From: Thomas Friedrich (Basecamp)

To: Peter Halfmann

Subject: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) There is already a review article...

Date: Sunday, December 12, 2021 4:49:06 PM

...on breakthrough infections, led by Marc Lipsitch, in <u>Nature Reviews Immunology</u>. Looks comprehensive.



You can reply to this email or respond in Basecamp.

This message was sent to Al Bateman, Anna Kocharian, Brittany Grogan, Dave OConnor, Hannah Segaloff, Kasen Riemersma, Katarina Grande, Kelsey Florek, Peter Halfmann, Ryan Westergaard, Sanjib Bhattacharyya, Thomas Friedrich, and Yoshihiro Kawaoka.

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From: Thomas Friedrich (Basecamp)

To: Peter Halfmann

Subject: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Relevant paper in Nature Medicine

Date: Thursday, December 2, 2021 9:45:25 AM

Hi all. I saw this recent <u>brief communication</u> in Nature Med today relevant to our paper. Key passage:

Focusing on the RdRp gene, regression coefficients for vaccinated over unvaccinated, representing the difference in Ct between the groups, started with 4.6 (95% confidence interval (CI), 2.2–6.9) for BTI 7–30 d after the second vaccine dose, yet decayed over time down to 0.6 (95% CI, 0.05–1.12) after about 2 months (P = 0.00005, Methods: 'Change in Ct over time'), and vanished to insignificant values for infections 6 months or longer after vaccination. Analyzing data for up to 34 d after inoculation revealed that this decline, however, was overturned after the booster shot, which was associated with an increase of 2.4 (95% CI, 2.0–2.9) in the Ct.



You can reply to this email or respond in Basecamp.

This message was sent to Al Bateman, Anna Kocharian, Brittany Grogan, Dave OConnor, Hannah Segaloff, Kasen Riemersma, Katarina Grande, Kelsey Florek, Peter Halfmann, Ryan Westergaard, Sanjib Bhattacharyya, Thomas Friedrich, and Yoshihiro Kawaoka.

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To: <u>Peter Halfmann</u>

Subject: Basecamp (University of WI - Madison): Here's the latest activity

Date: Monday, November 29, 2021 9:33:25 AM



University of WI - Madison Here's the latest activity across everything

Since 9am on Sunday, November 28

g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

These messages were posted



Shelby O. posted **Antibody assays**

HI all -- I'm working on the approach for project 2, but I imagine this question will apply to other projects. I need to state how we will measure antibody titers. ELISA assays are one way, but not the only way. Here are my questions: 1. Are we just going to propose ELISA assays? I found a r...





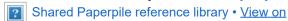
Corrie B. posted Meeting today, 10am

Reminder, we have an all hands meeting today for the submission of the P01. Here is an agenda, feel free to add more agenda items. 1. Administrative Announcements-any info from NIH about approval to submit? 2. Project 1, specific aims updates 10 minutes 3. Project 2, specific aims updates 1...

Something was added to Docs & Files



Thomas F. linked up **Shared Paperpile reference library**



Someone commented on **Shared Paperpile reference library**



Thomas Friedrich

Here's the link in case the button above does not work: https://paperpile.com/shared/GCkrUm

Someone commented on <u>Are there any specific biohazards with aBSL-3</u> that need to be addressed?



Thomas Friedrich

We will need a specific Biohazards section where we describe containment facilities, though. I am sure Amy has relevant boilerplate for IRI.

Someone commented on group paperstack?



Thomas Friedrich

Here's a link to a shared Paperpile reference library: https://paperpile.com/shared/GCkrUm

Someone commented on **Project 3 immune suppression: preliminary data**



Thomas Friedrich

For our future reference, here is an excerpt from one of the Osterhaus group papers describing immune suppressive treatment for ferrets that results in prolonged shedding of influenza virus. Smith Jacqueline Dixon, do the doses given to ferrets sound relevant/proportional to human dosing? "Immuno...

Someone commented on **Specific Aims**



Dave OConnor

Thomas - it is definitely not great, but I vomited out an Aims page for the Overall section.

Someone commented on **Project timeline**



Shelby O'Connor

Dave That is a good question. Actually, I think that last Rituxan dose would be at week 11, or day 77. Personally, I think it would be more cost effective to just stop at day 77 or 80 and I don't think we would lose much scientifically. Basically, I proposed administering Rituxan 1x every 4 we...





Shelby O'Connor

Dave I just fixed the more detailed timeline to reflect the 4 week Rituxan intervals. Sorry I didn't notice that yesterday. [StudyTimeline sampling.pdf]



Someone commented on Research Strategy



Dave OConnor

Thomas - I also vomited out part of a Significance section here and outlined the Innovation and Approach section. Feel free to completely

revise.

People discussed **Antibody assays**

Thomas Friedrich

Shelby we proposed full-virus neut assays as part of Project 3 but on Monday's call decided to put that in the Immunology Core. I think you need neut.

Shelby O'Connor

So, no ELISAs Thomas ??

Shelby O'Connor

Sorry, I have more questions now Thomas. Are you proposing full neut assays or pseudo virus neut assays? And, how will you incorporate the new spike variants that are detected in the long term shedders?

Thomas Friedrich
I would use pseudotype assays to clone the new variant Spike.

Thomas Friedrich

Well, I think there are a few questions here. 1. If a patient/animal is immunocompromised, what is their ability to respond to SARS-CoV-2 infection? Do they make detectable antibodies against the virus? 2. If Spike variants arise in a patient/animal, are they selected by that patient's/animal's ...

Shelby O'Connor

How's about that - you can get a pseudo type kit from BEI:

https://www.beiresources.org/Catalog/BEIPlasmidVectors/NR53816.aspx Also - I agree with your questions. I had written down similar ones in my own notes: 1. Will antibodies generated during early infection detect late Spike proteins? 2...

Nancy Wilson

It would be interesting if the specificity of the antibodies changed during infection after immunosuppression. I would think that the spike protein would remain immunodominant, just lower titer, or perhaps off target as the virus escapes, but I guess that is what we are asking here! The chall...

People discussed Make org chart

Corrie Burmeister

Will do!

Amanda Espinosa

Corrie I made a sheet in the google drive, "P01_2021_tracking" that should help. There are a few highlighted notes that will need to be addressed Dave.

m: Emergence of a globally unique SARS-CoV-2 Spike E484T mutation in a persistently infected immunocompromised individual

People discussed Final Figure Review - Week of Nov. 29th

Dave OConnor

Nick - A few questions: 1. Are we still meeting tomorrow at 11? There isn't a meeting on my calendar? 2. If so, can you please try to get the clinical figure and Peter 's figure before we meet so we can finalize the figures? I know that this is somewhat out of your control, but I don't think i...

Thomas Friedrich

Yes, I think at this point it is better to postpone a day or two to make sure we have all the pieces we need Dave Nick. Luis Gage Kat what do you think?

Dave OConnor

We really need to get these figures finished though - Kat have you been in touch with the clinical folks to get this polished? What is the latest data that we have from this patient? Is there anything new from Mayo Joseph? Peter - I'm losing track of time - when are the assays with the new anti...

Dave OConnor

From Peter: "The four mAbs from Invivogen should arrive this week. With last week being a holiday week, it seems shipping is behind. I will report the results as IC99 values for the two viruses in a table though a heat map could be generated from the data if you wanted to."

m: Shedding of Infectious SARS-CoV-2 Despite Vaccination

People discussed Manuscript update

Katarina Grande

?

Current status is now "under review." Brittany, do we have the data file we need from DHS to gauge what our booster/3rd dose BTs are looking like right now?

Brittany Grogan

We don't, Katarina, but it's something I can pull together manually, just have to download some files from WEDSS. I can work on developing a masterlist of booster breakthroughs today that we can use in the meantime until DHS adds those to our daily files! To be consistent with "regular" breakthro...

Basecamp emails this report every morning. Stop sending it to me.



To: Peter Halfmann

Subject: Basecamp (University of WI - Madison): Here's the latest activity

Date: Tuesday, November 30, 2021 9:17:10 AM



University of WI - Madison Here's the latest activity across everything

Since 9am on Monday, November 29

g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

This was checked off on Resource Sharing Plan

Paste Resource Sharing Plan from previous SIV/SARS-CoV-2 submission into gDoc Assigned to: Dave O.

These were checked off on Facilities and other resources

Add DHO facilities and resources from air sampling P01 Assigned to: Dave O. Add SLO facilities and resources from air sampling P01 Assigned to: Dave O.

These were checked off on **Equipment**

Add DHO equipment from air sampling P01 to gDoc Assigned to: Dave O. Add SLO equipment from air sampling P01 to gDoc Assigned to: Dave O.

These were checked off on Biographical sketches

Shelby O'Connor bio sketch

Should we include scientist biosketches? Assigned to: Amanda E.

This was checked off on **Budget justification**

Copy initial budget justification from pre-proposal to gDoc Assigned to: Dave O.

This was checked off on <u>Authentication of key biological resources</u>

Copy SIV/SARS-CoV-2 authentication document to gDoc to modify Assigned to: Dave O.

This was checked off on **Biographical sketches**

Jens Eickhoff biosketch Assigned to: Corrie B.

These messages were posted



Shelby O. posted <u>T cell assays</u>

Nancy AMY I thought I would start a chat about the T cell assays. Basically, I think we need to know: a. Are there antiviral T cells that exist? b. Are there mutations in SARS-CoV-2 from late-stage infections that are located in T cell epitopes? c. Will known antiviral T cells (from early in i...



Corrie B. posted Meeting notes

Updates - P01 submission, are we approved to submit? Dave emailed Eric Stemy, Program Officer yesterday. No respond as of yet. Biostetch updates, other conceptual developments any barriers? None mentioned. P2 updates: Shelby updated the group and shared timeline.

Aims have changed since last ...

Someone commented on **Antibody assays**



Shelby O'Connor

Nancy yes, we need to do T cell assays. I need a separate discussion for that. Although AMY and I have briefly brought up the topic.

People discussed P1 question: Selection of immunosuppressive drug regimen for NHP?



Jacqueline Garonzik Wang

Hi All - first I want to apologize for being behind on our aims - the holiday week/weekend got a little ahead of me, but I plan to dive back in today and tomorrow re q's 1 - its not unreasonable but its not standard of care. the protocol dixon sent is close to standard of care for our transpla...



Dave OConnor

Thanks Jacqueline (CC:Shelby AMY CHRISTINA DAWN), For Project 2, I think we decided this morning that we'd use Dixon's protocol initially in 3 animals. If that doesn't result in prolonged shedding in 2 of 3 macaques, we'll intensify with Rituxan. Smith also shared the NIH standard protocol wit...

People discussed <u>T cell assays</u>



Nancy Wilson

Disagree that T cell assays are less important than antibody. There was a study of HCW in UK in which pre-existing T cell responses to transcription complex from other previous Coronavirus infections resulted in resistance to SARS CoV2 infection. And, T cell assays are more flexible in that we ...



AMY ELLIS

We can also include markers that are important for B cell help (like CD154/CD40L, and/or ICOS, etc.....) in T cell functional assays. CD154 is already a part of my AIM assay and I can include it in an ICS assay pretty easily, for a "combo" assay (AIM+ICS). Then we can get information about B cel...



Nancy Wilson

That sounds awesome Amy! Would you also add CD20, to easily identify the B cells?



Thomas Friedrich

Rituximab is anti-CD20. If we gave it, would it confound a phenotyping panel?



Nancy Wilson

Absolutely. There will be no B cells. There may be some late stage memory B cells, esp in some compartments like LN, BM, but no B cells circulating. There may also be plasmablasts circulating or in spleen/BM and plasma cells in BM. In hamsters maybe PC in spleen as well, since we have them the...



Nancy Wilson

Also may still be pre-B cells in BM, before CD20 is upregulated. But it will shift the immunophenotyping profoundly. In our Ritux patients, we saw an increase in T cells, but not monocytes, implying disregulation rather than just that we deleted B cells so now we have more B cells in the lympho...

Someone commented on <u>Are there any specific biohazards with aBSL-3 that need to be addressed?</u>



Corrie Burmeister

Added language from Peter here as a launching point. https://docs.google.com/document/d/1ALTYeVIHh8JXQH79xgCx7_rDfy-TPs9G73OyAxZ-D50/edit

People discussed Meeting notes

Shelby O'Connor

Corrie I didn't think I needed to follow up with Hartman or the pharmacy because I thougth Peter was getting leftovers from UHS. Did I misunderstand Peter Dave?

Dave OConnor

?

?

?

?

That is right. For the purposes of the grant, if not reality, we can point to that is how we will get vaccine.

Corrie Burmeister

Oh, yes, sorry! That conversation evolved so both you, Shelby and Dave have no action to take regarding vaccine accessibility for NHP. Peter has the info we need.

Thomas Friedrich

Update on Rituximab -- Buddy said that they give doses ranging from 7 mg/kg to 20 mg/kg in NHP. Peter I would suggest that the IACUC protocol say we will give a single dose of rituximab at 5-25 mg/kg 1-10 days before virus challenge. Does that sound reasonable?

Nancy Wilson

This is the dose our ABMR patients received.... All patients received a single dose of rituximab (375 mg/m2 BSA), IVIG(200 mg/kg every 2 weeks for 3 months) and dexamethasone (100 mg and taper). BSA = body surface area.

People discussed Make org chart

Corrie Burmeister

https://lucid.app/lucidchart/4b431cd3-e06d-4c9c-b832-65b8e28c2090/edit? viewport_loc=-684%2C885%2C6363%2C3335%2Cp2lqPbRw6Nftp&invitationId=inv_54444410-f264-4a16-87db-d56fa87c979d Dave I can work in Visio, however I just outlined the org chart above in the LucidChart b/c that was the platform use...

Dave OConnor

Corrie I can't see the link. I have no problem paying for LucidChart if we need it for a few months

Corrie Burmeister

Boo! I just tried to email you a link. I think you need the OmniGraffle extension downloaded to open Lucid Chart (not sure if you have that). Dave

Dave OConnor

I just had to register. This looks like a good start. Remember that Thomas and I are co-multi PI on the entire thing.

Corrie Burmeister

Okay-thanks! I'll keep at it, and try to pretty it up a bit. Glad you were able to access this.

Someone commented on Add SMPH BSL-3 facilities to gDocs - where are we going to process the tissues from infected anim...

Dave OConnor

I pinged SMPH to fill in the document.

Someone commented on Add WNPRC aBSL-2/aBSL-3 facilities to gDoc

Dave OConnor

Added call-out for this information to the document.

People discussed Jens Eickhoff biosketch

Dave OConnor

Corrie can you follow up with Jens about a bio sketch?

Corrie Burmeister



Yep, Jens will be sending me his biosketch yet today, Dave .

Someone commented on **Biographical sketches**



Corrie Burmeister

Here it is, and has been added to the Admin Core folder. https://docs.google.com/document/d/1bPOYqxEwZEdKvIS1B28wJQADQgLQrhus/edit

m: Emergence of a globally unique SARS-CoV-2 Spike E484T mutation in a persistently infected immunocompromised individual

People discussed Final Figure Review - Week of Nov. 29th



Nick Minor

I also agree that it makes sense to postpone till more folks are available. Here's a when2meet poll that we can use to find a good time: https://www.when2meet.com/?13771595-QaW8U Happy to take any suggestions for when works for people too. Excepting tomorrow morning's labwide meeting and office ...



Dave OConnor

Nick meanwhile can you coordinate with Kat and the other clinicians to see if there is anything we can do to move those figures to completion?



Nick Minor

Sure thing. I just emailed Kat to see if the figure was remade with the clinicians, and we'll go from there. I'll touch base tomorrow morning with a status update.



Thomas Friedrich

Sounds good Nick. I hope we can push this out this week.



Dave OConnor

OK - sounds good. If you have downtime and want to work on the manuscript text, I'd encourage you to spend some time harmonizing that with the figures. We 100% *need* to have this in Medrxiv before our P01 goes in, and it is very relevant vis a vis Omicron, so I'm going to be pushier than norma...



Nick Minor

That sounds good to me. I'm itching to finish it too. When are you planning to submit the P01? Also, that sounds good on the text. I'll start working on it. Is this (https://docs.google.com/document/d/17PWL1ROUQ_3t-q8rWb-ACcOLRDP2Kbpapw29Dui6jUw/edit?usp=sharing) the version I should work on, or...



Thomas Friedrich

Luis I know it's become a busy week, but you are able to work with Nick to harmonize the draft text and figures, that would be great. I agree with Dave that it is important to get this out as soon as we can. If you guys can get a draft in place that we can collaboratively polish, that would defin...



Nick Minor

Update: Sounds like Kat emailed the clinicians after our last figure meeting, but has not heard back. She's trying them again today. In light of our timeline, it seems like the quickest way to finish the figure is to get their notes and translate them into a figure ourselves (which is to say, my...



Dave OConnor

Yes, but I defer to Kat and her better understanding. I don't want to undermine our clinical colleagues and their desire to contribute. By the same token, there is urgency to get this done. Kat what do you advise?



Thomas Friedrich

Agree, I would like Kat to weigh in here.

Kat Braun

?

?

?

?

?

Let me try to email again and relay the desired timeline. To clarify, Thomas + Dave, you would like an improved version of the clinical timeline I put together, one summary graf of the clinical story, and then a more detailed version to be used as supplement?

Dave OConnor

All three: 1. We need updated text for the narrative text. 2. We need a clinical timeline for the main figures. 3. We need a comprehensive timeline for supplement.

Luis Antonio Haddock

Thomas yes, I can work on that with Nick. I asume we are still using the Drive Document that has been around for a while, correct?

Kat Braun

I re-iterated the desired timeline and specific tasks to our clinical partners. I will assist/coordinate with them in any way I can. I do think it's worth waiting for their expertise.

Dave OConnor

Kat - we can wait a few days, but not much longer. If they can do that we'd love to have them involved. We really need to get this out the door.

Joseph D. Yao

Nothing new on this patient at the Mayo Clinic site. We are sending the 3 residual positive specimens collected on this patient at our clinic (Sept. 28, Oct. 25, Oct. 27) via FedEx (frozen) to Robert at AVRL tomorrow. Thanks, Joseph

Someone commented on Spike E484A Omicron

David Baker

[image.png]Sample size 1 (delta083121_rep1). Here is where artic v4 has low depth of coverage for a Delta sample. Artic V3 is a lot worse in general. [image.png]



David Baker

V4 gets decent coverage in the spike region except for positions 22786 to 22974 which it gets very LOW coverage.

David Baker

I am not seeing any clear statistically significant difference in the spike region for these mutations based on peptide array intensity data alone. [image.png] We used 15-mers, which means all peptides within that 15 mer position range can be impacted by the mutation. Looking at IGG affinity (i...



David Baker

It is not a clear cut conclusion based on this data alone.

m: Shedding of Infectious SARS-CoV-2 Despite Vaccination

People discussed Manuscript update

Dave OConnor

14 days is the definition I'd use if possible. Otherwise you run the risk of underestimating booster effectiveness. It would be excellent to start cross-checking these cases against viral load. I feel like I've asked this before, but is PHMDC also planning to break out booster vs. non-booster in...

