. These factors coupled with poorly ventilated indoor settings and without mask wearing might have facilitated presymptomatic and/or asymptomatic transmission among the vaccinated workers. Physical distancing measures remain critical to reduce

SARS-CoV-2 Delta variant transmission, thereby mitigating the impact of the ongoing COVID-19 pandemic.

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LEGENDS TO TABLES AND FIGURES

Table 1: Demographics and clinical characteristics of the study participants

Figure 1: Flowchart showing timelines and results of SARS-CoV-2 RT-PCR screening before and during the lockdown (11-25 June 2021)

Notes to Figure 1: *The remaining members of staff were working from home.

Figure 2: Viral load analyses, A) plot outlining kinetics of viral loads in relation to illness onset of the 49 study participants who were either symptomatic or presymtomatic at admission, B) comparison between peak viral loads of breakthrough infections (cases) and those (controls) infected with old SARS-CoV-2 strains detected between March and April 2020 in Vietnam

Notes to Figure 2: Vertical dashed line indicates the time point of illness onset. Horizontal dashed line indicates detection limit of PCR assay. A) Black lines indicates median viral loads, B) black dots represent for whole groups, red dots represent for symptomatic cases and blue dots represent for asymptomatic cases. Peak viral loads comparison between symptomatic and asymptomatic groups of the cases and controls: median $\log_{10}$ viral load in copies per mL (range): 9.2 (4.3–10.1) vs. 6.9 (3.7–9.5), $p<0.001$ and 4.7 (2.8–10.2) vs. 4.9 (1.9–8.6), $p=0.511$.

Figure 3: Maximum likelihood tree illustrating the relatedness between SARS-CoV-2 Delta variant strains obtained from cases of vaccine breakthrough infection (red) and contemporary Delta variant sequences obtained from cases of community transmission in Ho Chi Minh City (blue) and other provinces in Vietnam or countries (black).

Note to Figure 3: Cases of vaccine breakthrough infections were derived from 12/19 affected department of the Hospital for Tropical Diseases

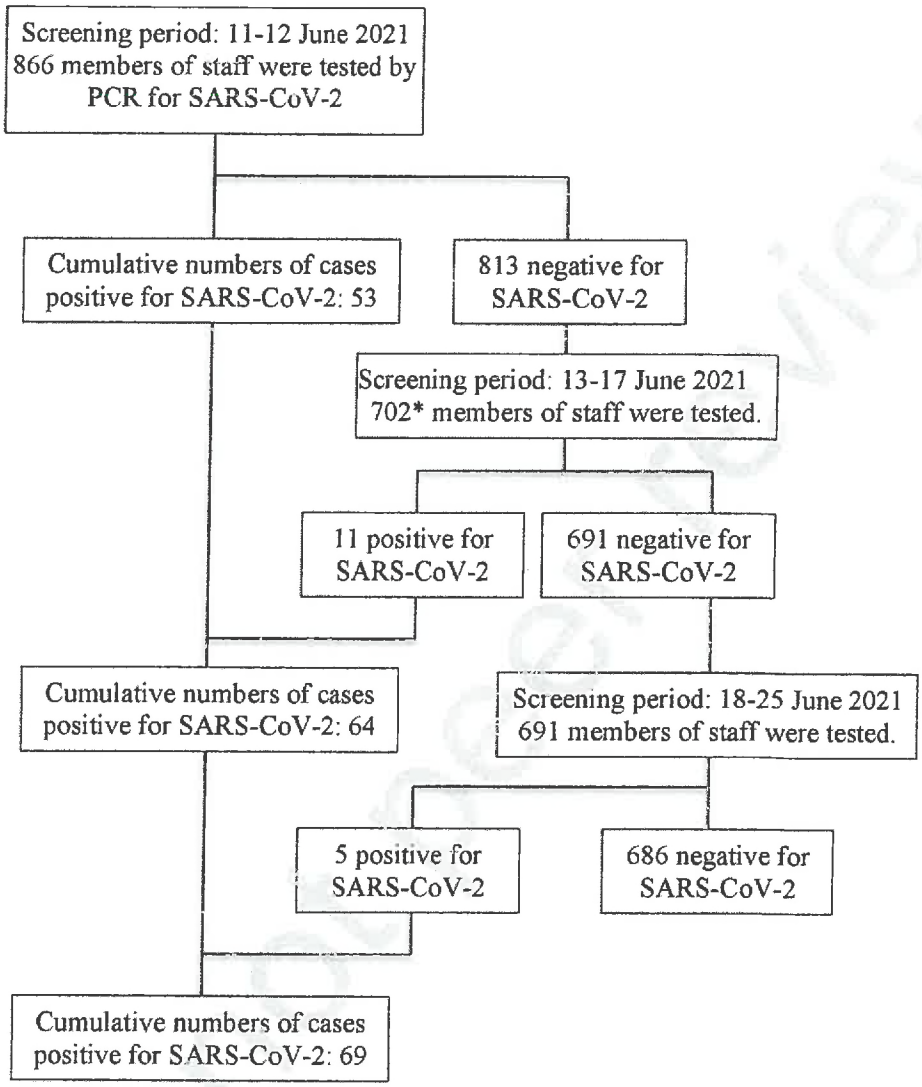
Figure 4: Correlation between neutralizing antibodies at diagnosis and peak viral loads during the course of infection