Brittany Grogan

Dave I'll chat with Katarina and the rest of the data team at our meeting tomorrow morning, but I think that yes, we can certainly explore breaking out unvaccinated vs vaccinated non-booster vs vaccinated booster, perhaps even on this week's data snapshot. Should we send a list of

booster breakt...



Thomas Friedrich

Thanks Brittany and Katarina. I think it is worth analyzing breakthrough viral loads stratified by booster vs. no booster in general, and in preparation of potential reviewer requests for more recent data. We can certainly sequence breakthroughs along with everything else. Luis is the person to c...



Brittany Grogan

Sounds good, I added a file to Teams with all of our booster breakthroughs so far where the lab was processed by Exact or UW. There are 43 on the list with the majority being from November.



Dave OConnor

Just to be clear, breakthrough equals >= 14 days after final dose? If so, that's surprisingly high to me.



Brittany Grogan

Correct; we have 80 total since 8/13/21. 56 of those are from November, compared to a total of 3,693 total cases so far in November. On last week's data snapshot we reported that so far 1/3 of Dane County residents who have completed the initial vaccine series have received a booster or third dose.



Dave OConnor

So if roughly 72% of Dane County is fully vaccinated, that means that roughly 24% have been boosted (.72 * .3) This would mean that if the vaccine was having no effect, you'd expect 886 of these November cases to be in vaccinees (3693 *.24). An actual number of 56 doesn't seem that bad - about 6...

Basecamp emails this report every morning. Stop sending it to me.



To: <u>Peter Halfmann</u>

Subject: Basecamp (University of WI - Madison): Here's the latest activity

Date: Friday, December 3, 2021 9:16:49 AM



University of WI - Madison Here's the latest activity across everything

Since 9am on Thursday, December 02

g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

People discussed Project 3 immune suppression: preliminary data

Dave OConnor

Dixon - could you attach a PDF preprint? It looks like the article you referenced isn't yet available online. The latest journal issue is Vol 196(5). [image.png]



Shelby O'Connor

[RADE-20-00246.1.pdf]this one Dave Dixon?



Dave OConnor

Wizardry Shelby!

Dixon Kaufman
Well done!

Someone commented on Research Strategy

?

Shelby O'Connor

DAWN CHRISTINA AMY Nancy Dave Thomas We got back the data from the SIV/SARS-CoV-2 animals. I am working through the data, so I'm not showing pictures. here are the early reports: 1. I don't see mutations in Spike -- perhaps there are no antibodies to select for them? 2. In one animal, there is ...

m: Emergence of a globally unique SARS-CoV-2 Spike E484T mutation in a persistently infected

immunocompromised individual

People discussed 2021-11-03 figure meeting

Nick Minor

Here's that updated plot, where the june timepoint has variants called from ARTICv3 and midnight reads mapped together. As you can see, there's not much of a qualitative difference, but the number of mutations that reach consensus frequency in june has gone from 95 down to 87. [allele frequency.pdf]

?

Dave OConnor

Does the combined mapping reduce the dropouts Nick?

Thomas Friedrich
Yah, we need to understand what coverage across the genome looks like at each timepoint now.

Nick MinorLooks like in the june timepoint, which is the only timepoint we have midnight reads for, there is still a 224 bp region in spike with low coverage, ranging from 22 to 33 reads. This region lines up our previous spike dropouts. There's also a very small stretch of 16 bases toward the end of ORF1 ...

m: Shedding of Infectious SARS-CoV-2 Despite Vaccination

A message was posted

?

Thomas F. posted <u>Relevant paper in Nature Medicine</u>

Hi all. I saw this recent brief communication in Nature Med today relevant to our paper. Key passage: "Focusing on the RdRp gene, regression coefficients for vaccinated over unvaccinated, representing the difference in Ct between the groups, started with 4.6 (95% confidence interval (CI), 2.2–6....

Someone commented on Relevant paper in Nature Medicine

Dave OConnor
So, like, we were right?

Someone commented on **Manuscript update**

Brittany GroganDave FYI we have included booster case rate data in our snapshot that

was released this evening! We only release hospitalization and death data by vaccination status once a month, so we'll release that in the same format (not vaxxed/vaxxed initial series/vaxxed + boosted) in two weeks, for both O...

Basecamp emails this report every morning. Stop sending it to me.



To: Peter Halfmann

Subject: Basecamp (University of WI - Madison): Here's the latest activity

Date: Wednesday, December 8, 2021 9:17:01 AM



University of WI - Madison Here's the latest activity across everything

Since 9am on Tuesday, December 07

m: Shedding of Infectious SARS-CoV-2 Despite Vaccination

Someone commented on Relevant paper in Nature Medicine



Katarina Grande

yep. well done!

Basecamp emails this report every morning. Stop sending it to me.



To: Peter Halfmann

Subject: Basecamp (University of WI - Madison): Here's the latest activity

Date: Monday, December 13, 2021 9:30:28 AM



University of WI - Madison Here's the latest activity across everything

Since 9am on Sunday, December 12

m: Shedding of Infectious SARS-CoV-2 Despite Vaccination

A message was posted



Thomas F. posted <u>There is already a review article...</u>
...on breakthrough infections, led by Marc Lipsitch, in Nature Reviews Immunology. Looks comprehensive.

Basecamp emails this report every morning. Stop sending it to me.



To: Peter Halfmann

Subject: Basecamp (University of WI - Madison): Here's the latest activity

Date: Friday, December 17, 2021 9:07:49 AM



University of WI - Madison Here's the latest activity across everything

Since 9am on Thursday, December 16

m: Shedding of Infectious SARS-CoV-2 Despite Vaccination

This was added to 2021-12-16 draft

Read draft Assigned to: Dave O.

Basecamp emails this report every morning. Stop sending it to me.



To: Peter Halfmann

Subject: Basecamp (University of WI - Madison): Here's the latest activity

Date: Saturday, January 8, 2022 9:03:04 AM



University of WI - Madison Here's the latest activity across everything

Since 9am on Friday, January 07

m: Shedding of Infectious SARS-CoV-2 Despite Vaccination

This was checked off on 2021-12-16 draft

Read draft Assigned to: Dave O.

This was checked off on Cover letter

Suggested and excluded reviewers?

This was checked off on **Acknowledgements**

Make sure funding and ethical approvals are correctly acknowledged in letter format. Assigned to: Dave O. and Thomas F.

This was added to 2021-12-16 draft

Follow-up with PLOS Pathogens Due: Jan 17 • Assigned to: Katarina G.

Basecamp emails this report every morning. Stop sending it to me.



To: Peter Halfmann

Subject: Basecamp (University of WI - Madison): Here's the latest activity

Date: Tuesday, January 11, 2022 9:04:51 AM



University of WI - Madison Here's the latest activity across everything

Since 9am on Monday, January 10

m: Shedding of Infectious SARS-CoV-2 Despite Vaccination

Someone commented on Follow-up with PLOS Pathogens



Katarina Grande

Yep, can do!

Basecamp emails this report every morning. Stop sending it to me.



To: <u>Peter Halfmann</u>

Subject: Basecamp (University of WI - Madison): Here's the latest activity

Date: Thursday, November 25, 2021 9:13:26 AM



University of WI - Madison Here's the latest activity across everything

Since 9am on Wednesday, November 24

g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

This was checked off on Research Strategy

What influenza strain should be used for these experiments? Assigned to: Thomas F.

Someone commented on <u>What influenza strain should be used for these experiments?</u>



Thomas Friedrich

Sorry I missed this post. I think we decided to leave influenza out of the P01. For NHP studies I would probably focus on A/California/04/2009 (H1N1pdm), because we have most experience with this virus and we know it replicates well in macaques. For ferrets I might choose to focus on H3N2 because...

m: Emergence of a globally unique SARS-CoV-2 Spike E484T mutation in a persistently infected immunocompromised individual

People discussed Final Figure Review - Week of Nov. 29th



Nick Minor

Here's a draft of that supplemental table. There's only one discrepancy for the iSNV at position 19656. In the Artic data, the SNV was found at a frequency of 0.8178, whereas in the Midnight data, its frequency was 0.0065. This prompted me to include read depth in the table, which reveals that Ar...



- **Dave OConnor**
- Great, small suggestion round frequencies to three digits.
- **Thomas Friedrich**
- Here's a link to the Nature Communications paper mentioned above.

People discussed 2021-11-03 figure meeting

- Gage Moreno ?
 - I agree Thomas. As long as we present it in a way that says it popped up at consensus frequency which led us to go back and look for its presence below consensus level, then I think it should be okay. Is there even leftover sample to sequence by Illumina at those timepoints? If yes, why couldn't ...
- **Dave OConnor** I think that had been the plan, but my understanding is that there was a bit of an internal miscommunication which is why these were resequenced by ONT Midnight.
- **Thomas Friedrich** ? Dave that is my understanding also, but IIRC in a conversation earlier this week Luis said that there should be vRNA and/or cDNA available from all timepoints, so Illumina sequencing should be possible also. We did want to do Midnight sequencing as well to fill in amplicon gaps, especially in Spi...
- **Dave OConnor** Thomas so how should Nick reconcile those in his Figure? One way. conceivably, would be to map both ARTIC and Midnight reads simultaneously and variant call against both to eliminate gaps. It's pretty unconventional, but I think it could be justified. After thinking about this a bit more. I thin...

m: Shedding of Infectious SARS-CoV-2 Despite **Vaccination**

People discussed Manuscript update

- **Thomas Friedrich**
 - Any further updates Katarina? One question for you and Dave -- we have continued to collect data on Ct value and vaccination status. We could update the figures if this version does not get sent out for review...
- **Dave OConnor Great point Thomas**
- **Dave OConnor** We could also start looking at third vaccine breakthroughs to see if there is any difference in VL in those cases.



Basecamp emails this report every morning. Stop sending it to me.



To: Peter Halfmann

Subject: Basecamp (University of WI - Madison): Here's the latest activity

Date: Tuesday, November 23, 2021 9:17:23 AM



University of WI - Madison Here's the latest activity across everything

Since 9am on Monday, November 22

g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

This was added to Research Strategy

P1 question: Selection of immunosuppressive drug regimen for NHP? Assigned to: Jacqueline G. and Jeannia S.

A message was posted



Dave O. posted Managing Basecamp notifications

Hi everyone, Following on from Jeannia and Jacqueline 's question this morning, here is a brief tutorial on Basecamp notifications. First, here is the official documentation on notifications. It is a bit lengthy, so the TL;DR is: 1. Click your Avatar in the upper right corner [image.png] 2. E...







People discussed Key Persons biosketches in 2022 format due



Dave OConnor

I think that we decided we wouldn't include Scientists, but I don't hold that opinion strongly. Do others have strong opinions?



Jeannia Smith

No, I don't. Jeannina Smith M.D. Associate Professor of Medicine (CHS) Medical Director of Transplant Infectious Disease Program Program Director of Infectious Disease Fellowship Assistant Block Leader Invaders and Defense; University of Wisconsin School of Medicine and Public Health University ...

People discussed 2021-11-22 all-hands meeting

ANDREA WEILER

11/22/21 meeting notes: Administrative update: Amanda -still waiting to hear from program about invitation to submit proposal. Timeline: If we are invited to submit this, it will be due January 11, we will aim to have documents submitted by January 7. (In order to make this work with the holida...

Kristi Hall

Thanks for taking notes ANDREA I am also attaching the chat from the meeting. [11-22-21-meeting_chat.pdf]



Thomas Friedrich

Thanks for the excellent notes ANDREA!

Dave OConnor

For anyone who is interested, here is a remapped Project 2 plan that several of us discussed this morning after the call. [image.png]



People discussed <u>Preliminary budget review</u>

Dave OConnor

DAWN CHRISTINA AMY Can you redo the budget estimate with the experimental design discussed this morning? Thanks! https://storage.3.basecamp.com/4362286/blobs/9810a570-4bda-11ec-b73e-ce416d59e241/download/image.png

CHRISTINA NEWMAN

Dave We are meeting tomorrow at AVRL to revamp the budget.

Dave OConnor

I'm planning on spending the next hour or two reading about rituximab in macaques to figure out a preliminary dosing timeline and strategy. Following up on this, there seems to be a reasonably common practice of combining rituximab with other immunosuppressives when trying to avoid anti-ABO anti...



m: Emergence of a globally unique SARS-CoV-2 Spike E484T mutation in a persistently infected immunocompromised individual

A message was posted

Nick M. posted Final Figure Review - Week of Nov. 29th

Hi everyone, Our figures are nearly finished for the persistent infection manuscript, so I'd like to schedule one last figure review session for early next week. Could we tentatively plan on meeting Monday 11/29 at 11AM CST? If that doesn't work, I can send out a scheduling poll or suggest other...

People discussed Final Figure Review - Week of Nov. 29th

Dave OConnor

?

?

This works well for me. What would be ideal is if everyone who contributed to the Figures could coordinate with Nick to put them into a shared set of Google Slides/Keynote/Powerpoint that has both the Figure and then a draft legend on each slide (or a slide, with a legend on the following slide, ...

Gage Moreno

I won't be able to make 11AM CST on Monday but if that works better for everyone else, I can catch up over slack/basecamp/email.

Nick Minor

Great suggestion on the shareable slides. Here's a keynote with a slide for each figure followed by a slide for the associated caption: https://www.icloud.com/keynote/0GgMUGeZOLlrwmgNCO0ijdfg#final figures 20211122

Dave OConnor

Can I suggest putting the captions in the presenter notes Nick? These slides look good. In Supp Figure 1, E484 is still weird. It isn't both E484A AND E484T at the same time as it appears now. The E484A should go down when the E484T is up, and vice versa. Would limiting this just to non-synonym...

Nick Minor

Sure thing, just updated the slides. And yeah, that weirdness with E484 is one of the not ideal consequences of classifying G-23012-A and A-23013-C as separate iSNVs rather than merging them. That said, Gage just pointed out that to solve this, we just need to subtract the G-23012-A frequencies ...

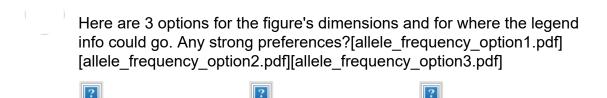
?

Dave OConnor

Nick - can you add another Supplemental Table that compares the iSNV frequencies in the June timepoint between ARTICv3 and Midnight? That would help make the point that the unusual pattern of variants observed in this timepoint aren't a technical artifact.

Someone commented on 2021-11-03 figure meeting

Nick Minor



m: Shedding of Infectious SARS-CoV-2 Despite Vaccination

People discussed Manuscript update

Katarina Grande agreed, very annoying. same status today.

Dave OConnor A bit of insight: I spoke to a journalist who told me how our paper is being weaponized by the far right. It might be that journals don't want to

being weaponized by the far right. It might be that journals don't want to publish it and deal with the potential backlash.

Katarina Grande Ok, that's helpful context. Unfortunate! Wonder if there is a different frame we could build out in a submission that would help with this. Or is it a lost cause at this point...

Probably a "lost" cause, but I'm not sure I'd welcome the term "lost." A paper that has been seen by more than 100,000 people is arguably the most impactful thing I've ever been involved with. Even if it means that it just becomes an opportunity to educate about what the data says and why the wea...

Katarina Grande Great point!

Basecamp emails this report every morning. Stop sending it to me.



To: <u>Thomas Friedrich</u>

Subject: Basecamp (University of WI - Madison): Here's what's on your plate

Date: Monday, January 3, 2022 9:06:57 AM



University of WI - Madison Here's what's on your plate

As of 9:06am on January 03, 2022

Overdue

Sunday, Jan 31, 2021

2020 Action Items in project: TCF Lab DEI Work

Annual big-picture reflection: Dedicated time at annual lab retreat to evaluate progress, failure... Assigned to: Chelsea C., Gabrielle B., Kasen R., and Thomas F.

Due this week

Monday, Jan 03, 2022

Research Strategy in g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

Condense text, including porting some evolutionary analysis methods to Project 3 Assigned to: Thomas F.

Your other assignments

Consortium/Contractual arrangements in g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

<u>Koelle subaward (Project 3)</u> Assigned to: Amanda E., Katia K., and Thomas F.

Drafts in g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

Full draft in InDesign Assigned to: Thomas F.

Facilities and other resources in g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

<u>Update Kawaoka lab biosafety protocol for transmission experiments</u> Assigned to: Peter H. and Thomas F.

Research Strategy in g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

Figure: probability of fixed mutations during SARS-CoV-2 transmission Assigned to: Thomas F.

Figure: Gantt chart Assigned to: Thomas F.

Research Strategy in g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

<u>Submit pre-print describing persistently infected patient</u> Assigned to: Dave O. and Thomas F.

Specific Aims in g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

<u>Define research foci that integrate across all projects</u> Assigned to: Dave O. and Thomas F.

Acknowledgements in m: Shedding of Infectious SARS-CoV-2 Despite Vaccination

Make sure funding and ethical approvals are correctly acknowledged in letter format. Assigned to: Dave O. and Thomas F.

2020 Action Items in project: TCF Lab DEI Work

Evaluate our physical space at AVRL to ensure it is welcoming to people of different socioeconomi... Assigned to: ANDREA W., Luis A., and Thomas F. Actively participate in programs that support and mentor aspiring scientists from underrepresente... Assigned to: Mason B. and Thomas F.

Basecamp emails this report every Monday morning. Stop sending it to me.

To: <u>Thomas Friedrich</u>

Subject: Basecamp (University of WI - Madison): Here's what's on your plate

Date: Monday, December 13, 2021 9:25:52 AM



University of WI - Madison Here's what's on your plate

As of 9:25am on December 13, 2021

Overdue

Sunday, Jan 31, 2021

2020 Action Items in project: TCF Lab DEI Work

Annual big-picture reflection: Dedicated time at annual lab retreat to evaluate progress, failure... Assigned to: Chelsea C., Gabrielle B., Kasen R., and Thomas F.

Your other assignments

Consortium/Contractual arrangements in g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

<u>Koelle subaward (Project 3)</u> Assigned to: Amanda E., Katia K., and Thomas F.

Facilities and other resources in g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

<u>Update Kawaoka lab biosafety protocol for transmission experiments</u> Assigned to: Peter H. and Thomas F.

Research Strategy in g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

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Specific Aims in g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

<u>Define research foci that integrate across all projects</u> Assigned to: Dave O. and Thomas F.

Acknowledgements in m: Shedding of Infectious SARS-CoV-2 Despite Vaccination

Make sure funding and ethical approvals are correctly acknowledged in letter format. Assigned to: Dave O. and Thomas F.

2020 Action Items in project: TCF Lab DEI Work

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Basecamp emails this report every Monday morning. Stop sending it to me.

To: <u>Thomas Friedrich</u>

Subject: Basecamp (University of WI - Madison): Here's what's on your plate

Date: Monday, December 27, 2021 9:06:16 AM



University of WI - Madison Here's what's on your plate

As of 9:06am on December 27, 2021

Overdue

Sunday, Jan 31, 2021

2020 Action Items in project: TCF Lab DEI Work

Annual big-picture reflection: Dedicated time at annual lab retreat to evaluate progress, failure... Assigned to: Chelsea C., Gabrielle B., Kasen R., and Thomas F.

Your other assignments

Consortium/Contractual arrangements in g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

<u>Koelle subaward (Project 3)</u> Assigned to: Amanda E., Katia K., and Thomas F.

Drafts in g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

<u>2021-12-13 draft</u> Assigned to: Amanda E., Corrie B., Jacqueline G., Nancy W., Shelby O., and Thomas F.

Facilities and other resources in g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

<u>Update Kawaoka lab biosafety protocol for transmission experiments</u> Assigned to: Peter H. and Thomas F.

Research Strategy in g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

<u>Submit pre-print describing persistently infected patient</u> Assigned to: Dave O. and Thomas F.

Specific Aims in g: "Evolutionarily advanced" respiratory virus variants in immunocompromised individuals

<u>Define research foci that integrate across all projects</u> Assigned to: Dave O. and Thomas F.

Acknowledgements in m: Shedding of Infectious SARS-CoV-2 Despite Vaccination

Make sure funding and ethical approvals are correctly acknowledged in letter format. Assigned to: Dave O. and Thomas F.

2020 Action Items in project: TCF Lab DEI Work

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Basecamp emails this report every Monday morning. Stop sending it to me.

From: DAVID H O"CONNOR
To: plosmedicine@plos.org

Cc: Thomas Friedrich; Grande, Katarina

Subject: Direct transfer from Medrxiv to PLOS Medicine **Date:** Saturday, November 6, 2021 4:53:13 PM

Attachments: cover letter 2021-11-06.pdf

Dear PLOS Medicine,

Today my co-authors and I tried to use the direct transfer tool of a manuscript from Medrxiv to PLOS Medicine. We've never used this tool before and it seems almost too easy - I simply chose a journal and clicked a button. Is this all there is to the process? Or do we need to submit a cover letter or additional information to the editors of PLOS Medicine? Just in case, I've attached a cover letter to this email.

Is there anything else we need to do? Should the manuscript be visible from within one (or all) of our PLOS author portals?

Sorry if these are naive questions - this seems like a terrific initiative but one where existing documentation is pretty scarce (or I am looking in the wrong place).

Thanks in advance,

dave

Dave O'Connor | UW Medical Foundation Professor dhoconno@wisc.edu | +1 http://dho.pathology.wisc.edu

I choose to work flexibly & send emails outside normal office hours. No need to respond to my emails outside yours.





Phone (608) 266-4821 Fax (608) 266-4858 www.publichealthmdc.com

6 November 2021

Dear editors:

Please consider our attached manuscript, "Shedding of Infectious SARS-CoV-2 Despite Vaccination," for publication as a brief communication in *PLOS Medicine*. For our study, we assembled a team of virologists, epidemiologists, and public health officials to determine whether individuals infected with SARS-CoV-2 despite full vaccination had the potential to transmit the virus. Our study was conducted in Wisconsin at a time when the Delta variant dramatically increased in prevalence to account for almost all new infections; this, together with sequencing data from our own laboratory, suggests that most infections reported here involved Delta.

Our study complements recent epidemiological investigations suggesting that post-vaccination infections with Delta are transmissible, and it **adds three important observations**:

First, in contrast to previous investigations of individual outbreaks that involved healthcare settings (Hetemäki et al. 2021; Mlcochova et al. 2021) or particularly large gatherings (Brown et al. 2021), our study involves persons who sought SARS-CoV-2 testing from community sites spread over a wide geographic area in Wisconsin and thus represents mostly infection in a community setting.

Second, we show that a large proportion of individuals (68%) infected despite full vaccination test positive with Ct <25. Although RT-qPCR Ct values alone are not rigorously quantitative, this low Ct value strongly suggests a high viral load in nasal secretions. Notably, in our study RT-qPCR was performed by a single commercial laboratory using a single assay protocol, helping to control for variability in approaches that could confound comparisons of Ct values generated by different laboratories.

Finally, we show that almost all specimens tested from individuals with Ct values <25 harbor infectious SARS-CoV-2, including 95% of individuals with post-vaccination infections. These findings establish that SARS-CoV-2 RNA detected in vaccinated individuals cannot be due only to cell debris or non-infectious particles.

We believe our findings are significant and timely, and help to inform public health and infection control practices needed to cope with a new surge in COVID-19 cases. We note that one author, Dr. Segaloff, is a CDC Epidemic Intelligence Service officer, and therefore the attached manuscript has undergone CDC clearance prior to submission. We have also shared our findings as a preprint on the nonprofit medrxiv server: https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v5.

PLOS Medicine is an especially attractive destination for this paper because of its innovative stance towards Complementary Research. The impact of this work is demonstrably high; the mredrxiv preprint has been downloaded by than 100,000 times and the full-text HMTL version has been viewed more than 79,000 times. While additional work from other groups (cited in this manuscript) has substantiated and complemented our key findings, our early documentation of transmission-competent SARS-CoV-2 in vaccinated individuals infected with the delta variant remains important and would be of interest to the broad readership of *PLOS Medicine*.

We suggest the following experts as potential reviewers for this work.

Dr. Brian O'Roak, Oregon Health and Science University: oroak@ohsu.edu

Dr. Bronwyn MacInnis, Broad Institute: <u>bronwyn@broadinstitute.org</u>

Finally, please note that three senior authors contributed equally to this work: Drs. O'Connor, Friedrich, and myself.

Thank you for your consideration.

Sincerely, on behalf of all authors,

Kafu Shode

Katarina Grande

From: Rose, Dale A. (CDC/DDID/NCEZID/DPEI)

To: Peter Halfmann

Subject: FW: Wisconsin-CDC Touch base on positive viral culture in breakthrough cases

Attachments: <u>image002.png</u>

concept proposal submission form aug11.docx

Viral loads in vaccinees MMWR.pdf

----Original Appointment----

From: Rose, Dale A. (CDC/DDID/NCEZID/DPEI)

Sent: Wednesday, August 11, 2021 2:02 PM

To: Rose, Dale A. (CDC/DDID/NCEZID/DPEI); Westergaard, Ryan P - DHS; Walke, Henry (CDC/DDID/NCEZID/DPEI); Brooks, John T. (CDC/DDID/NCHHSTP/DHP); Limbago, Brandi (CDC/DDID/NCIRD/OD); Azziz-Baumgartner, Eduardo (CDC/DDID/NCIRD/ID); MacNeil, Adam (CDC/DDID/NCIRD/DV); Christie, Athalia (CDC/DDPHSIS/CGH/OD); Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI)

Cc: Kasen Riemersma; Grande, Katarina; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Thomas

Friedrich; DAVID H O'CONNOR; Florek, Kelsey; Dowell, Deborah (Debbie) (CDC/DDNID/NCIPC/DOP)

Subject: Wisconsin-CDC Touch base on positive viral culture in breakthrough cases

When: Wednesday, August 11, 2021 5:00 PM-5:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Microsoft Teams Meeting

Importance: High

Dr. Westergaard,

Thanks very much for agreeing to meet with us today to discuss this important topic. I've attached your MMWR concept proposal and recent preprint. Below is the graphic you provided, from your preprint, providing additional information on evidence of infectious virus and Ct values by vax status.

[from preprint]

To determine whether high viral loads might indicate the presence of infectious SARS-CoV-2, we attempted to culture infectious virus from a subset of 55 specimens with Ct values. Infectious SARS-CoV-2 was isolated from 14 of 16 specimens (88%) from unvaccinated individuals and 37 of 39 specimens (95%) from vaccinated people, suggesting that Ct < 25 is frequently associated with the capacity to shed infectious SARS-CoV-2, even in fully vaccinated persons.

Microsoft Teams meeting

Join on your computer or mobile app

Click here to join the meeting https://teams.microsoft.com/l/meetup-join/19%3ameeting_NDVkNmEyY2QtZGYyYy00ODliLTgyMTUtMTUyZThlNzJlOWU3%40thread.v2/0? context=%7b%22Tid%22X3a%229ce70869-60db-44fd-abe8-d2767077fc8f%22%2c%22Oid%22%3a%222abce934-1c33-4711-806e-284725ccbcf5%22%7d>

Or call in (audio only)

+1 404-718-3800, # <tel:+14047183800, #> United States, Atlanta (888) 994-4478,,5 # <tel:8889944478, #> United States (Toll-free) Phone Conference ID: #

Find a local number https://dialin.teams.microsoft.com/f157e5c8-9e01-4021-b245-b3aec6e9a1bc?id=540878995 | Reset PIN https://mysettings.lync.com/pstnconferencing

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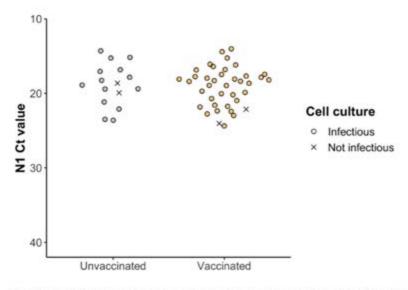


Figure 2. Infectious virus detected in nasal swab specimens from unvaccinated and fully vaccinated cases with Ct values < 25. Infectiousness was determined by the presence of cytopathic effects (CPE) after 5 days of replication in Vero E6 TMPRSS2 cells. Specimens with visually apparent CPE under a light microscope are represented by filled circles, and specimens with apparent CPE are represented by 'X'.

COVID-19 Publication Proposal Form Template

This template may be used by Task Forces to prepare MMWR and manuscript concepts for submission through the electronic form: COVID-19 Publication Proposal Form

1. Proposed title of MMWR or manuscript:

SARS-CoV-2 infection with high viral loads despite vaccination when the Delta variant is prevalent - Wisconsin, July 2021

2. Responsible author name/POC for submission:

Hannah Segaloff

3. Kasen Riemersma

4. Responsible author/POC email:

hannah.segaloff@dhs.wisconsin.gov riemersma@wisc.edu

5. Other authors (name, organization):

Kasen K. Riemersma, DVM, PhD¹; Brittany E. Grogan, MPH²; Amanda Kita-Yarbro, MPH²; Peter Halfmann, PhD¹; Anna Kocharian, MS³; Kelsey R. Florek, PhD⁴; Ryan Westergaard, MD, PhD³, Allen Bateman, PhD⁴; Hannah E. Segaloff, PhD³, Gunnar E. Jeppson, BS³; Yoshihiro Kawaoka, DVM, PhD¹; David H. O'Connor, PhD⁰; Thomas C. Friedrich, PhD¹; Katarina M. Grande, MPH²

¹ Department of Pathobiological Sciences, University of Wisconsin-Madison, Madison, WI, USA; ² Public Health Madison & Dane County, Madison, WI, USA; ³ Wisconsin Department of Health Services; ⁴ Wisconsin State Laboratory of Hygiene; ⁵ Department of Medicine, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin; ⁶ CDC COVID-19 Response Team; ⁷ Epidemic Intelligence Service, CDC; ⁸ Exact Sciences, Madison, WI, USA; ⁹ Department of Pathology and Laboratory Medicine, University of Wisconsin-Madison, Madison, WI, USA.

6. CDC first or senior author (Yes or No):

No

7. MMWR or Journal Manuscript (select one):

MMWR

8. Background and Objective (character limit- 870):

Prevalence of the Delta variant has been associated with increased SARS-CoV-2 spread and high viral loads. A recent investigation of a large outbreak suggested that individuals infected with Delta despite vaccination could also have high viral loads and contribute to SARS-CoV-2 spread; however, it is not known whether similarly high viral loads with the potential for onward

transmission are observed among vaccinated persons in community settings.

9. Data Source & Study Design (character limit- 700):

We analyzed specimens from 719 persons collected 29 June - 31 July 2021. Delta prevalence in Wisconsin increased from 69% to 95% during this period. Vaccination status was confirmed for 322 persons using public health databases, identifying n=293 fully vaccinated and n=29 unvaccinated at the time of testing. An additional n=18 self-reported as fully vaccinated and n=379 self-reported as unvaccinated. We compared Ct values according to vaccination status and presence of symptoms at the time of testing. We compared time from illness onset to testing in vaccinated vs. unvaccinated individuals with symptomatic infection. We attempted virus isolation from a subset of 79 specimens with Ct < 25.

10. Major Findings (character limit- 700):

We detected no significant differences in median Ct values between fully vaccinated (21.7 [18.1-27.2]) and not fully vaccinated specimens (22.9 [18.4-27.3]). 212 of 311 (68%) of persons with infection despite full vaccination had extremely low Ct values < 25, consistent with very high viral loads. Full vaccination did not affect Ct values observed in infected persons, either with or without symptoms, at the time of testing. SARS-CoV-2 was isolated from 74 of 79 specimens with Ct < 25 for which culture was attempted.

11. Public Health Implications and Research Novelty

Individuals who are infected despite vaccination could serve as sources of onward transmission to others. Policies that require workers to be vaccinated or routinely tested should be reevaluated; these reinforce an incorrect belief that those who are vaccinated should be exempt from testing. Vaccinated persons, particularly those who may have high levels of community or occupational exposure to SARS-CoV-2, should be tested for SARS-CoV-2 when symptomatic or exposed, to limit community spread. Continued adherence to non-pharmaceutical interventions, such as masking and distancing, will remain important for both vaccinated and unvaccinated persons because some vaccinated individuals will experience infections with high viral loads.

12. Science Agenda Priority Questions the Publication Addresses. <i>Please select all that apply. The</i> 19 Priority Questions are listed <u>here</u> .
X Question #1 Question #2 Question #3 Question #4 X Question #5
Question #6 Question #7 Question #8 X Question #9 X Question #10
X Question #11 X Question #12 Question #13 X Question #14 X Question #15
Question #16 Question #17 Question #18 Question #19

14. Team/Working Group (if applicable):

13. Submitting Task Force or home Center/Program:

HDS

STLT

15. Proposal reviewed and approved by Task Force Lead or Response ADS (Yes or No): Required prior to submission for proposals originating within an IM TF.

16. Urgent review requested* (Yes or No):

17. Comments (optional):

An MMWR-formatted version of the manuscript is attached and will be submitted concurrently with this Concept Proposal to medrxiv as an update to

https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v1

- All proposals must be submitted by an author or point of contact (POC) with a CDC user ID.
- Proposals submitted electronically by 4:00pm on Monday will be reviewed by Response leadership on Wednesday and receive a decision on Thursday.
- *For urgent submissions, the TF Lead may send an email to eocevent172@cdc.gov in addition to the author submitting the form, and a decision will be made in 24 hours.

Questions may be sent to eocevent172@cdc.gov.

Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021

Kasen K. Riemersma, DVM, PhD¹; Brittany E. Grogan, MPH²; Amanda Kita-Yarbro, MPH²; Peter Halfmann, PhD¹; Anna Kocharian, MS³; Kelsey R. Florek, PhD⁴; Ryan Westergaard, MD, PhD³; Allen Bateman, PhD⁴; Gunnar E. Jeppson, BS⁶; Yoshihiro Kawaoka, DVM, PhD¹; David H. O'Connor, PhD³; Thomas C. Friedrich, PhD¹; Katarina M. Grande, MPH²

Summary

What is already known about this topic?

Prevalence of the Delta variant has been associated with SARS-CoV-2 spread and high viral loads among vaccinated individuals in a concentrated outbreak. It is unclear whether similarly high viral loads are observed in community settings, or whether high viral RNA burdens in vaccinated individuals are correlated with shedding of infectious virus.

What is added by this report?

In the setting of community transmission where Delta is highly prevalent, SARS-CoV-2 viral loads are similar at the time of testing regardless of vaccine status. High viral loads (PCR Ct <25) were measured in 68% of individuals with infection despite vaccination, and in 63% of unvaccinated persons. Ct <25 was strongly correlated with shedding of infectious virus in both vaccinated and unvaccinated persons.

What are the implications for public health practice?

High viral loads correlated with presence of infectious SARS-CoV-2 frequently occur in people infected despite vaccination, suggesting that such individuals could transmit the virus to others. Although vaccinated individuals are likely protected against severe COVID-19, they should take steps to avoid infecting others, such as wearing masks and getting tested when experiencing COVID-like symptoms or after exposure.

¹ Department of Pathobiological Sciences, University of Wisconsin-Madison, Madison, WI, USA; ² Public Health Madison & Dane County, Madison, WI, USA; ³ Wisconsin Department of Health Services; ⁴ Wisconsin State Laboratory of Hygiene; ⁵ Department of Medicine, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin; ⁶ Exact Sciences, Madison, WI, USA; ⁷ Department of Pathology and Laboratory Medicine, University of Wisconsin-Madison, Madison, WI, USA.

[^] Author to whom all correspondence should be addressed. E-mail: KGrande@publichealthmdc.com

Main text

The SARS-CoV-2 Delta variant and its sublineages (B.1.617.2, AY.1, AY.2, AY.3; [1]) can cause high viral loads, are highly transmissible, and contain mutations that confer partial immune escape [2,3]. Using PCR threshold cycle (Ct) data from a single large contract laboratory, we show that individuals in Wisconsin, USA had similar viral loads in nasal swabs, irrespective of vaccine status, during a time of high and increasing prevalence of the Delta variant. Infectious SARS-CoV-2 was isolated from 51 of 55 specimens (93%) with Ct <25 from both vaccinated and unvaccinated persons, indicating that most individuals with Ct values in this range (Wilson 95% CI 83%-97%) shed infectious virus regardless of vaccine status. Notably, 68% of individuals infected despite vaccination tested positive with Ct <25, including at least 8 who were asymptomatic at the time of testing. Our data substantiate the idea that vaccinated individuals who become infected with the Delta variant may have the potential to transmit SARS-CoV-2 to others. Vaccinated individuals should continue to wear face coverings in indoor and congregate settings, while also being tested for SARS-CoV-2 if they are exposed or experience COVID-like symptoms.

We analyzed respiratory specimens from 719 individuals collected between 29 June 2021 and 31 July 2021. Delta and its sublineages accounted for 69% of all Wisconsin sequences in GISAID in the week beginning 27 June 2021; this proportion increased to 95% for the week ending 24 July, the most recent date for which data are available [4]. We recovered viral genome sequences from 122 of the specimens analyzed in this report; 110 of 122 (90%) belonged to Delta lineages. The high and increasing prevalence of Delta-lineage viruses during the study period, and high proportion of Delta-lineage viruses among our sequenced samples, together suggest that most infections in our dataset were caused by Delta, though this cannot be directly confirmed.

We defined fully vaccinated individuals as those who received a final vaccine dose at least 2 weeks prior to testing positive. Of the 719 individuals, vaccination status at the time of testing was available in the Wisconsin Immunization Registry and Wisconsin Electronic Disease Surveillance System for 322 (293 vaccinated and 29 unvaccinated), while self-reported vaccination status was available for the remaining 397 (18 vaccinated and 379 unvaccinated). We compared Ct values in specimens from these fully vaccinated and unvaccinated individuals at the time of testing (Figure 1). We detected no significant differences in Ct values by vaccination status. Notably, 212 of 311 (68%) of individuals with infection despite full vaccination had extremely low Ct values <25, consistent with high viral loads.