Figure 5: Comparison between neutralizing antibody levels of case patients (red) and uninfected controls (grey green). A) between the 10 case patients whose data on neutralizing antibodes at both week 2 after the second doses (8 weeks after the first dose) abd at diagnosis were available and the uninfected controls, B) between the 62 case patients and the uninfected controls for data at diagnosis

Table 1: Demographics and clinical characteristics of the study participants

Signs/Symptoms	All cases (n=62)	Male (n=33)	Female (n=29)
Age, y, median (range)	41.5 (24-60)	41 (27-60)	43 (24-59)
Occupation, n (%)			
Nurse	13	5	8
Pharmacist	10	3	7
IT	7	7	0
Clinician	7	5	2
Accountant	4	0	4
Technical staff	3	3	0
Cleaner	2	2	0
Others	16	8	8
Symptomatic, n (%)	49 (79.0)	24 (72.7)	25 (86.2)
PCR diagnosis to illness onset, d, (median; range)*	4 (0-15)	3 (0-8)	5 (0-15)
Comorbidity[#], n (%)	17 (27.4)	9 (27.3)	8 (27.6)
COVID-19 vaccination[¥], n (%)	62 (100)	33 (100)	29 (100)
Two doses	60 (96.7)	33 (100)	27 (93.1)
One dose	2 (3.3)	0	2 (6.9)
Fever, n (%)	17 (27.4)	9 (27.3)	8 (27.6)
Cough, n (%)	23 (37.1)	19 (57.6)	14 (48.3)
Sore throat, n (%)	21 (33.9)	9 (27.3)	12 (41.4)
Runny nose, n (%)	22 (35.5)	9 (27.3)	13 (44.8)
Loss of smell, n %)	24 (38.7)	14 (42.4)	10 (34.5)
Loss of taste, n (%)	5 (8.1)	3 (9.1)	2 (6.9)
Muscle pain, n (%)	17 (27.4)	13 (39.4)	4 (13.8)
Headache, n (%)	12 (19.4)	6 (18.2)	6 (20.7)
Chest pain, n (%)	2 (3.2)	0	2 (6.9)
Nausea, n (%)	5 (8.1)	3 (9.1)	2 (6.9)
Others, n (%)[$]	5 (8.1)	1 (3.0)	4 (13.8)
Pneumonia, n (%)**	3 (4.8)	0	3 (10.3)

Notes to Table 1:
*Symptomatic cases only
[¥]All receiving AstraZeneca vaccine; The second doses were given in last 2 weeks of April 2021.
[#]Overweight (n=6), obese (n=3), hypertension (n=3), hepatitis B (n=2), diabetes (n=1), pregnancy (n=1), diabetes and hepatitis B (n=1).
[$]Chills (n=2), sweating (n=1), giddiness (n=1), red eyes (n=1), and diarrhea (n=1)
**One requiring oxygen supplementation via cannula route for 3 days.