While a given Ct value cannot be used to infer infectiousness, previous studies suggested that infectious SARS-CoV-2 can frequently be recovered from specimens with Ct values of 25-30 or lower [5]. To determine whether high viral loads might indicate the presence of infectious SARS-CoV-2, we attempted to culture infectious virus from a subset of 55 specimens with Ct values <25 (Figure 2). Infectious SARS-CoV-2 was isolated from 14 of 16 specimens (88%) from unvaccinated individuals and 37 of 39 specimens (95%) from vaccinated people, suggesting that Ct <25 is frequently associated with the capacity to shed infectious SARS-CoV-2, even in fully vaccinated persons.

Data on symptom status were available from 516 of the 719 individuals evaluated here, so we further compared Ct values in test-positive specimens according to vaccination and symptom status (Figure 3A). For symptomatic cases, there was no significant difference in the time elapsed between symptom onset and testing for vaccinated vs. unvaccinated individuals (two-sample K-S test, p=0.49; Figure 3B).

Full vaccination did not affect Ct values observed in infected individuals, either with or without symptoms, at the time of testing. Among those for whom symptom status is known, 252 of 276 individuals who were not fully vaccinated (91%) reported symptoms at the time of testing, while 228 of 240 people who were fully vaccinated (95%) reported symptoms. Among individuals who were asymptomatic at the time of testing, Ct values <25 were detected in 7 of 24 unvaccinated individuals (29%; CI: 13-51%) and in 8 of 12 individuals who were infected despite being fully vaccinated (67%; CI: 35-90%). Infectious virus was detected in the sole specimen tested from an asymptomatic fully vaccinated individual. Although the number of asymptomatic individuals sampled is small, these results indicate that some individuals who are infected despite vaccination can have high viral loads and shed infectious virus even while being asymptomatic. Additional virus isolation data are needed to determine the frequency of infectious virus shedding in asymptomatic cases.

Our findings are consistent with other recent reports detecting high virus loads in some individuals infected despite vaccination in England [6] and Singapore [7]. Our detection of infectious virus in 93% of samples with Ct <25 indicates that high viral loads are consistent with the potential to transmit SARS-CoV-2, regardless of the individual's vaccination status. Notably, transmission of Delta from vaccinated healthcare workers to their household contacts was recently documented in an investigation of a hospital-associated outbreak in Finland [8]. An outbreak in Barnstable County, MA associated with large gatherings also involved a substantial proportion of fully vaccinated individuals [9]. The co-circulation of viruses belonging to Pango lineages B.1.617.2, AY.2, and AY.3, as well as the broad geographic distribution of our specimens, indicate that the infections analyzed here are not associated with any single large outbreak, and that Delta-lineage SARS-CoV-2 can achieve high viral loads consistent with transmissibility in fully vaccinated individuals across a range of exposure settings. Taken together, these studies indicate that individuals infected with Delta variants despite vaccination have the capacity to transmit infection to others.

Our study has at least three important limitations. First, we have only one specimen from most individuals, and therefore we cannot know the trajectory of viral loads at the time of testing. Indeed, a study of Delta infection dynamics suggests that viral loads decline more rapidly in vaccinated vs. unvaccinated individuals, as one might expect [7]. However, that study also indicates that viral loads in vaccinated and unvaccinated individuals remain similarly high for 5-6 days after illness onset, before declining more rapidly in vaccinated people. In our study, 91% of specimens from symptomatic cases were collected from 0-6 days after illness onset and the timing of tests relative to illness onset did not differ by vaccination status. These observations suggest that the Ct value comparisons in our study are likely not biased by the time of testing. A second limitation is that there may be differences in the populations of vaccinated and unvaccinated persons seeking testing that bias our results. Vaccinated individuals may not perceive a high risk of COVID-19 disease, and may be less likely to seek testing than unvaccinated people. It is difficult to determine from our data whether vaccinated and unvaccinated people experienced symptoms of similar severity. Thus, we cannot determine the extent to which our sampling failed to detect asymptomatic or paucisymptomatic infections. Such mild infections may be more frequent among vaccinated than unvaccinated individuals infected with Delta. Consistent with this, a recent report from England detected a substantially greater proportion of low-positive tests with Ct values between 35 and 40 in vaccinated individuals than in the unvaccinated [6]. Importantly, our study was not designed to estimate the rate of infection despite vaccination, but rather to determine whether individuals infected despite vaccination could have high viral loads consistent with the potential to transmit SARS-CoV-2. Finally, there is inherent variability in PCR Ct

values due to specimen variability that can be impacted by collection technique and other variables outside of our control.

The finding of high SARS-CoV-2 viral loads and replication-competent virus in vaccinated individuals has important implications for risk assessment and mitigation. The impact of Delta variants on vaccine effectiveness is currently being evaluated (see, e.g., [10]). Risk disinhibition may lead vaccinated people to increase behaviors that expose them to SARS-CoV-2 infection, and individuals who are infected despite vaccination could serve as sources of onward transmission to others. Vaccinated individuals, particularly those who may have high levels of community or occupational exposure to SARS-CoV-2, should be encouraged to continue frequent testing, especially when symptomatic, to limit community spread. Continued adherence to non-pharmaceutical interventions, such as masking and distancing, will remain important for both vaccinated and unvaccinated individuals because we cannot predict which vaccinated individuals will experience infections with high viral loads. While vaccines continue to provide outstanding protection against severe disease and mortality, the durability of this protection cannot be reliably predicted. Therefore, it is essential for public health policy to encourage vaccination while also planning for contingencies, including diminished long-term protection.

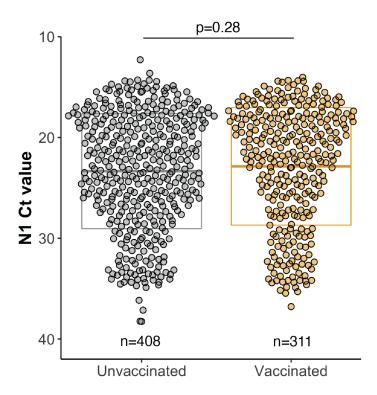


Figure 1. Distributions of SARS-CoV-2 PCR cycle threshold (Ct) values at the time of testing do not differ by vaccination status. N1 PCR Ct values for SARS-CoV-2-positive specimens grouped by vaccination status. Boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values between the groups by Welch two-sample t-test.

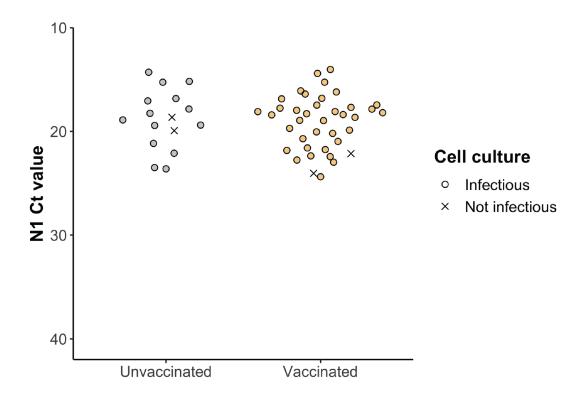


Figure 2. Infectious virus detected in nasal swab specimens from unvaccinated and fully vaccinated cases with Ct values < 25. Infectiousness was determined by the presence of cytopathic effects (CPE) after 5 days of replication in Vero E6 TMPRSS2 cells. Specimens with visually apparent CPE under a light microscope are represented by filled circles, and specimens without apparent CPE are represented by 'X'.

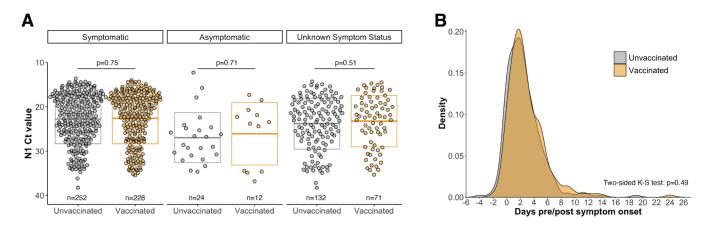


Figure 3. Symptom status does not affect distributions of SARS-CoV-2 PCR cycle threshold (Ct) values at the time of testing in vaccinated vs. unvaccinated persons. A) N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for symptomatic, asymptomatic, and unknown symptom status cases. Boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values between groups by Welch two-sample t-tests. B) Density distributions of unvaccinated and vaccinated specimen collection dates by day since symptom onset. Day 0 on the x-axis denotes self-reported day of symptom onset. Negative values for days indicate specimen collection prior to symptom onset. Symptom onset data were available for n=249 unvaccinated cases and n=222 vaccinated cases.

Acknowledgments

We would like to acknowledge the local health departments in Wisconsin who referred samples for SARS-CoV-2 testing. We gratefully acknowledge Shelby O'Connor and Hannah Segaloff for critical review of the manuscript and helpful discussion. We also acknowledge all Exact Sciences employees who contributed to sample testing. This work was supported by Centers for Disease Control and Prevention contracts 75D30120C09870 and 75D30121C11060 to D.H.O and T.C.F. The authors are also members of the Upper Midwest Regional Accelerator for Genomic Surveillance funded by the Rockefeller Foundation.

Conflict of interest

The authors declare no conflicting interests.

Ethics statement

Per the University of Wisconsin-Madison IRB, this project qualifies as public health surveillance activities as defined in the Common Rule, 45 CFR 46.102(I)(2). As such, the project is not deemed to be research regulated under the Common Rule and therefore, does not require University of Wisconsin-Madison IRB review and oversight.

Data availability

Data and processing workflows are available at https://go.wisc.edu/p22l16. To protect potentially personally identifiable information, the publicly available dataset contains only PCR Ct values, vaccine status, symptom status, and days from symptom onset to testing for each specimen.

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To-dos

- Perform subset analysis excluding "in-betweens" from the not-fully-vaccinated category
- Add phylogeny of Dane County cases
- Add culture data to introductory paragraph and main text when available
- Calculate percent of unvaccinated people with Ct < 20 at testing. Highlight this in Summary section.
- Check statewide exposure data in WEDSS: can we strengthen the statement that transmission in this cohort is mostly not driven by large gatherings?

From: medicine@us.nature.com
To: Thomas Friedrich

Subject: NMED-BC116676 Receipt of New Paper by Nature Medicine

Date: Tuesday, November 2, 2021 2:05:11 PM

Dear Dr. Friedrich,

Please note that you are listed as a co-author on the manuscript "Shedding of Infectious SARS-CoV-2 Despite Vaccination" (reference number: NMED-BC116676), which was recently submitted to Nature Medicine.

The corresponding author is solely responsible for communicating with the journal and managing communication between co-authors. Please contact the corresponding author directly with any queries you may have related to this manuscript.

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Editorial Assistant Nature Medicine medicine@us.nature.com

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From: <u>em.ppathogens.0.77467c.eff3e03c@editorialmanager.com</u> on behalf of <u>PLOS Pathogens</u>

To: <u>Thomas Friedrich</u>

Subject: PLOS Pathogens: Please confirm your authorship - [EMID:6e248a183751d6e1]

Date: Thursday, November 11, 2021 4:59:06 PM

Dear Friedrich,

You are receiving this email because Ms. Katarina M Grande listed you as an author on the manuscript titled "Shedding of Infectious SARS-CoV-2 Despite Vaccination," recently submitted to PLOS Pathogens.

All co-authors MUST confirm their authorship before a manuscript can be accepted for publication.

Click this link to CONFIRM your authorship and/or add your ORCID to this submission now:

The Corresponding Author has entered your name into our online submission system as indicated below. Please ensure your name is entered correctly, as this impacts indexing. If your name is not entered correctly, please confirm your authorship and then email the journal office at plospathogens@plos.org.

First Name: Thomas Middle Name: C. Last Name: Friedrich

Alternatively, if you are not aware of this submission, or if you should not be listed as a co-author, then please contact the journal office at plospathogens@plos.org.

We appreciate your timely response. The abstract follows below, for your reference.

Kind regards,

PLOS Pathogens Staff plospathogens@plos.org

Manuscript Title:

Shedding of Infectious SARS-CoV-2 Despite Vaccination

Article Type: Research Article

Authors:

Katarina Maria Grande; Kasen K. Riemersma; Brittany E. Grogan; Amanda Kita-Yarbro; Peter J. Halfmann; Hannah E. Segaloff; Anna Kocharian; Kelsey R. Florek; Ryan Westergaard; Allen Bateman; Gunnar E. Jeppson; Yoshihiro Kawaoka; David H. O'Connor; Thomas C. Friedrich

Abstract:

The SARS-CoV-2 Delta variant is highly transmissible and contains mutations that confer partial immune escape. We compared RT-PCR cycle threshold (Ct) data from 699 test-positive anterior nasal swab specimens from fully vaccinated (n = 310) or unvaccinated (n=389) individuals. We observed low Ct values (<25) in 212 of 310 fully vaccinated (68%) and 246 of 389 (63%) unvaccinated individuals. Testing a subset of these low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people. To determine whether infectious virus titers differed in vaccinated and unvaccinated persons, we performed plaque assays on an additional set of 48 samples with Ct <25, finding no difference in infectious virus titer between groups.

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From: **DAVID H O"CONNOR**

Thomas Friedrich; Grande, Katarina To:

Subject: RE: Backchannel: Re: Decision on Nature Medicine submission NMED-BC116676

Date: Thursday, November 4, 2021 12:52:08 PM

Attachments: image001.png

Yep, with a callout to their no-scoop policy in the cover letter. I just drafted an updated cover letter and put it in a folder called PLOS Medicine. Tom, would you review and submit?

dave

Dave O'Connor | UW Medical Foundation Professor

dhoconno@wisc.edu |

http://dho.pathology.wisc.edu

I choose to work flexibly & send emails outside normal office hours. No need to respond to my emails outside yours.

On Nov 4, 2021, 12:30 PM -0500, Grande, Katarina < KGrande@publichealthmdc.com>, wrote:

We might as well try!

From: Thomas Friedrich <tfriedri@wisc.edu> Sent: Thursday, November 4, 2021 12:27 PM

To: Grande, Katarina < KGrande@publichealthmdc.com> Cc: 'DAVID H O'CONNOR' <dhoconno@wisc.edu>

Subject: Backchannel: Re: Decision on Nature Medicine submission NMED-BC116676

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No offer to bounce to Nature Comms. Should we go to Plos Med?

Thomas Friedrich

Professor Dept. of Pathobiological Sciences University of Wisconsin School of Veterinary Medicine @tcfriedrich @tcf-lab

www.vetmed.wisc.edu/friedrichlab

Grande, Katarina wrote on 2021-11-04 12:21:

Thank you for the quick response, Dr. Monteiro!

-Katarina

KATARINA GRANDE, MPH (pronouns: she/her/hers)

Public Health Supervisor/COVID-19 Data Team Lead | Public Health Madison & Dane County

2300 South Park St, Rm 2010, Madison, WI 53713

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From: medicine@us.nature.com <medicine@us.nature.com>

Sent: Thursday, November 4, 2021 12:15 PM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Subject: Decision on Nature Medicine submission NMED-BC116676

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4th Nov 2021

Dear Dr. Grande:

Thank you very much for submitting your manuscript "Shedding of Infectious SARS-CoV-2 Despite Vaccination" (NMED-BC116676). I have had the chance to read your paper, assess the relevant literature and to discuss it with our editorial team.

Unfortunately, our opinion is that the paper would not be a strong candidate for Nature Medicine.

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Nevertheless, thank you very much for giving us the opportunity to consider your work. I am sorry that we cannot be more positive on this occasion and hope you are soon able to interest an alternative journal in your manuscript.

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From: Grande, Katarina

To: "medicine@us.nature.com"

DAVID H O"CONNOR; Thomas Friedrich Cc:

RE: Decision on Nature Medicine submission NMED-BC116676 Subject:

Date: Thursday, November 4, 2021 12:21:37 PM

Attachments: image002.png

image003.png

Thank you for the quick response, Dr. Monteiro!

-Katarina

KATARINA GRANDE, MPH (pronouns: she/her/hers)

Public Health Supervisor/COVID-19 Data Team Lead | Public Health Madison & Dane County

2300 South Park St, Rm 2010, Madison, WI 53713

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From: medicine@us.nature.com < medicine@us.nature.com >

Sent: Thursday, November 4, 2021 12:15 PM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Subject: Decision on Nature Medicine submission NMED-BC116676

4th Nov 2021

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Joao Monteiro Chief Editor Nature Medicine

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 Peter Halfmann

 To:
 Kasen Riemersma

 Cc:
 YOSHIHIRO KAWAOKA

 Subject:
 RE: New England Journal of Medicine - 21-14060

 Date:
 Tuesday, September 14, 2021 1:15:00 PM

 Attachments:
 Copy of Specimens for culture 20210909 PH.xlsx

Kasen,

Here are the titers for the first round of samples.

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Subject: Re: New England Journal of Medicine - 21-14060

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To: DAVID H O'CONNOR < dhoconno@wisc.edu>

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Hello Dr. O'Connor,

Thank you for your email. Your letter is currently with the editor and a decision regarding possible publication has not yet been made. You will be informed of the final editorial decision via email.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine From: NEJM Editorial < editorial@nejm.org>
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To: Letter < letter@nejm.org>

Subject: FW: New England Journal of Medicine - 21-14060

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Dear Ms. Grande and co-authors,

Thank you for submitting your manuscript, "Shedding of Infectious SARS-CoV-2 Despite Vaccination" to the New England Journal of Medicine.

Your manuscript has been forwarded to members of our editorial staff, who will make an initial evaluation and decide whether it merits further consideration. You will be notified of the decision as soon as possible.

Your manuscript ID is 21-14060.

Please mention the above manuscript ID in all future correspondence or when calling the office for questions. If there are any changes in your street address or e-mail address, please log in

appropriate. You may also view the status of your manuscript at any time by checking For Authors section of the site.

We are undertaking evaluation of your manuscript with the understanding that neither the substance of the article nor the figures or tables have been published or will be submitted for publication elsewhere during the period

of review.

Please provide the editors with copies of other manuscripts by you or your coauthors addressing similar or related research questions that are in preparation or under consideration at other journals. This does not apply to abstracts published in connection with scientific meetings or to news reports based on presentations at such meetings.

The Journal's policy is explained more fully at https://www.nejm.org/about-nejm/editorial-policies.

Please call us at 617-734-9800 if you have any questions.

Sincerely,

New England Journal of Medicine 10 Shattuck Street Boston, MA 02115 (617) 734-9800 Fax: (617) 739-9864 http://www.nejm.org

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http://dho.pathology.wisc.edu @dho • 608-890-0845

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Tube_ID	titer: pfu/ml N1_Ct		Collection_Date
1THKW	50	15.06350109	9/2/2021 11:07
1THGD	40	19.98705395	9/2/2021 10:58
1THI1	370	19.58691028	9/2/2021 14:57
1THG9	20	18.32912604	9/2/2021 11:19
1TFJR	0	21.29209604	9/2/2021 14:36
1TFDI	260	24.51859995	9/2/2021 12:05
1TF0Q	3800	15.51073314	9/2/2021 14:14
1TEX4	110	19.44054682	9/2/2021 12:51
1TF3W	120	19.56405534	9/2/2021 15:00
1TFLC	80	24.50682463	9/2/2021 17:35
1TG0H	0	24.9468493	9/2/2021 14:02
1TNRP	3400	17.43160031	9/5/2021 17:21
1THFG	5200	17.66851405	9/2/2021 9:36
1TEC7	730	19.42473556	9/2/2021 13:21
1TMU0	900	18.79827618	9/4/2021 11:44
1TMUL	30	19.8440396	9/4/2021 9:43
1TKJP	0	25.03431554	9/3/2021 9:52
1TKWD	0	19.85761006	9/3/2021 11:34
1TKV7	170	16.62752271	9/3/2021 10:02
1TN5K	5200	18.54030436	9/4/2021 11:33
1TJZ5	250	19.31552845	9/3/2021 12:34
1TJWD	60	20.73535029	9/3/2021 11:21
1TJUV	9000	15.49592228	9/3/2021 16:23
1TJUA	5300	16.47786494	9/3/2021 16:04

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Subject: RE: New England Journal of Medicine - 21-14060

Date: Wednesday, September 15, 2021 12:39:00 PM

We got that sample; from what the wells look like there was (bacterial) contamination so I don't to say it was negative.

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Cheers, Kasen

Sent from my iPhone

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appropriate. You may also view the status of your manuscript at any time by checking For Authors section of the site.

We are undertaking evaluation of your manuscript with the understanding that neither the substance of the article nor the figures or tables have been published or will be submitted for publication elsewhere during the period of review.

Please provide the editors with copies of other manuscripts by you or your coauthors addressing similar or related research questions that are in preparation or under consideration at other journals. This does not apply to abstracts published in connection with scientific meetings or to news reports based on presentations at such meetings.

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<Copy of Specimens for culture 20210910 PH.xlsx>

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I could see it going either way. I don't think we need to add them to the existing dataset. It might even be better to use recent samples because it shows that the trend is stable over time. But I don't feel strongly about it.

dave

Kasen Riemersma wrote on 9/7/21 8:40 AM:

Hi all,

I can definitely provide more samples for Peter to test. Peter, once I know how many you can process, I should be able to send them over quickly.

Tom, if these culture data may be added to our study, I'm inclined to select specimens from the same study period instead of more recent specimens. Do you agree?

Cheers, Kasen

From: Thomas Friedrich < tfriedri@wisc.edu>
Date: Sunday, September 5, 2021 at 12:43 PM

To: YOSHIHIRO KAWAOKA syoshihiro.kawaoka@wisc.edu Cc: DAVID H O'CONNOR syoshihiro.kawaoka@wisc.edu Cc: DAVID H O'CONNOR syoshihiro.kawaoka@wisc.edu Peter Halfmann

<peter.halfmann@wisc.edu>, Katarina Grande <kgrande@publichealthmdc.com>,

Kasen Riemersma riemersma@wisc.edu>

Subject: Re: New England Journal of Medicine - 21-14060

Hi all.

Okay, I agree with all this. In our emails last week, I was not sure whether you guys wanted to respond to Vincent as soon as possible. I completely agree that we would need to generate new titration data with samples that have not undergone multiple freeze-thaw cycles.

Luckily we are getting a large number of samples from Exact each week.

Kasen, can we identify a set of fresh samples that can be aliquoted for Peter to test?

Peter, what is a good number of samples for you to receive?

Best,

-Tom

YOSHIHIRO KAWAOKA wrote on 2021-09-03 19:33:

If we are going to respond to Vincent by sharing our new data, we should do the virus isolation with new samples that have not been thawed several times. I am concerned about the data showing that the number of no-virus-recovery samples from vaccinated individuals is higher than that from unvaccinated individuals. He will criticize this point if we send him the current data.

Best,

Yoshi

From: DAVID H O'CONNOR dhoconno@wisc.edu
Sent: Saturday, September 4, 2021 8:11 AM

To: Thomas Friedrich stfriedri@wisc.edu

<yoshihiro.kawaoka@wisc.edu>; Katarina Grande

 $\underline{<\!kgrande@publichealthmdc.com}\!>$

Subject: Re: New England Journal of Medicine - 21-14060

Hi Tom,

I updated Medrxiv with the NEJM submission. I didn't update with this week's data. I suggest waiting until we get a disposition on the NEJM paper before updating Medrxiv again.

In terms of Vincent, I'm fine if someone else wants to connect with him and Daniel on the data. I'm not enthusiastic about doing it myself.

dave

--

I often work on email outside of work hours, but you don't have to! If you're receiving this outside of your work hours, I don't expect a response until you are back in the office.

http://dho.pathology.wisc.edu

608.890.0845

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Friday, September 3, 2021 18:04

To: DAVID H O'CONNOR < dhoconno@wisc.edu>

Cc: Peter Halfmann < peter.halfmann@wisc.edu >; YOSHIHIRO KAWAOKA

<yoshihiro.kawaoka@wisc.edu>; Katarina Grande

Subject: Re: New England Journal of Medicine - 21-14060

Thanks Dave.

Did we update the medrxiv paper with the titration data? If so I can update my Twitter thread on the paper and include it. As you guys have said, even through the samples have undergone multiple freeze-thaw cycles, it is clear that titers are not systematically lower in vaccinees vs. unvaccinated.

Would you guys also email Daniel and Vincent directly to call their attention to these data?

-T

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 3 Sep 2021, at 17:15, DAVID H O'CONNOR < dhoconno@wisc.edu wrote:

What will come first, an NEJM decision on a 400 word letter or Nonetheless, I pinged the editor (see below) and offered the titer data should it be helpful.

dave

--

I often work on email outside of work hours, but you don't have to! If you're receiving this outside of your work hours, I don't expect a response until you are back in the office.

http://dho.pathology.wisc.edu

608.890.0845

From: Letter < letter@nejm.org>
Sent: Friday, September 3, 2021 14:05

To: DAVID H O'CONNOR < dhoconno@wisc.edu>

Subject: RE: New England Journal of Medicine - 21-14060

Hello Dr. O'Connor,

Thank you for your email. Your letter is currently with the editor and a decision regarding possible publication has not yet been made. You will be informed of the final editorial decision via email.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: NEJM Editorial < editorial@nejm.org Sent: Friday, September 3, 2021 2:58 PM

To: Letter < < letter@nejm.org >

Subject: FW: New England Journal of Medicine - 21-14060

From: Dave O'Connor < dhoconno@wisc.edu Sent: Friday, September 3, 2021 10:17 AM
To: NEJM Editorial < editorial@nejm.org

Subject: Re: New England Journal of Medicine - 21-14060

To whom it may concern,

I am writing on behalf of our co-authors to ask if there are any updates on the status of the 400 word correspondence we submitted to NEJM on August 23. We are keenly aware that this is timely data given the current landscape of SARS-CoV-2 infection despite vaccination.

One small note: some vocal scientists have criticized our work on

social media. The primary claim they make is that virus culture in low Ct samples does not mean that there is similar amounts of replication-competent virus in these samples. Subsequent to our August 23 submission, we re-thawed these samples and showed that virus titers are similar in those who are unvaccinated and infected despite infection (see attached), generally tracking with PCR RNA levels. We would likely want to include a version of this plot in a revised NEJM correspondence to silence this inaccurate criticism.

Thanks in advance for your consideration,

dave

New England Journal of Medicine wrote on 8/23/21 1:39 PM:

Dear Ms. Grande and co-authors,

Thank you for submitting your manuscript, "Shedding of Infectious SARS-CoV-2 Despite Vaccination" to the New England Journal of Medicine.

Your manuscript has been forwarded to members of our editorial staff, who will make an initial evaluation and decide whether it merits further consideration. You will be notified of the decision as soon as possible.

Your manuscript ID is 21-14060.

Please mention the above manuscript ID in all future correspondence or when calling the office for questions. If there are any changes in your street address or e-mail address, please log in

appropriate. You may also view the status of your manuscript at any time by checking For Authors section of the site.

We are undertaking evaluation of your manuscript with the understanding that neither the substance of the article nor the figures or tables have been published or will be submitted for publication elsewhere during the period of review.

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Please call us at 617-734-9800 if you have any questions.

Sincerely,

New England Journal of Medicine 10 Shattuck Street Boston, MA 02115 (617) 734-9800 Fax: (617) 739-9864 http://www.nejm.org

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Tube_ID	N1_Ct	Collection_Date	Virus titers: PFU/ml
1SEH2	21.08310128	8/24/2021 8:47	130
1SHM6	21.58934574	8/24/2021 12:38	120
1SHPW	21.54627886	8/24/2021 13:12	0
1SE2X	15.7339903	8/24/2021 9:41	20000
1SHRU	16.50421287	8/24/2021 17:01	3100
1SHSV	18.87103606	8/24/2021 16:51	1900
1SHJN	18.28345724	8/24/2021 12:10	860
1SHS3	21.74136158	8/24/2021 16:57	300
1SHJV	12.59247242	8/24/2021 13:20	3400
1SHFS	18.57897209	8/24/2021 13:41	3100
1SHLF	14.6042653	8/24/2021 13:21	2900
1SHLU	24.83442105	8/24/2021 12:40	0
1SHKY	17.43457586	8/24/2021 12:37	2800
1SHAK	23.66621923	8/24/2021 13:54	0
1SHIC	16.69530582	8/24/2021 16:49	ND
1SJEK	15.23684453	8/25/2021 12:33	53000
1SIY5	21.10522528	8/25/2021 14:22	60
1SDYB	20.30754385	8/24/2021 13:43	420
1SHPG	15.97163045	8/24/2021 14:08	860
1SIZF	15.64100204	8/25/2021 14:41	370
1SKHE	18.25545253	8/25/2021 9:55	110
1SIX6	19.99673466	8/24/2021 9:28	30
1SJ6J	22.95399616	8/25/2021 10:07	0
1SIZP	17.3381538	8/25/2021 10:47	3700

 From:
 Grande, Katarina

 To:
 Thomas Friedrich

 Cc:
 DAVID H O"CONNOR

 Subject:
 RE: PLOS Medicine

Date: Wednesday, November 10, 2021 2:35:40 PM

Attachments: PMEDICINE-S-21-05677.pdf

ok, submitted! Sorry that took so long. Attached for your reference, hopefully I didn't mess anything up.

-Kat

From: Thomas Friedrich <tfriedri@wisc.edu> **Sent:** Wednesday, November 10, 2021 10:52 AM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Cc: DAVID H O'CONNOR < dhoconno@wisc.edu>

Subject: Re: PLOS Medicine

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Yep, unfortunately all too common. Our CDC contract should pay for that.

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab

www.vetmed.wisc.edu/friedrichlab

Grande, Katarina wrote on 2021-11-10 10:50:

Fun. Did we realize PLOS charges a publication fee??

From: Thomas Friedrich <a href="mailto:striedri@wis

Cc: Grande, Katarina < KGrande@publichealthmdc.com>

Subject: Re: PLOS Medicine

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Yes

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

DAVID H O'CONNOR wrote on 2021-11-09 17:50:

I think we should go with Research Article (it is just a short one).

dave

Dave O'Connor | UW Medical Foundation Professor dhoconno@wisc.edu | 2 +1 http://dho.pathology.wisc.edu

I choose to work flexibly & send emails outside normal office hours. No need to respond to my emails outside yours.

On Nov 9, 2021, 4:03 PM -0600, Grande, Katarina <<u>KGrande@publichealthmdc.com</u>>, wrote:

Yes—sorry for delay! Unfortunately it didn't populate everything nicely, so my next step is to find one of our previous submissions in order to answer these questions (below) consistently. There's also a bunch of missing author info, like institution/affiliation, address, contact info etc. For article type, the options are:Research articleGuidelines and guidancePolicy ForumCollection review (invitation only)Editorial (invitation only)Perspective (invitation only)PLOS Medicine Debate (invitation) ...I was going to select Perspective, but since it's invitation only, how about 'research article'? They can then see that it is a brief research article. **Dual Publication** Have the results, data, or figures in this manuscript been published elsewhere? Are they under consideration for publication elsewhere? **If no:**Enter *No*

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Answer Character Count: 0

Limit 20000 characters

From: DAVID H O'CONNOR <a href="mailto:sda

November 9, 2021 3:56 PM**To:** Grande, Katarina <<u>KGrande@publichealthmdc.com</u>>; Thomas Friedrich

<tfriedri@wisc.edu>Subject: PLOS Medicine

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Kat,

Did you get the info from PLOS Medicine that we need to submit the paper to them? I directly transferred the paper but they said they would reach out to you to get a bit more information.

Meant to ask this morning but it slipped my mind,

dave

Dave O'Connor | UW Medical Foundation Professor dhoconno@wisc.edu | 2 +1

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I choose to work flexibly & send emails outside normal office hours. No need to respond to my emails outside yours.

PLOS Medicine

Shedding of Infectious SARS-CoV-2 Despite Vaccination -- Manuscript Draft--

Manuscript Number:		
Full Title:	Shedding of Infectious SARS-CoV-2 Despite Vaccination	
Short Title:	Shedding of Infectious SARS-CoV-2 Despite Vaccination	
Article Type:	Research Article	
Section/Category:	Health Systems	
Corresponding Author:	Katarina M Grande Public Health Madison & Dane County Madison, WI UNITED STATES	
Corresponding Author Secondary Information:		
Corresponding Author's Institution:	Public Health Madison & Dane County	
Corresponding Author's Secondary Institution:		
First Author:	Kasen K Riemersma, DVM, PhD	
First Author Secondary Information:		
Order of Authors:	Kasen K Riemersma, DVM, PhD	
	Brittany E Grogan, MPH	
	Amanda Kita-Yarbro, MPH	
	Peter Halfmann, PhD	
	Anna Kocharian, MS	
	Kelsey R Florek, MPH, PhD	
	Ryan Westergaard, MD, PhD	
	Allen Bateman, PhD	
	Gunnar E Jeppson, BS	
	Yoshihiro Kawaoka, DVM, PhD	
	David H O'Connor, PhD	
	Thomas C Friedrich, PhD	
	Katarina M Grande, MPH	
Order of Authors Secondary Information:		
Abstract:	The SARS-CoV-2 Delta variant is highly transmissible and contains mutations that confer partial immune escape. We compared RT-PCR cycle threshold (Ct) data from 699 test-positive anterior nasal swab specimens from fully vaccinated (n = 310) or unvaccinated (n=389) individuals. We observed low Ct values (<25) in 212 of 310 fully vaccinated (68%) and 246 of 389 (63%) unvaccinated individuals. Testing a subset of these low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people. To determine whether infectious virus titers differed in vaccinated and unvaccinated persons, we performed plaque assays on an additional set of 48 samples with Ct <25, finding no difference in infectious virus titer between groups.	
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> Phone (608) 266-4821 Fax (608) 266-4858 www.publichealthmdc.com

6 November 2021

Dear editors:

Please consider our attached manuscript, "Shedding of Infectious SARS-CoV-2 Despite Vaccination," for publication as a brief communication in *PLOS Medicine*. For our study, we assembled a team of virologists, epidemiologists, and public health officials to determine whether individuals infected with SARS-CoV-2 despite full vaccination had the potential to transmit the virus. Our study was conducted in Wisconsin at a time when the Delta variant dramatically increased in prevalence to account for almost all new infections; this, together with sequencing data from our own laboratory, suggests that most infections reported here involved Delta.

Our study complements recent epidemiological investigations suggesting that post-vaccination infections with Delta are transmissible, and it **adds three important observations**:

First, in contrast to previous investigations of individual outbreaks that involved healthcare settings (Hetemäki et al. 2021; Mlcochova et al. 2021) or particularly large gatherings (Brown et al. 2021), our study involves persons who sought SARS-CoV-2 testing from community sites spread over a wide geographic area in Wisconsin and thus represents mostly infection in a community setting.

Second, we show that a large proportion of individuals (68%) infected despite full vaccination test positive with Ct <25. Although RT-qPCR Ct values alone are not rigorously quantitative, this low Ct value strongly suggests a high viral load in nasal secretions. Notably, in our study RT-qPCR was performed by a single commercial laboratory using a single assay protocol, helping to control for variability in approaches that could confound comparisons of Ct values generated by different laboratories.

Finally, we show that almost all specimens tested from individuals with Ct values <25 harbor infectious SARS-CoV-2, including 95% of individuals with post-vaccination infections. These findings establish that SARS-CoV-2 RNA detected in vaccinated individuals cannot be due only to cell debris or non-infectious particles.

We believe our findings are significant and timely, and help to inform public health and infection control practices needed to cope with a new surge in COVID-19 cases. We note that one author, Dr. Segaloff, is a CDC Epidemic Intelligence Service officer, and therefore the attached manuscript has undergone CDC clearance prior to submission. We have also shared our findings as a preprint on the nonprofit medrxiv server: https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v5.

PLOS Medicine is an especially attractive destination for this paper because of its innovative stance towards Complementary Research. The impact of this work is demonstrably high; the mredrxiv preprint has been downloaded by than 100,000 times and the full-text HMTL version has been viewed more than 79,000 times. While additional work from other groups (cited in this manuscript) has substantiated and complemented our key findings, our early documentation of transmission-competent SARS-CoV-2 in vaccinated individuals infected with the delta variant remains important and would be of interest to the broad readership of *PLOS Medicine*.

We suggest the following experts as potential reviewers for this work.

Dr. Brian O'Roak, Oregon Health and Science University: oroak@ohsu.edu

Dr. Bronwyn MacInnis, Broad Institute: <u>bronwyn@broadinstitute.org</u>

Finally, please note that three senior authors contributed equally to this work: Drs. O'Connor, Friedrich, and myself.

Thank you for your consideration.

Sincerely, on behalf of all authors,

Kafu Shode

Katarina Grande

Shedding of Infectious SARS-CoV-2 Despite Vaccination

Kasen K. Riemersma, DVM, PhD¹; Brittany E. Grogan, MPH²; Amanda Kita-Yarbro, MPH²; Peter J. Halfmann, PhD¹; Hannah E. Segaloff, PhD³; Anna Kocharian, MS⁴; Kelsey R. Florek, MPH, PhD⁵; Ryan Westergaard, MD, PhD⁶; Allen Bateman, PhD⁵; Gunnar E. Jeppson, BS⁻; Yoshihiro Kawaoka, DVM, PhD¹; David H. OʻConnor, PhD⁶; Thomas C. Friedrich, PhD¹ˆ; Katarina M. Grande, MPH²ˆ

Katarina Grande KGrande@publichealthmdc.com

¹ Department of Pathobiological Sciences, University of Wisconsin-Madison, Madison, WI, USA

² Public Health Madison & Dane County, Madison, WI, USA

³ Epidemic Intelligence Service, CDC, Atlanta, GA, USA

³ Wisconsin Department of Health Services, Madison, WI, USA

⁵ Wisconsin State Laboratory of Hygiene, Madison, WI, USA

⁶ Department of Medicine, University of Wisconsin School of Medicine and Public Health, Madison, WI, USA

⁷ Exact Sciences, Madison, WI, USA

⁸ Department of Pathology and Laboratory Medicine, University of Wisconsin-Madison, Madison, WI, USA

[^]These authors contributed equally. Correspondence can be addressed to:

Abstract

The SARS-CoV-2 Delta variant is highly transmissible and contains mutations that confer partial immune escape. We compared RT-PCR cycle threshold (Ct) data from 699 test-positive anterior nasal swab specimens from fully vaccinated (n = 310) or unvaccinated (n=389) individuals. We observed low Ct values (<25) in 212 of 310 fully vaccinated (68%) and 246 of 389 (63%) unvaccinated individuals. Testing a subset of these low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people. To determine whether infectious virus titers differed in vaccinated and unvaccinated persons, we performed plaque assays on an additional set of 48 samples with Ct <25, finding no difference in infectious virus titer between groups.