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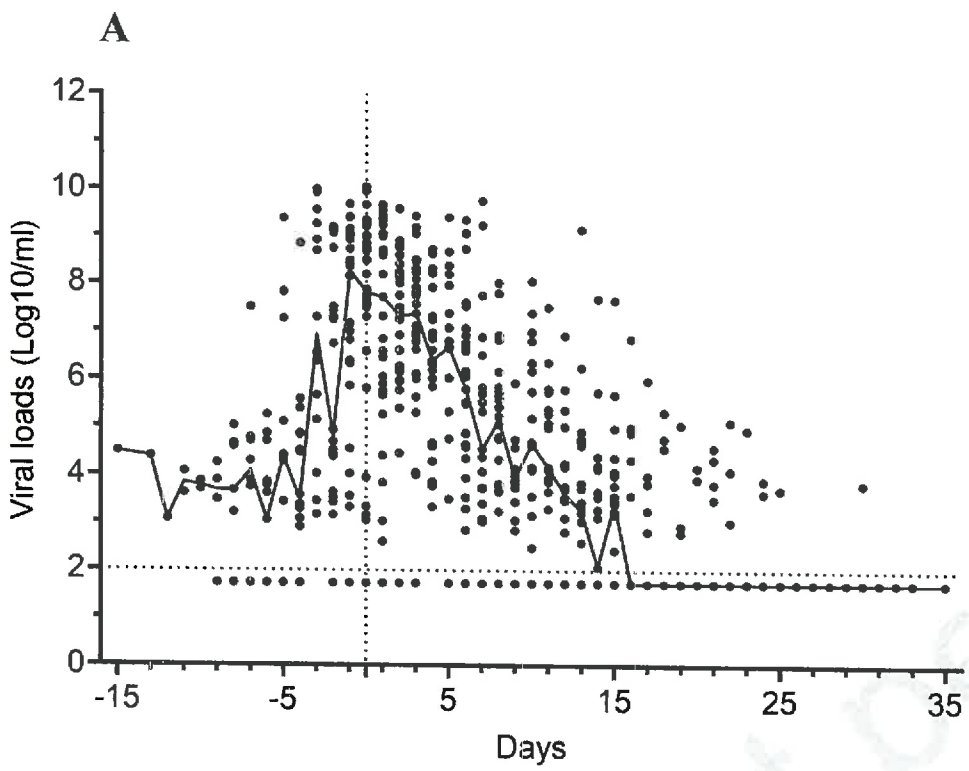