Main text

Introduction

The SARS-CoV-2 Delta variant is highly transmissible and contains mutations that confer partial immune escape. Outbreak investigations suggest that vaccinated persons can spread Delta^{1,2} but it is uncertain whether vaccine-induced immune responses reduce nasal viral RNA burden or the titer of infectious SARS-CoV-2 in people infected despite vaccination relative to unvaccinated persons.

Methods

To estimate nasal viral RNA burden, we compared RT-PCR cycle threshold (Ct) data from 699 test-positive anterior nasal swab specimens from fully vaccinated (n = 310) or unvaccinated (n=389) individuals. "Fully vaccinated" is defined as having received a second mRNA vaccine dose or single adenovirus vector vaccine dose ≥ 2 weeks prior to testing positive. Samples were collected in Wisconsin 29 June through 31 July 2021 and tested by a single contract laboratory. During the study period, estimated prevalence of Delta variants in Wisconsin increased from 69% to over 95%. Vaccination status was determined via self-reporting and validated with state immunization records (Supplemental Figure 1). Infectious virus was quantified using plaque assays on a subset of samples with Ct values <25.

Results

RT-PCR Ct values <25 had previously been associated with shedding of infectious SARS-CoV-2. We observed low Ct values (<25) in 212 of 310 fully vaccinated (68%; **Figure 1A**) and 246 of 389 (63%) unvaccinated individuals. Low Ct values were detected in vaccinated people regardless of symptoms at the time of testing (**Figure 1B**). Ct values <25 were detected in 7 of 24 unvaccinated (29%; Cl: 13-51%) and 9 of 11 fully vaccinated asymptomatic individuals (82%; Cl: 48-97%), and 158 of 232 unvaccinated (68%, Cl: 62-74%) and 156 of 225 fully vaccinated (69%; Cl: 63-75%) symptomatic individuals. Testing a subset of these low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people. Infectious virus was detected in the sole specimen tested from an asymptomatic fully vaccinated individual (**Supplemental Figure 2**). Although few asymptomatic individuals were sampled, these results indicate that even asymptomatic, fully vaccinated people might shed infectious SARS-CoV-2.

To determine whether infectious virus titers differed in vaccinated and unvaccinated persons, we performed plaque assays on an additional set of 48 samples with Ct <25, finding no difference in infectious virus titer between groups (**Figure 1C**). Notably time from symptom onset to testing did not vary by vaccination status, suggesting that our observations are not confounded by biases in test-seeking behavior between vaccinated and unvaccinated persons (p=0.40; **Supplemental Figure 3**).

Discussion

Combined with other studies^{3,4} these data indicate that vaccinated as well as unvaccinated individuals infected with the Delta variant might transmit infection, though other studies suggest this may be relatively inefficient⁵. Importantly, we show that infectious SARS-CoV-2 is found at similar titers in vaccinated and unvaccinated persons when specimen Ct values are low. The inclusion of viruses from multiple counties without a linking outbreak (more than 80% of samples were not associated with an outbreak known to public health), indicate that Delta-lineage SARS-CoV-2 can achieve low Ct values consistent with transmissibility in fully vaccinated individuals across a range of settings.

Preventing infections with the Delta variant is therefore critical to stem transmission. Vaccinated and unvaccinated persons should get tested when symptomatic or after close contact with someone with suspected or confirmed COVID-19. Continued adherence to non-pharmaceutical interventions during periods of high community transmission to mitigate spread of COVID-19 remain important for both vaccinated and unvaccinated individuals. Moreover, the administration of an additional vaccine dose after the initial vaccine series dramatically reduces susceptibility to infection with the Delta variant⁶, providing another valuable strategy for interrupting transmission.

Figure

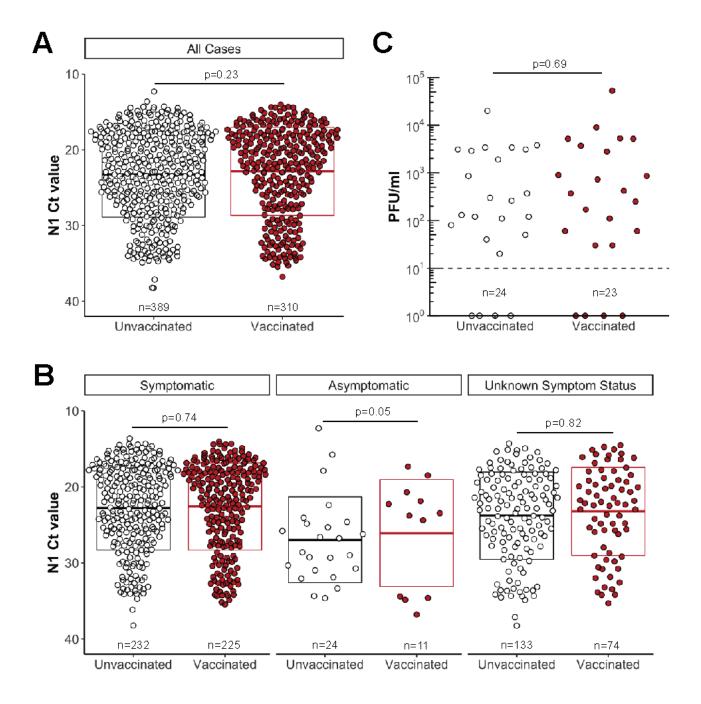
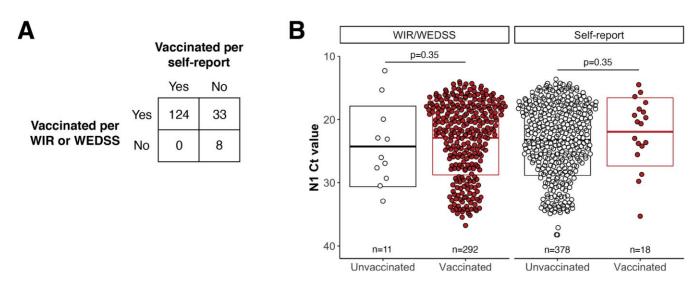


Figure 1. Individuals infected with SARS-CoV-2 despite full vaccination have low Ct values and shed similar amounts of infectious virus as uninfected individuals. A. Ct values for SARS-CoV-2-positive specimens grouped by vaccination status. RT-PCR was performed by Exact Sciences Corporation, responsible for over 10% of all PCR tests in Wisconsin during this period, using a qualitative diagnostic assay targeting the SARS-CoV-2 N gene (oligonucleotides identical to CDC's N1 primer and probe set) that has been authorized for emergency use by FDA

(https://www.fda.gov/media/138328/download). **B.** N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for individuals who were symptomatic or asymptomatic, or those whose symptom status was not determined, at the time of testing. **C.** We performed plaque assays on Vero E6 TMPRSS2 cells on a subset of specimens. Specimens were selected by N1 Ct-matching between fully vaccinated and unvaccinated persons, then specimens from persons with unknown vaccination status were excluded from the analysis. Infectious titers are expressed as plaque-forming units (pfu) per milliliter specimen. Specimens underwent a freeze-thaw cycle prior to virus titration. In **A** and **B**, boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values by independent two-group Mann-Whitney U tests.

Supplemental materials

Supplemental figure 1



Supplemental figure 1. Concordance between self-reported vaccination status and the Wisconsin Immunization Registry (WIR) or Wisconsin Electronic Disease Surveillance System (WEDSS). For all individuals, vaccination status was determined using WIR/WEDSS electronic registries when data were available. Individuals were identified as unvaccinated at the time of testing if WIR/WEDSS data indicated receipt of a first SARS-CoV-2 vaccine dose after the test date.

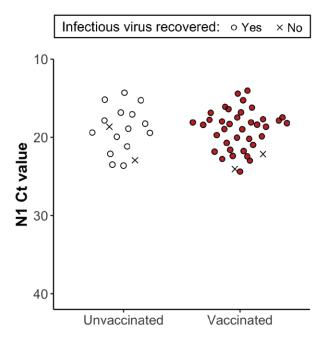
Individuals were considered fully vaccinated based on WIR/WEDSS data if the registries indicated receipt of a final vaccine dose at least 14 days prior to testing. For individuals whose vaccination status could not be verified in WIR/WEDSS, self-reported data collected at the time of testing were used. Individuals were considered unvaccinated based on self-report only if there was an explicit declaration of unvaccinated status in the self-reported data. Individuals were considered fully vaccinated based on self-report if they fulfilled all of the following criteria: (1) indicated that they had received a COVID vaccine prior to testing; (2) indicated that they did not require another vaccine dose; and (3) reported a date of last vaccine dose that was at least 14 days prior to testing.

Specimens lacking data on vaccination status were excluded from the study. Specimens from partially vaccinated individuals (incomplete vaccine series, or <14 days post-final dose) were also excluded. Fully vaccinated status was determined by WIR/WEDSS for 292 specimens and by self-reported data for 18. Unvaccinated status was determined by WIR/WEDSS for 11 and by self-reported data by 378.

A. Of the 699 specimens with vaccination status available from at least one source, 165 specimens had data available from both sources. For self-reporting, under-reporting of full vaccination status (33/157)

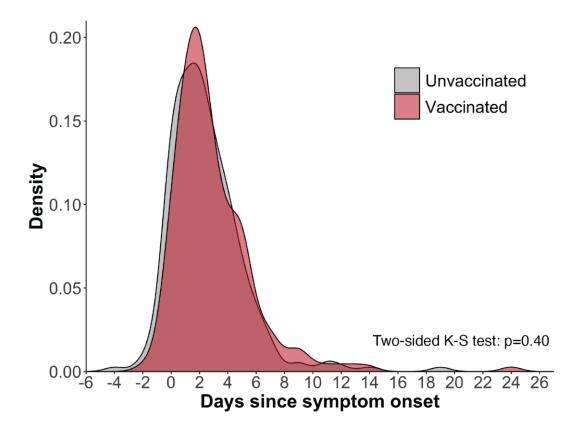
was more common than over-reporting (0/124). **B.** N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for individuals whose vaccination status was determined by WIR/WEDDS or by self-reported data. Boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values by independent two-group Mann-Whitney U tests.

Supplemental figure 2



Supplemental figure 2. Infectious SARS-CoV-2 detected in the majority of fully vaccinated individuals with low Ct values. Infectiousness was determined for a subset of N1 Ct-matched specimens with Ct <25 by inoculation onto Vero E6 TMPRSS2 cells and determining presence of cytopathic effects (CPE) after 5 days in culture. Specimens with unknown vaccination status were excluded from the analysis. Circles indicate presence of CPE; 'X' indicates no CPE detected.

Supplemental figure 3



Supplemental figure 3. Density distributions of unvaccinated and vaccinated specimen collection dates by day since symptom onset. Day 0 on the x-axis denotes self-reported day of symptom onset. Negative values for days indicate specimen collection prior to symptom onset. Symptom onset data were available for n=263 unvaccinated cases and n=232 vaccinated cases.

Conflict of interest

The authors declare no conflicting interests.

Ethics statement

Per the University of Wisconsin-Madison IRB, this project qualifies as public health surveillance activities as defined in the Common Rule, 45 CFR 46.102(I)(2). As such, the project is not deemed to be research regulated under the Common Rule and therefore, does not require University of Wisconsin-Madison IRB review and oversight.

The opinions expressed by authors contributing to this journal do not necessarily reflect the opinions of the Centers for Disease Control and Prevention or the institutions with which the authors are affiliated.

Data availability

Data and processing workflows are available at https://go.wisc.edu/p22l16. To protect potentially personally identifiable information, the publicly available dataset contains only PCR Ct values, vaccine status, symptom status, virus culture status, and days from symptom onset to testing for each specimen.

References

- 1. Shitrit P, Zuckerman NS, Mor O, Gottesman B-S, Chowers M. Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021. *Euro Surveill*. 2021;26(39). doi:10.2807/1560-7917.ES.2021.26.39.2100822
- 2. Eyre DW, Taylor D, Purver M, et al. The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission. *bioRxiv*. Published online September 29, 2021:2021.09.28.21264260. doi:10.1101/2021.09.28.21264260
- 3. Pouwels KB, Pritchard E, Matthews P, et al. Impact of Delta on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK. *bioRxiv*. Published online August 24, 2021:2021.08.18.21262237. doi:10.1101/2021.08.18.21262237
- 4. Chia PY, Xiang Ong SW, Chiew CJ, et al. Virological and serological kinetics of SARS-CoV-2 Delta variant vaccine-breakthrough infections: a multi-center cohort study. *bioRxiv*. Published online July 31, 2021. doi:10.1101/2021.07.28.21261295
- 5. Bergwerk M, Gonen T, Lustig Y, et al. Covid-19 breakthrough infections in vaccinated health care workers. *N Engl J Med*. 2021;385(16):1474-1484.
- 6. Bar-On YM, Goldberg Y, Mandel M, et al. Protection of BNT162b2 vaccine booster against Covid-19 in Israel. *N Engl J Med.* Published online September 15, 2021. doi:10.1056/NEJMoa2114255

Shedding of Infectious SARS-CoV-2 Despite Vaccination

Kasen K. Riemersma, DVM, PhD¹; Brittany E. Grogan, MPH²; Amanda Kita-Yarbro, MPH²; Peter J. Halfmann, PhD¹; Hannah E. Segaloff, PhD³; Anna Kocharian, MS⁴; Kelsey R. Florek, MPH, PhD⁵; Ryan Westergaard, MD, PhD⁶; Allen Bateman, PhD⁵; Gunnar E. Jeppson, BS⁷; Yoshihiro Kawaoka, DVM, PhD¹; David H. O'Connor, PhD®ˆ; Thomas C. Friedrich, PhD¹ˆ; Katarina M. Grande, MPH²ˆ

Katarina Grande K Grande @ publichealthmdc.com

¹ Department of Pathobiological Sciences, University of Wisconsin-Madison, Madison, WI, USA

² Public Health Madison & Dane County, Madison, WI, USA

³ Epidemic Intelligence Service, CDC, Atlanta, GA, USA

³ Wisconsin Department of Health Services, Madison, WI, USA

⁵ Wisconsin State Laboratory of Hygiene, Madison, WI, USA

⁶ Department of Medicine, University of Wisconsin School of Medicine and Public Health, Madison, WI, USA

⁷ Exact Sciences, Madison, WI, USA

⁸ Department of Pathology and Laboratory Medicine, University of Wisconsin-Madison, Madison, WI, USA

[^]These authors contributed equally. Correspondence can be addressed to:

Abstract

The SARS-CoV-2 Delta variant is highly transmissible and contains mutations that confer partial immune escape. We compared RT-PCR cycle threshold (Ct) data from 699 test-positive anterior nasal swab specimens from fully vaccinated (n = 310) or unvaccinated (n=389) individuals. We observed low Ct values (<25) in 212 of 310 fully vaccinated (68%) and 246 of 389 (63%) unvaccinated individuals. Testing a subset of these low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people. To determine whether infectious virus titers differed in vaccinated and unvaccinated persons, we performed plaque assays on an additional set of 48 samples with Ct <25, finding no difference in infectious virus titer between groups.

Main text

Introduction

The SARS-CoV-2 Delta variant is highly transmissible and contains mutations that confer partial immune escape. Outbreak investigations suggest that vaccinated persons can spread Delta^{1,2} but it is uncertain whether vaccine-induced immune responses reduce nasal viral RNA burden or the titer of infectious SARS-CoV-2 in people infected despite vaccination relative to unvaccinated persons.

Methods

To estimate nasal viral RNA burden, we compared RT-PCR cycle threshold (Ct) data from 699 test-positive anterior nasal swab specimens from fully vaccinated (n = 310) or unvaccinated (n=389) individuals. "Fully vaccinated" is defined as having received a second mRNA vaccine dose or single adenovirus vector vaccine dose ≥ 2 weeks prior to testing positive. Samples were collected in Wisconsin 29 June through 31 July 2021 and tested by a single contract laboratory. During the study period, estimated prevalence of Delta variants in Wisconsin increased from 69% to over 95%. Vaccination status was determined via self-reporting and validated with state immunization records (Supplemental Figure 1). Infectious virus was quantified using plaque assays on a subset of samples with Ct values <25.

Results

RT-PCR Ct values <25 had previously been associated with shedding of infectious SARS-CoV-2. We observed low Ct values (<25) in 212 of 310 fully vaccinated (68%; **Figure 1A**) and 246 of 389 (63%) unvaccinated individuals. Low Ct values were detected in vaccinated people regardless of symptoms at the time of testing (**Figure 1B**). Ct values <25 were detected in 7 of 24 unvaccinated (29%; Cl: 13-51%) and 9 of 11 fully vaccinated asymptomatic individuals (82%; Cl: 48-97%), and 158 of 232 unvaccinated (68%, Cl: 62-74%) and 156 of 225 fully vaccinated (69%; Cl: 63-75%) symptomatic individuals. Testing a subset of these low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people. Infectious virus was detected in the sole specimen tested from an asymptomatic fully vaccinated individual (**Supplemental Figure 2**). Although few asymptomatic individuals were sampled, these results indicate that even asymptomatic, fully vaccinated people might shed infectious SARS-CoV-2.

To determine whether infectious virus titers differed in vaccinated and unvaccinated persons, we performed plaque assays on an additional set of 48 samples with Ct <25, finding no difference in infectious virus titer between groups (**Figure 1C**). Notably time from symptom onset to testing did not vary by vaccination status, suggesting that our observations are not confounded by biases in test-seeking behavior between vaccinated and unvaccinated persons (p=0.40; **Supplemental Figure 3**).

Discussion

Combined with other studies^{3,4} these data indicate that vaccinated as well as unvaccinated individuals infected with the Delta variant might transmit infection, though other studies suggest this may be relatively inefficient⁵. Importantly, we show that infectious SARS-CoV-2 is found at similar titers in vaccinated and unvaccinated persons when specimen Ct values are low. The inclusion of viruses from multiple counties without a linking outbreak (more than 80% of samples were not associated with an outbreak known to public health), indicate that Delta-lineage SARS-CoV-2 can achieve low Ct values consistent with transmissibility in fully vaccinated individuals across a range of settings.