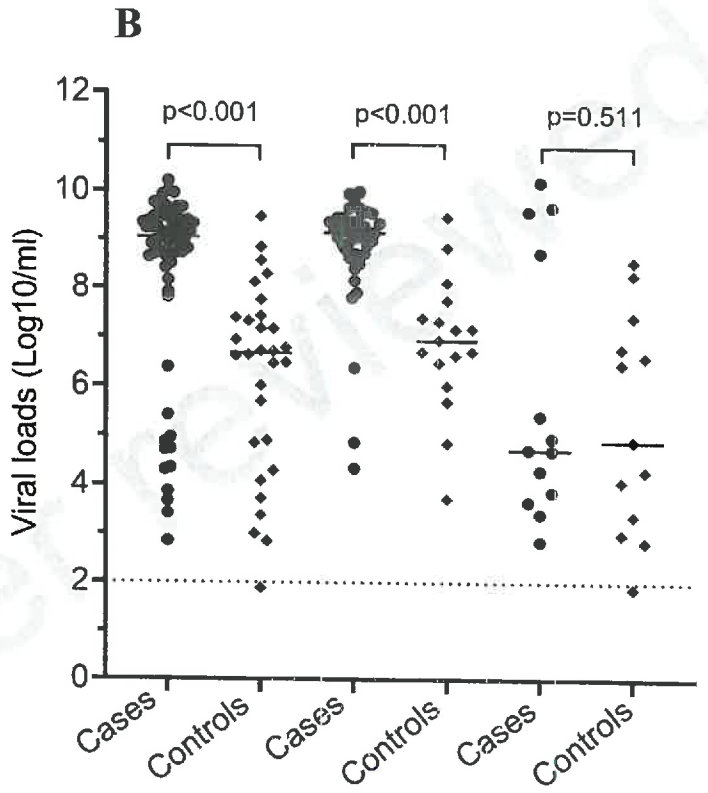

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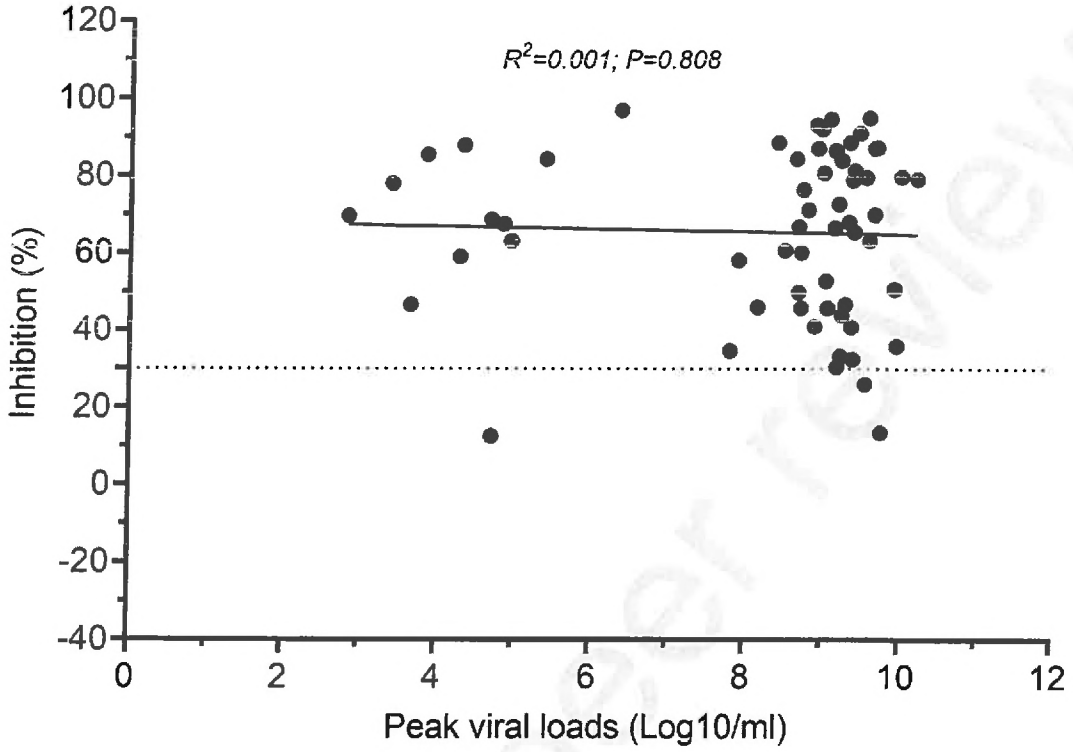


Figure 4: Correlation between neutralizing antibodies at diagnosis and peak viral loads during the course of infection