Preventing infections with the Delta variant is therefore critical to stem transmission. Vaccinated and unvaccinated persons should get tested when symptomatic or after close contact with someone with suspected or confirmed COVID-19. Continued adherence to non-pharmaceutical interventions during periods of high community transmission to mitigate spread of COVID-19 remain important for both vaccinated and unvaccinated individuals. Moreover, the administration of an additional vaccine dose after the initial vaccine series dramatically reduces susceptibility to infection with the Delta variant⁶, providing another valuable strategy for interrupting transmission.

Figure

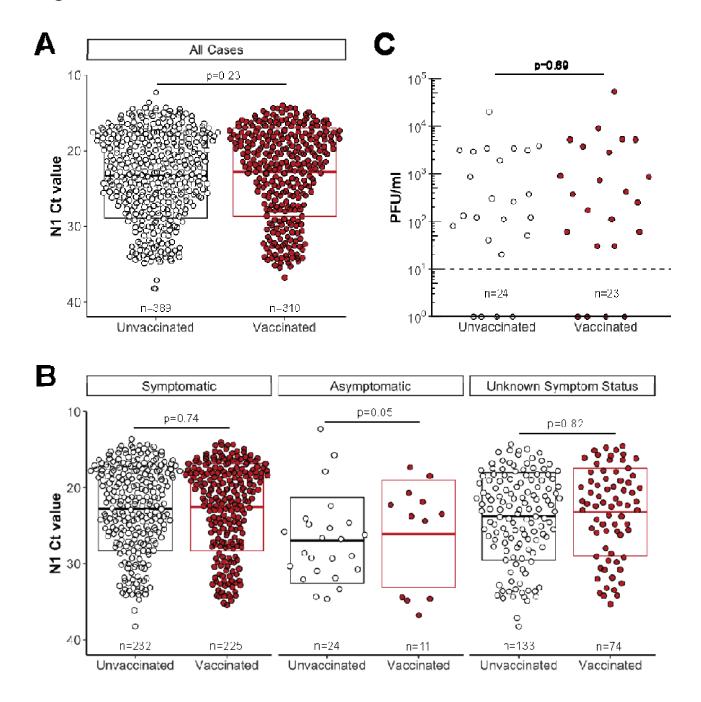
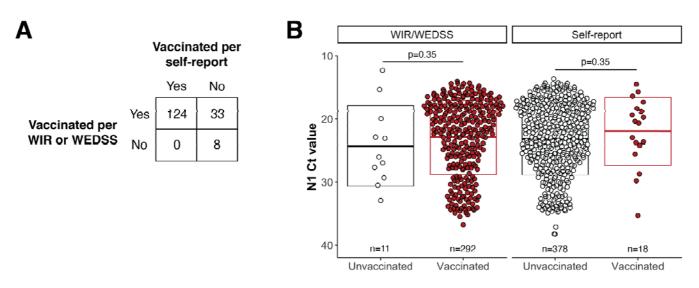


Figure 1. Individuals infected with SARS-CoV-2 despite full vaccination have low Ct values and shed similar amounts of infectious virus as uninfected individuals. A. Ct values for SARS-CoV-2-positive specimens grouped by vaccination status. RT-PCR was performed by Exact Sciences Corporation, responsible for over 10% of all PCR tests in Wisconsin during this period, using a qualitative diagnostic assay targeting the SARS-CoV-2 N gene (oligonucleotides identical to CDC's N1 primer and probe set) that has been authorized for emergency use by FDA

(https://www.fda.gov/media/138328/download). **B.** N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for individuals who were symptomatic or asymptomatic, or those whose symptom status was not determined, at the time of testing. **C.** We performed plaque assays on Vero E6 TMPRSS2 cells on a subset of specimens. Specimens were selected by N1 Ct-matching between fully vaccinated and unvaccinated persons, then specimens from persons with unknown vaccination status were excluded from the analysis. Infectious titers are expressed as plaque-forming units (pfu) per milliliter specimen. Specimens underwent a freeze-thaw cycle prior to virus titration. In **A** and **B**, boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values by independent two-group Mann-Whitney U tests.

Supplemental materials

Supplemental figure 1



Supplemental figure 1. Concordance between self-reported vaccination status and the Wisconsin Immunization Registry (WIR) or Wisconsin Electronic Disease Surveillance System (WEDSS). For all individuals, vaccination status was determined using WIR/WEDSS electronic registries when data were available. Individuals were identified as unvaccinated at the time of testing if WIR/WEDSS data indicated receipt of a first SARS-CoV-2 vaccine dose after the test date.

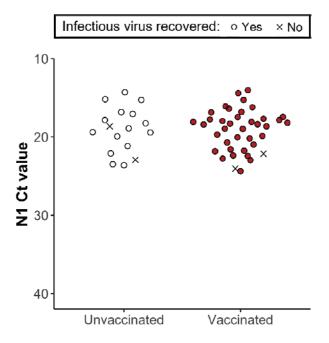
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A. Of the 699 specimens with vaccination status available from at least one source, 165 specimens had data available from both sources. For self-reporting, under-reporting of full vaccination status (33/157)

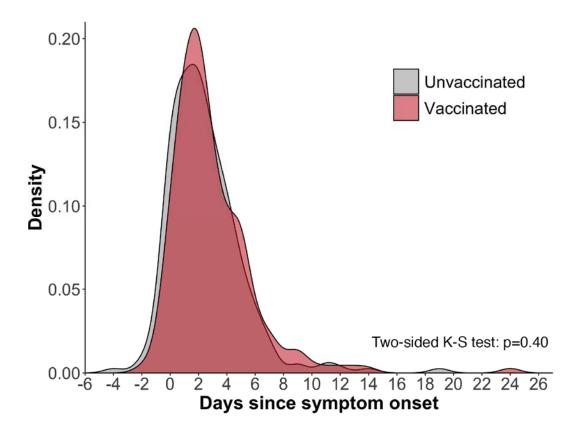
was more common than over-reporting (0/124). **B.** N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for individuals whose vaccination status was determined by WIR/WEDDS or by self-reported data. Boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values by independent two-group Mann-Whitney U tests.

Supplemental figure 2



Supplemental figure 2. Infectious SARS-CoV-2 detected in the majority of fully vaccinated individuals with low Ct values. Infectiousness was determined for a subset of N1 Ct-matched specimens with Ct <25 by inoculation onto Vero E6 TMPRSS2 cells and determining presence of cytopathic effects (CPE) after 5 days in culture. Specimens with unknown vaccination status were excluded from the analysis. Circles indicate presence of CPE; 'X' indicates no CPE detected.

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The authors declare no conflicting interests.

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The opinions expressed by authors contributing to this journal do not necessarily reflect the opinions of the Centers for Disease Control and Prevention or the institutions with which the authors are affiliated.

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References

- 1. Shitrit P, Zuckerman NS, Mor O, Gottesman B-S, Chowers M. Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021. *Euro Surveill*. 2021;26(39). doi:10.2807/1560-7917.ES.2021.26.39.2100822
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- 3. Pouwels KB, Pritchard E, Matthews P, et al. Impact of Delta on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK. *bioRxiv*. Published online August 24, 2021:2021.08.18.21262237. doi:10.1101/2021.08.18.21262237
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 From:
 Peter Halfmann

 To:
 Thomas Friedrich

 Cc:
 DAVID H O"CONNOR

Subject: RE: [EXTERNAL] Automatic reply: Preprint: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the

Delta Variant is Prevalent - Wisconsin, July 2021

Date: Thursday, August 19, 2021 6:17:00 PM

Thanks Tom –yeah there will be a set this weekend and other on Tuesday

From: Thomas Friedrich <tfriedri@wisc.edu> Sent: Thursday, August 19, 2021 6:03 PM

To: Peter Halfmann <peter.halfmann@wisc.edu> **Cc:** DAVID H O'CONNOR <dhoconno@wisc.edu>

Subject: Re: [EXTERNAL] Automatic reply: Preprint: Shedding of Infectious SARS-CoV-2 Despite

Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021

Hey Peter. I am not sure when they would need updated info. Should we tell them that we expect new data by Monday?

Sent from my iPhone

On Aug 19, 2021, at 16:08, Peter Halfmann < peter.halfmann@wisc.edu wrote:

TWIV – is this a Tuesday or Thursday thing? We have some samples infected but won't stain and count until Friday/Saturday.

I don't have Daniel on this email.

Thanks

From: dg2810@cumc.columbia.edu <dg2810@cumc.columbia.edu>

Sent: Thursday, August 19, 2021 3:45 PM

To: DAVID H O'CONNOR < dhoconno@wisc.edu>

Cc: Thomas Friedrich < tfriedri@wisc.edu>; Peter Halfmann

<peter.halfmann@wisc.edu>

Subject: Re: [EXTERNAL] Automatic reply: Preprint: Shedding of Infectious SARS-CoV-2

Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021

Dave and Thomas,

Any quantitative stuff hot off the press so when I discuss your preprint and Vincent starts to rant I can give him some info?

Thanks,
Daniel
On Aug 15, 2021, at 1:56 PM, Dave O'Connor < dhoconno@wisc.edu > wrote:
Yeah, Tom and I were on TWIV a few times several years back. At that time we were talking about predicting future pandemic threats and coping with Zika virus with real-time data sharing. In this era of preprints and what not, it seems both quaint and forever ago!
dave
dg2810@cumc.columbia.edu wrote on 8/15/21 12:45 PM:
Dave,
Appreciate the information. I am planning on discussing your preprint on our next TWIV so would look forward to the quantitative data! Not sure if you are a listener to any of our podcasts. https://www.microbe.tv
Daniel
On Aug 15, 2021, at 10:58 AM, DAVID H O'CONNOR < dhoconno@wisc.edu > wrote:
Hi Daniel,
Not yet. Hopefully Peter from Yoshi's lab will have quantitative data later this coming week or next week. Initial goal was to simply address the criticism that the high PCR levels didn't correspond to replication competent virus.
Cheers,
Dave

Get <u>Outlook for iOS</u>

From: dg2810@cumc.columbia.edu <dg2810@cumc.columbia.edu>

Sent: Sunday, August 15, 2021 7:22 AM

To: DAVID H O'CONNOR

Subject: Fwd: [EXTERNAL] Automatic reply: Preprint: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent - Wisconsin, July 2021

Dr O'Connor,

I forwarded my email you way as suggested by Dr Grande,

Look forward to your response

I hope this email finds you well. I was hoping to a ask a few questions about the

preprint Shedding of Infectious SARS-CoV-2
Despite Vaccination when the Delta
Variant is Prevalent - Wisconsin, July 2021.

You report "Infectious SARS-CoV-2 was isolated from 14 of 16 specimens (88%) from unvaccinated individuals and 37 of 39 specimens (95%) from vaccinated people.'

In figure 2 According to figure 2 Infectiousness was determined by the presence of cytopathic effects (CPE) after 5 days of replication in Vero E6 TMPRSS2 cells with visually apparent CPE under a light microscope. Any real time monitoring or quantification?

Sincerely,

Daniel Griffin, MD PhD CTropMed CTH
Chief, Division of Infectious Disease
- ProHEALTH, an OPTUM Company
Senior Fellow for Infectious Disease - UHG

Research and Development
Clinical Instructor of Medicine - Columbia
University College of Physicians and Surgeons
Department of Medicine-Division of Infectious
Diseases

President -Parasites Without Borders 1 Dakota Drive Suite 205 New Hyde Park, NY 11042 Office Tel: (516)-656-6500

Cell: (347)-276-6116

Email: danielgriffinmd@gmail.com www.parasiteswithoutborders.com www.microbe.tv

Twitter @DanielGriffinMD

Begin forwarded message:

From: "Grande, Katarina"

<KGrande@publichealthmdc.com>

Subject: [EXTERNAL] Automatic reply: Preprint: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021

Date: August 14, 2021 at 10:43:41

PM EDT

To: "Griffin, Daniel"

<dg2810@cumc.columbia.edu>

I will return to the office on Monday, August 16. For public health COVID data questions, please reach out to Brittany Grogan, Manjari Ojha, or Crystal Gibson.

For questions related to the medRxiv pre-print, please contact Tom Friedrich [tfriedri@wisc.edu] or Dave O'Connor [dhoconno@wisc.edu]

If you need to reach someone at Public Health Madison & Dane County more urgently,

please call 608-266-4821 to speak with a receptionist.

--

http://dho.pathology.wisc.edu @dho • 608-890-0845
 From:
 Grande, Katarina

 To:
 DAVID H O"CONNOR

 Cc:
 Thomas Friedrich

Subject: RE: medRxiv -- Manuscript Screened

Date: Wednesday, August 11, 2021 3:45:27 PM

Got it!

From: Dave O'Connor <dhoconno@wisc.edu>
Sent: Wednesday, August 11, 2021 3:43 PM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Cc: Thomas Friedrich <tfriedri@wisc.edu> **Subject:** Re: medRxiv -- Manuscript Screened

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Nope, our previous experience with MMWR was not positive. CDC can take our data if they want it for MMWR. If they don't, that's OK too. Their preprint policy is backwards and nonsensical.

dave

Grande, Katarina wrote on 8/11/21 3:33 PM:

Should we intervene/revoke given MMWR just said they don't allow data shared in a pre-print???

----Original Message----

From: medrxiv@cshlbp.org <medrxiv@cshlbp.org>
Sent: Wednesday, August 11, 2021 3:33 PM
To: dhoconno@wisc.edu; Grande, Katarina
<KGrande@publichealthmdc.com>
Subject: medRxiv -- Manuscript Screened

Caution: This email was sent from an external source. Avoid unknown links and attachments.

MS ID#: MEDRXIV/2021/261387
MS TITLE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021

Dear Dr. Grande,

We are pleased to inform you that the above manuscript has passed screening and will be online shortly. Processing typically completes same or next day (occasionally longer if over a weekend or a holiday).

Once an article is published in a journal, medRxiv will automatically update the preprint with a link to the published version. Depending on the journal, this process may take up to two weeks.

The medRxiv team

--

http://dho.pathology.wisc.edu @dho • 608-890-0845

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 22, 2021 2:30:54 PM

A bit of insight: I spoke to a journalist who told me how our paper is being weaponized by the far right. It might be that journals don't want to publish it and deal with the potential backlash.



You can reply to this email or respond in Basecamp.

This message was sent to Al Bateman, Anna Kocharian, Brittany Grogan, Dave OConnor, Hannah Segaloff, Kasen Riemersma, Katarina Grande, Kelsey Florek, Peter Halfmann, Ryan Westergaard, Sanjib Bhattacharyya, Thomas Friedrich, and Yoshihiro Kawaoka.

Unsubscribe • Change your notification settings





From: Brittany Grogan (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 8:28:52 AM

We don't, Katarina, but it's something I can pull together manually, just have to download some files from WEDSS. I can work on developing a masterlist of booster breakthroughs today that we can use in the meantime until DHS adds those to our daily files!

To be consistent with "regular" breakthroughs, do we want to consider a 'booster breakthrough' as an episode date (i.e. earliest date between symptom onset or test collection date) 14 or more days after the booster shot? CDC said on a call last week that they're finding it takes about 7 days to see a benefit from the booster, and I know that the Israel data Davesent us shows more of a benefit at 12 days vs. 7 days. I'll reach out to Anna to see if DHS is planning on presenting booster breakthrough data and if so, what interval they will use to define it.



You can reply to this email or respond in Basecamp.

This message was sent to Al Bateman, Anna Kocharian, Brittany Grogan, Dave OConnor, Hannah Segaloff, Kasen Riemersma, Katarina Grande, Kelsey Florek, Peter Halfmann, Ryan Westergaard, Sanjib Bhattacharyya, Thomas Friedrich, and Yoshihiro Kawaoka.

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To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 9:24:55 AM

14 days is the definition I'd use if possible. Otherwise you run the risk of underestimating booster effectiveness.

It would be excellent to start cross-checking these cases against viral load. I feel like I've asked this before, but is PHMDC also planning to break out booster vs. non-booster infection and severe case rates?



You can reply to this email or respond in Basecamp.

This message was sent to Al Bateman, Anna Kocharian, Brittany Grogan, Dave OConnor, Hannah Segaloff, Kasen Riemersma, Katarina Grande, Kelsey Florek, Peter Halfmann, Ryan Westergaard, Sanjib Bhattacharyya, Thomas Friedrich, and Yoshihiro Kawaoka.

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From: <u>Brittany Grogan (Basecamp)</u>

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 1:46:54 PM

Sounds good, I added a file to Teams with all of our booster breakthroughs so far where the lab was processed by Exact or UW. There are 43 on the list with the majority being from November.



You can reply to this email or respond in Basecamp.

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From: Thomas Friedrich (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 12:28:36 PM

Thanks Prittanyand Katarina. I think it is worth analyzing breakthrough viral loads stratified by booster vs. no booster in general, and in preparation of potential reviewer requests for more recent data. We can certainly sequence breakthroughs along with everything else. Luis is the person to coordinate with, yes.



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To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 1:57:33 PM

Just to be clear, breakthrough equals >= 14 days after final dose?



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From: Brittany Grogan (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 2:18:42 PM

Correct; we have 80 total since 8/13/21. 56 of those are from November, compared to a total of 3,693 total cases so far in November. On last week's data snapshot we reported that so far 1/3 of Dane County residents who have completed the initial vaccine series have received a booster or third dose.



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To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 3:03:54 PM

So if roughly 72% of Dane County is fully vaccinated, that means that roughly 24% have been boosted (.72 * .3)

This would mean that if the vaccine was having no effect, you'd expect 886 of these November cases to be in vaccinees (3693 *.24). An actual number of 56 doesn't seem that bad - about 6% as likely to be infected after boosting than if unvaccinated.

Unless I can't do math anymore, which is entirely possible:)



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To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Relevant paper in Nature Medicine

Date: Thursday, December 2, 2021 9:48:16 AM

So, like, we were right?



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From: Brittany Grogan (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Thursday, December 2, 2021 9:11:04 PM

Dave FYI we have included booster case rate data in our snapshot that was released this evening! We only release hospitalization and death data by vaccination status once a month, so we'll release that in the same format (not vaxxed/vaxxed initial series/vaxxed + boosted) in two weeks, for both October and November.



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From: Katarina Grande (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Relevant paper in Nature Medicine

Date: Tuesday, December 7, 2021 4:34:34 PM

yep. well done!



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From: Katarina Grande (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 22, 2021 1:33:18 PM

agreed, very annoying. same status today.



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From: Brittany Grogan (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 11:10:34 AM

② Davel'll chat with ② Katarinaand the rest of the data team at our meeting tomorrow morning, but I think that yes, we can certainly explore breaking out unvaccinated vs vaccinated non-booster vs vaccinated booster, perhaps even on this week's data snapshot.

Should we send a list of booster breakthroughs for potential sequencing? It's been a couple months since I've sent a request for sequencing; is this something I would send to Luis?



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This message was sent to Al Bateman, Anna Kocharian, Brittany Grogan, Dave OConnor, Hannah Segaloff, Kasen Riemersma, Katarina Grande, Kelsey Florek, Peter Halfmann, Ryan Westergaard, Sanjib Bhattacharyya, Thomas Friedrich, and Yoshihiro Kawaoka.

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From: Katarina Grande (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 22, 2021 4:17:44 PM

Great point!