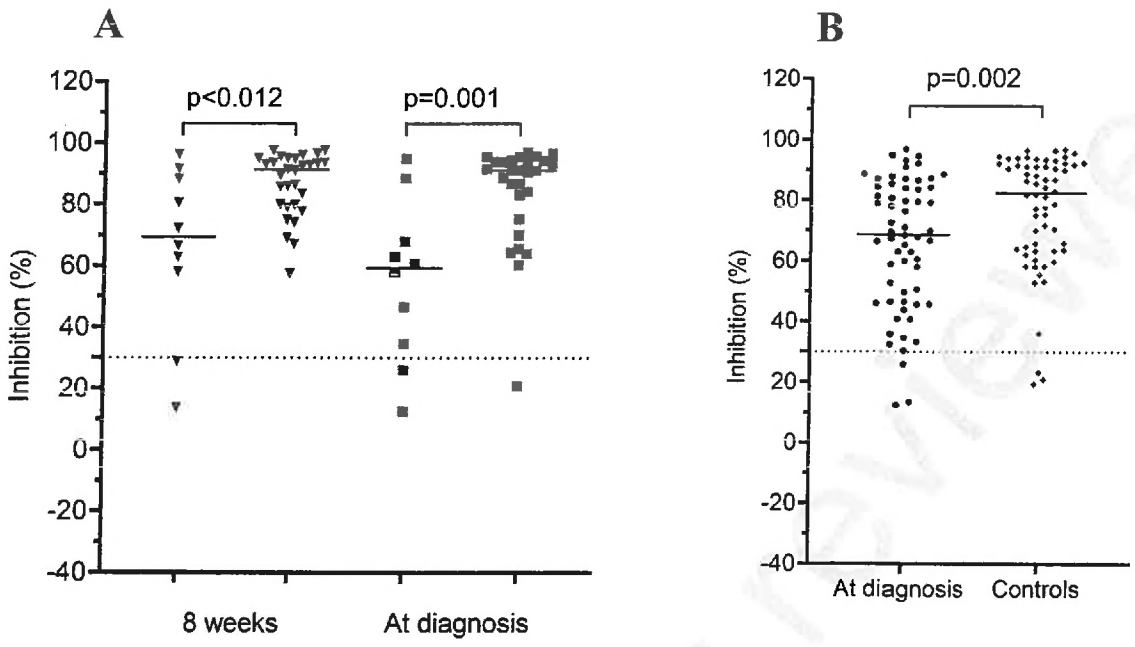
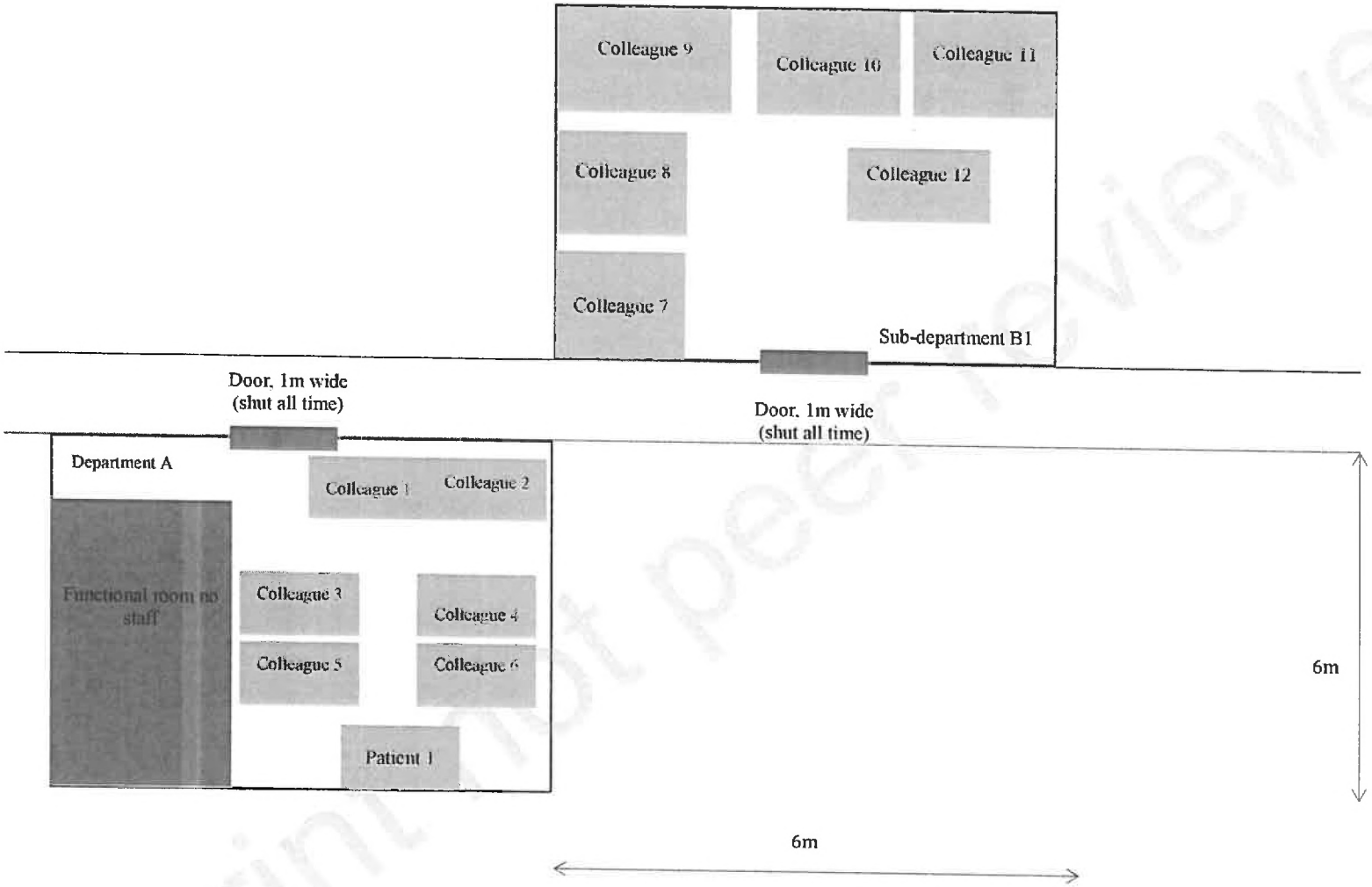


Figure 5: Comparison between neutralizing antibody levels of case patients (red) and uninfected controls (grey green). A) between the 10 case patients whose data on neutralizing antibodes at both week 2 after the second doses (8 weeks after the first dose) abd at diagnosis were available and the uninfected controls, B) between the 62 case patients and the uninfected controls for data at diagnosis

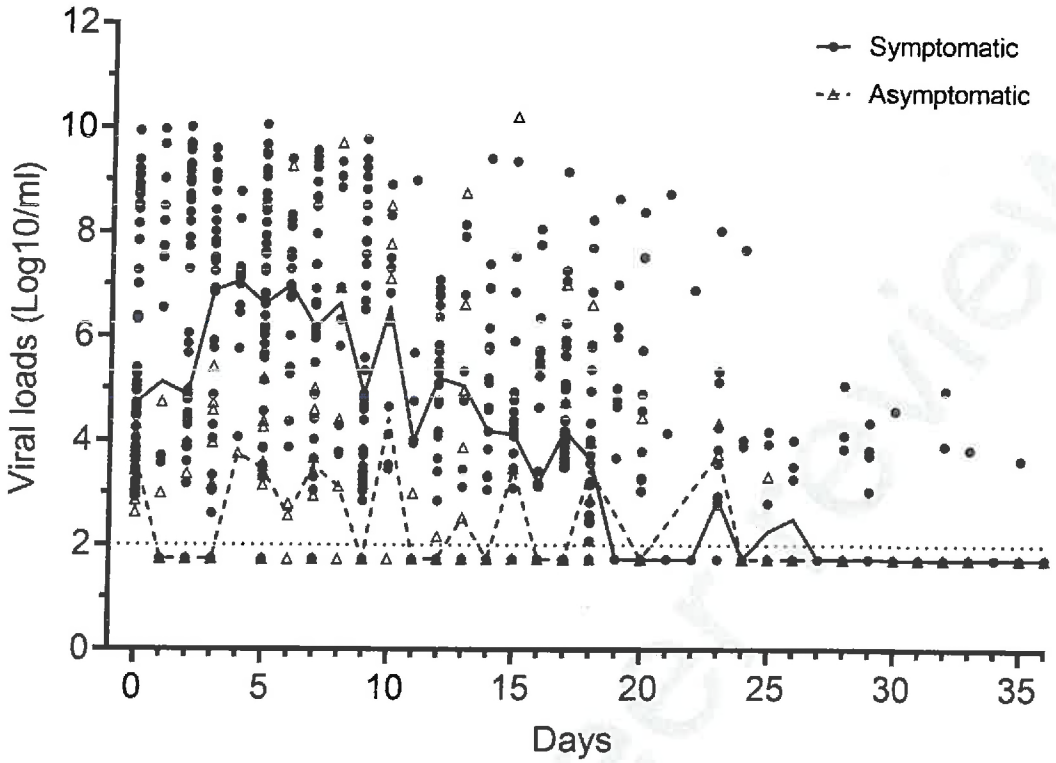
SUPPLEMENTARY MATERIALS

Supplementary Table 1: Numbers of PCR confirmed cases detected per department

Name of department*	Functions	Number of staff	Number of staff tested positive (%)	Numbers genomes obtained
Department A	Supportive service	7	7 (100)	5
Department B	Supportive service	56	16 (29)	6
Sub-department B1	Supportive service	8	7 (88)	6
Sub-department B2	Supportive service	7	4 (57)	0
Sub-department B3	Supportive service	8	3 (38)	0
Sub-department B4	Supportive service	9	2 (22)	0
Department C	Supportive service	3	3 (100)	3
Department D	Supportive service	60	12 (20)	3
Department E	Patient care	75	6 (8)	1
Department F	Supportive service	36	4 (11)	0
Department G	Patient care	50	3 (6)	0
Department H	Supportive service	20	3 (15)	0
Department I	Supportive service	6	2 (33)	1
Department J	Patient care	28	1 (4)	1
Department K	Patient care	31	1 (3)	1
Department L	Patient care	32	1 (3)	0
Department N	Patient care	28	1 (4)	0
Department O	Patient care	19	1 (5)	1
Department P	Patient care	29	1 (3)	0
Department Q	Supportive service	11	1 (9)	0
Department R	Supportive service	15	1 (7)	1
Department S	Patient care	17	1 (5.9)	0
Department T	Patient care	18	1 (5.6)	0

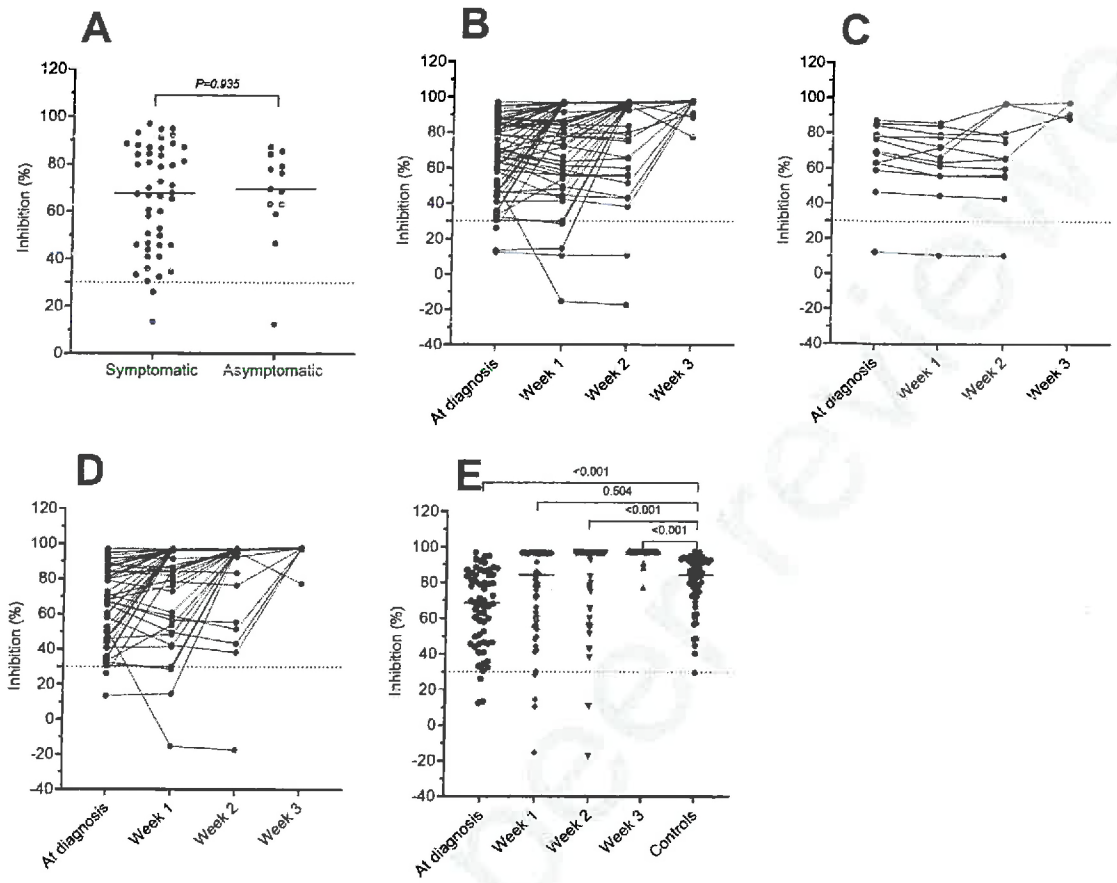


Supplementary Figure 1: Layout of office of patient 1 and a close office where 7/8 members were tested positive on 11th-12th June 2021. Office names are linked with Supplementary Table 1. Offices are equipped with air conditioners without mechanical ventilation. During working hours, doors are kept closed to maintain cooling air.



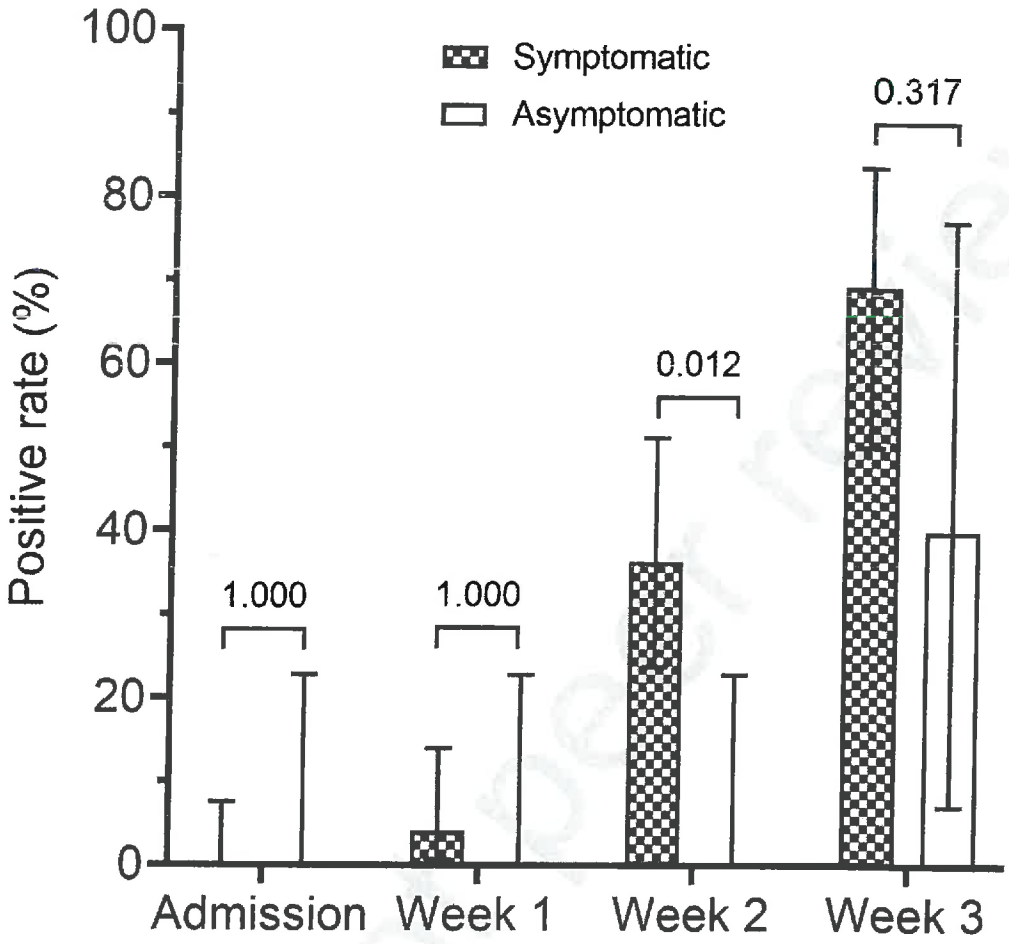
Supplementary Figure 2: Plot outlining kinetics of viral loads since PCR diagnosis during the course of hospitalization of the asymptomatic and symptomatic cases

Notes to Supplementary Figure 2: (Dashed) lines indicate median viral loads.



Supplementary Figure 3: Results of neutralizing antibody measurement, A) at diagnosis of symptomatic (including those developed symptoms after diagnosis) and asymptomatic cases, and kinetics of neutralizing antibodies at admission and at week 1, 2 and 3 after admission of B) the whole group, C) the asymptomatic group, D) the symptomatic group, and E) in comparison with the control group

Supplementary Notes to Figure 3: Dashed line indicates assay cut-off (30%). The asymptomatic case (panel C) who remained seronegative during infection did not respond to the vaccine (data not shown). Neutralizing antibody measurement were repeated twice for the symtomatic case who became seronegative at week 1 and week 2. Age and gender comparison between cases and controls: median in years (ragne): 41.5 (24-60) vs. 37.5 (24-58), p=0.47, and male/female 33/29 vs. 23/29, p=0.07.



Supplementary Figure 4: Seroconverion rates against N protein at admission, and week 1, 2 and 3 after admission.

Note to Supplementary Figure 4: For the whole group, the seroconverstion rates for antibodies against N protein increased from 0% at baseline to 3.3% (2/61) at week 1, 28.1% (16/57) at week 2 and 65% (20/31) at week 3.