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From: Thomas Friedrich (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Wednesday, November 24, 2021 2:52:36 PM

Any further updates <a> Ratarina?

One question for you and <a> Dave -- we have continued to collect data on Ct value and vaccination status. We could update the figures if this version does not get sent out for review...



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This message was sent to Al Bateman, Anna Kocharian, Brittany Grogan, Dave OConnor, Hannah Segaloff, Kasen Riemersma, Katarina Grande, Kelsey Florek, Peter Halfmann, Ryan Westergaard, Sanjib Bhattacharyya, Thomas Friedrich, and Yoshihiro Kawaoka.

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To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Wednesday, November 24, 2021 2:59:46 PM

Great point P Thomas



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To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 22, 2021 3:08:44 PM

Probably a "lost" cause, but I'm not sure I'd welcome the term "lost." A paper that has been seen by more than 100,000 people is arguably the most impactful thing I've ever been involved with. Even if it means that it just becomes an opportunity to educate about what the data says and why the weaponization is wrong.



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To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Wednesday, November 24, 2021 3:00:10 PM

We could also start looking at third vaccine breakthroughs to see if there is any difference in VL in those cases.



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From: Thomas Friedrich (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Wednesday, November 24, 2021 3:00:33 PM



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From: Katarina Grande (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 8:11:47 AM

Current status is now "under review."

Brittany, do we have the data file we need from DHS to gauge what our booster/3rd dose BTs are looking like right now?



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From: Katarina Grande (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 22, 2021 2:37:09 PM

Ok, that's helpful context. Unfortunate! Wonder if there is a different frame we could build out in a submission that would help with this. Or is it a lost cause at this point...



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 From:
 Thomas Friedrich

 To:
 Grande, Katarina

 Cc:
 DAVID H O"CONNOR

Subject: Re: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

Date: Friday, October 29, 2021 6:25:26 PM

Attachments: image.png

Okay, I will do it Sunday.

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

Thomas Friedrich wrote on 2021-10-29 17:01:

Did either of you guys happen to submit today? I feel like we should do this asap. I have a family thing tomorrow but could potentially do it Sunday.

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

Grande, Katarina wrote on 2021-10-29 13:43:

Looks good! Thanks for this work!

-Kat

From: DAVID H O'CONNOR dhoconno@wisc.edu

Sent: Friday, October 29, 2021 11:27 AM

To: Thomas Friedrich <a href

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How's this?

dave

Dave O'Connor | UW Medical Foundation Professor dhoconno@wisc.edu | ☎ +1

http://dho.pathology.wisc.edu

I choose to work flexibly & send emails outside normal office hours. No need to respond

to my emails outside yours.

On Oct 29, 2021, 11:15 AM -0500, Grande, Katarina < KGrande@publichealthmdc.com >, wrote:

Attached!

From: DAVID H O'CONNOR < dhoconno@wisc.edu>

Sent: Friday, October 29, 2021 11:14 AM

To: Grande, Katarina < KGrande@publichealthmdc.com >; Thomas Friedrich

<tfriedri@wisc.edu>

Subject: Re: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

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I can do it but I don't have the cover letter from MMWR or suggested reviewers? Can you forward to me?

dave

Dave O'Connor | UW Medical Foundation Professor

dhoconno@wisc.edu | ☎ +1 http://dho.pathology.wisc.edu

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On Oct 29, 2021, 10:23 AM -0500, Thomas Friedrich < tfriedri@wisc.edu >, wrote:

Okay, so now we need a cover letter and some suggested reviewers.

I am going to be tied up with deadlines for much of the rest of the day, but we should be able to go back to the initial MMWR submission prep to find the reviewers we suggested there.

Kat/Dave, do you have time to update the cover letter accordingly?

-T

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

Grande, Katarina wrote on 2021-10-28 13:51:

Love it! Submit!

Tried to offer a compromise to the comment. Also fine either way.

Submit!

From: DAVID H O'CONNOR <a href

Sent: Thursday, October 28, 2021 1:48 AM

To: Thomas Friedrich **Cc:** Grande, Katarina

Subject: Re: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2

Despite Vaccination)

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Just submit.

On Oct 27, 2021, 11:54 PM -0500, Thomas Friedrich striedri@wisc.edu, wrote:

Great, thanks. I responded to your comment -- I think the text should stay -- but we will see what Kat thinks.

Also, should we share this version with coauthors, or just submit?

Thomas Friedrich

Professor

Dept. of Pathobiological Sciences University of Wisconsin School of Veterinary Medicine @tcfriedrich @tcf-lab www.vetmed.wisc.edu/friedrichlab

DAVID H O'CONNOR wrote on 2021-10-27 19:16:

This looks great Tom. I added one comment to your comment. I also made the spacing between text and superscripted references consistent throughout. Once you resolve the comment (either way is fine with me) I think it's good to go.

dave

_

Dave O'Connor | UW Medical Foundation Professor dhoconno@wisc.edu | +1 http://dho.pathology.wisc.edu

I choose to work flexibly & send emails outside normal office hours. No need to respond to my emails outside yours.

On Oct 27, 2021, 6:13 PM -0500, Thomas Friedrich <friedri@wisc.edu>, wrote:

Hi both.

I went through the text and edited carefully. I expanded it in a few places where the very short text constraints of previous formats made some things less clear than they could be. I also added in a few points to cite papers that are really recent and/or had been excluded from previous versions due to format constraints. This includes all the citations Kat suggested in the Google Doc. Please take a look and let me know what you think. I really hope this does not need to go back to CDC clearance.

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

Thomas Friedrich wrote on 2021-10-27 15:24:

Thanks Kat.

I am going to edit the doc now and try to get to a near-final draft we can submit, pending the okay from you and Dave.

-T

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

Grande, Katarina wrote on 2021-10-26 17:29:

Ok! Added a few citation ideas to the Google doc. And added the ones you cited that I didn't have to the running list I have going, here:

Evidence of transmission from fully vaccinated individuals in a large outbreak of the SARS-CoV-2 Delta variant in Provincetown,

Massachusetts | medRxiv (published 10/20) (Siddle and Gage, et al)

Together, genomic epidemiology provides a high-resolution picture of the Provincetown outbreak, revealing multiple cases of transmission of Delta from fully vaccinated individuals. However, despite its magnitude, the outbreak was restricted in its onward impact in MA and the US, likely due to high vaccination rates and a robust public health response

Personal communication with Contra Costa Health Officer and Medical Director (10/18)

"Agree it would be nice for CDC to come out and say what is only logical of course milder disease and shorter course of illness (results of vaccine) lead to reduced transmission on a community level - it only makes sense - less time sneezing and aerosolizing virus by infected vaccinated individuals compared to the unvaccinated will lead to less transmission. This is

sort of reminiscent of the early days of masking when they would not say that masks reduce transmission despite it being common sense and the literature took about 6 months to catch up...Agree it puts the locals like us in a tougher position. –Dr. Tzvieli

"Since the well publicised and by now well critiqued Cape Cod study, there have been several other papers that suggest the duration of infectivity is less, the area under the curve of viral load over time is less, and even some research that suggests simply measuring levels of viral shedding in the nose is insufficient as much of that virus may be coated with antibodies in the fully vaccinated and thus rendered less infectious. Good studies of real world transmission from fully vaccinated to others would be ideal but so far seem to be lacking, so we must rely on these other proxy studies." –Dr. Farnitano

https://www.npr.org/sections/health-shots/2021/10/12/1044553048/covid-data-vaccines-breakthrough-infections-transmission

• NPR summary of the science around transmission after breakthrough infection. Links to NEJM article from 10/14; virological characteristics of BT infections from 8/21; intramuscular vaccines elicit varying degrees of plasma and salivary antibody response from 8/30

https://www.nejm.org/doi/full/10.1056/NEJMoa2109072 (published 10/14) (Bergwerk et al) Covid-19 Breakthrough Infections in Vaccinated Health Care Workers

- In all 37 case patients for whom data were available regarding the source of infection, the suspected source was an unvaccinated person
- No onward transmission among the 39 primary infections after vaccination

No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups Infected with SARS-CoV-2 Delta Variant | medRxiv (published 10/5) (Acharya)

- Viral loads (Ct) similar for asymptomatic and symptomatic infected people regardless of vaccine status, age, or gender
- This is different than the finding in the UK study, which found higher Cts among vaccinated than unvaccinated

Eurosurveillance | Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021 (published 9/30) (Shitrit, et al)

 Rapid nosocomial spread occurred among vaccinated, including individuals wearing surgical masks The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission | medRxiv (published 9/29) (Eyre)

- Robust contact tracing study from England, looking at secondary infections in contacts of vaccinated and unvaccinated index cases.
- Vaccination lowered the odds of transmitting to contacts.
- This effect may go away after 12 weeks.
- Ct values didn't
 have much impact
 on likelihood of
 onward
 transmission.
 Authors: "factors
 other than PCRmeasured viral
 load at diagnosis
 are important in
 vaccine-associated
 transmission
 reductions"

Protection of BNT162b2 Vaccine Booster against Covid-19 in Israel -PubMed (nih.gov) (published 9/15) (Bar-On et al)

In this study involving participants who were 60 years of age or older and had received two doses of the BNT162b2 vaccine at least 5 months earlier, we found that the rates of confirmed Covid-19 and severe illness were substantially lower among

those who received a booster (third) dose of the BNT162b2 vaccine.

CDC science brief (updated 9/15)

Together, these studies suggest that vaccinated people who become infected with Delta have potential to be less infectious than infected unvaccinated people. However, more data are needed to understand how viral shedding and transmission from fully vaccinated persons are affected by SARS-CoV-2 variants, time since vaccination, and other factors, particularly as transmission dynamics may vary based on the extent of exposure to the infected vaccinated person and the setting in which the exposure occurs.

> Effect of Vaccination on Transmission of SARS-CoV-2 | NEJM (published 9/8)

- Looked at how commonly household members get COVID from a vaccinated healthcare worker household member
- Very large sample size.
- Pre-Delta. (Delta became dominant in Scotland in mid-May). Timing of study was when only healthcare workers were eligible for vaccine, 12/8-3/3/2020.
- Saw that COVID was less common among household members of vaccinated healthcare workers compared to before vaccination; saw this effect after 1 dose.

 "We provide empirical evidence suggesting that vaccination may reduce transmission by showing that vaccination of health care workers is associated with a decrease in documented cases of Covid-19 among members of their households."

Longitudinal analysis of SARS-CoV-2 vaccine breakthrough infections reveal limited infectious virus shedding and restricted tissue distribution | medRxiv (Illinois study) (published 9/2)

- Looked at where virus was hanging out among 23 vaccinated and unvaccinated people with (Alpha!) COVID
- "The durations of both infectious virus shedding and symptoms were significantly reduced in vaccinated individuals compared with unvaccinated individuals."
- "We also observed that breakthrough infections are associated with strong tissue compartmentalization and are only detectable in saliva in some cases. These data indicate that vaccination shortens the duration of time of high transmission potential, minimizes symptom duration, and may restrict tissue dissemination."

Intramuscular SARS-CoV-2 vaccines elicit varying degrees of plasma and salivary antibody responses as compared to natural infection | medRxiv (published 8/30)

• Large amount of

antibodies in mucosal membranes in the nose and mouth, two of the primary entry points for COVID

Viral dynamics of SARS-CoV-2 variants in vaccinated and unvaccinated individuals | medRxiv (NBA study) (published 8/25)

- Longitudinal look at NBA players' PCR tests during pre-Delta and Delta time periods
- Vaccinated individuals' viral loads went down faster than unvaccinated (as seen in Singapore study)
- "These findings are in keeping with the hypothesis that vaccination protects against the severe manifestations of disease but offers less protection against infection in the upper airway. Precautions are therefore necessary to prevent onward transmission even from vaccinated individuals"

Impact of Delta on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK | medRxiv (published 8/24) (Pouwels et al)

 Infections occurring following 2 vaccinations had similar peak viral burden to those in unvaccinated individuals. COVID vax still reduces new infections, but effectiveness and attenuation of peak viral burden are reduced with Delta.

Virological characteristics of SARS-CoV-2 vaccine breakthrough infections in health care workers | medRxiv (published 8/21)

- Looked at 161 breakthrough cases among 24,706 vaccinated Dutch healthcare workers
- Found lower Ct values in symptomatic breakthrough infections than asymptomatic breakthrough infections
- Found vaccination decreased the probability of culture positivity

Transmission dynamics and epidemiological characteristics of Delta variant infections in China | medRxiv (published 8/13)

- Contact tracing study from China, rather small sample size, looked at one outbreak
- Lots of transmission (73.9%) occurred before symptoms showed up, could be because of high

viral loads during this period

Ct values higher in unvaccinated cases. "The vaccinated Delta cases in our study with a decreased viral load might have a reduced transmission potential given that viral RNA load of SAS-CoV-2 was independently associated with the shedding of transmissible viruses"

Transmission of SARS-CoV-2 Delta Variant Among Vaccinated Healthcare Workers, Vietnam (published 8/10)

- Studied breakthroughs among healthcare workers in Vietnam, small sample size (62)
- "Breakthrough Delta variant infections are associated with high viral loads, prolonged PCR positivity, and low levels of vaccineinduced neutralizing antibodies, explaining the transmission between the vaccinated people."

Virological and serological kinetics of SARS-CoV-2 Delta variant vaccinebreakthrough infections: a multi-center cohort study medRxiv (published 7/31) (Chia et al) The Singapore study Vaccination associated with a faster decline in viral RNA load and a robust serological response <image.png> Covid-19 Breakthrough Infections in Vaccinated Health Care Workers -PubMed (nih.gov) (published 7/28) (Bergwerk) Alpha.

- No secondary infections documented.
- Most BT infections were mild or asymptomatic.

From: DAVID H O'CONNOR dhoconno@wisc.edu>
Sent: Monday, October 25, 2021 6:25 PM

To: Thomas Friedrich <tfriedri@wisc.edu>; Grande, Katarina

<KGrande@publichealthmdc.com>

Subject: RE: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

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Yep!

dave

Dave O'Connor | UW Medical Foundation Professor dhoconno@wisc.edu | +1 http://dho.pathology.wisc.edu

I choose to work flexibly & send emails outside normal office hours. No need to respond to my emails outside yours.

On Oct 25, 2021, 5:49 PM -0500, Grande, Katarina < KGrande@publichealthmdc.com >, wrote:

Sorry, got pulled in to infinite meetings today! Will try to highlight a few papers tomorrow—didn't Gage's group post one last week finding transmission indeed occurring from vax'ed in Provincetown?

From: Thomas Friedrich
<tfriedri@wisc.edu>
Sent: Monday, October
25, 2021 9:25 AM
To: DAVID H O'CONNOR
<dhoconno@wisc.edu>
Cc: Grande, Katarina

< KGrande@publichealthmdc.com>

Subject: Re: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

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Just
because it
can be
2000
words
doesn't
mean it
needs to
have 2000
words.

Exactly.

We will want to edit the abstract you had in the medrxiv version, because IIRC it just repeats a lot of the language in the paper itself.

We should also add a sentence or two to the discussion so we can cite a few more recent papers. Kat, could you possibly take a stab at that? You could even just suggest a few talking points that we could wordsmith collaboratively.

Dave, should we still edit the SharePoint version?

-T

Thomas Friedrich

Professor
Dept. of
Pathobiological
Sciences
University of
Wisconsin
School of Veterinary
Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

DAVID H O'CONNOR wrote on 2021-10-25 09:22:

Alrighty.
Just
because it
can be
2000
words
doesn't
mean it
needs to
have 2000
words.

If you look at the Medrxiv version, I had to create an

abstract or else they don't accept the submission, so we can use that as a start. I'm on this WHO webinar all morning but could help later. dave Dave O'Connor | UW Medical Foundation Professor dhoconno@wisc.edu +1http://dho.pathology.wisc.edu I choose to workflexibly & send emails outside normalofficehours. No need to respond to my emails outsideyours. On Oct 25, 2021, 9:19 AM -0500, Thomas Friedrich <tfriedri@wisc.edu>, wrote: I think a Nat Med Brief Communication would require minimal reformatting:

Brief Communication A Brief Communication is a format intended for reporting of timely new results that, while limited scope, are of substantial clinical or public health importance, and that therefore need to be quickly vetted and shared. Brief Communications begin with a unreferenced abstract (150 words) followed by the main text (a single section containing

				introduction, results
				and discussion).
				The
				main
				text can be
				up to
				2000
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				and
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				Brief
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	and include received/accepted dates. They may be accompanied by supplementary information.
	Thomas Friedrich Professor Dept. of Pathobiological Sciences University of Wisconsin School of Veterinary Medicine @tcfriedrich @tcf- lab www.vetmed.wisc.edu/friedrichlab DAVID H O'CONNOR wrote on 2021- 10-25 09:16: Either one is fine with me, though I'd really like to submit as- is without a

lengthy reformatting/modification. I'm happy to do this after we get some traction if requested by editors/reviewers, I just don't want to invest the time only to have another desk rejection. dave Dave O'Connor UW Medical Foundation Professor dhoconno@wisc.edu I choose to work fleexibly & send emails outside normal office	1 1	į l	
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		hours. No need to respond to my emails outside yours. On Oct 25, 2021, 9:10 AM
		wrote:
		other option might be a brief communication to Nature Medicine: https://www.nature.com/nm/content T T Thomas Friedrich Professor Dept. of Pathobiological Sciences University of Wisconsin School of Veterinary Medicine @tcfriedrich @tcf-lab www.vetmed.wisc.edu/friedrichlab
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						< <u>KGrande@publichealthmdc.com</u> >
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Katarina KATARINA GRANDE, MPH (pronouns: she/her/hers) Public Health Supervisor/COVID-19 Data Team Lead <u>Public</u> <u>Health</u> Madison <u>Dane</u> County 2300 South Park St, Rm 2010, Madison, WI 53713 Phone: (608)243-0409 Cell: Fax: (608) 266-4858 Healthy People. Healthy Places. f 💿 💆 🖸 This email, including any attachments, may contain

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			to 7 authors, and we cannot make an exception. Would you be willing to decrease the number of authors to 7? If not, we will not be able to consider your manuscript. Sincerely, Jody W Zylke, MD Deputy Editor, JAMA Email: Jody.Zylke@jamanetwork.org

From: <u>Thomas Friedrich</u>

To: KGrande@publichealthmdc.com

Subject: Re: FW: Receipt of NMED-BC116676

Date: Tuesday, November 2, 2021 3:03:38 PM

No worries -- fingers crossed!

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

KGrande@publichealthmdc.com wrote on 2021-11-02 14:53:

Nope, looks great. Thanks again for your work on getting this edited and submitted!

From: Thomas Friedrich <tfriedri@wisc.edu>
Sent: Tuesday, November 2, 2021 2:30 PM

To: Grande, Katarina < <u>KGrande@publichealthmdc.com</u>>

Subject: Re: FW: Receipt of NMED-BC116676

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Nope. I think that is just for you as corresponding author.

Any issues there?

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

KGrande@publichealthmdc.com wrote on 2021-11-02 14:06:

Did you get a copy of this receipt?

From: medicine@us.nature.com <medicine@us.nature.com>

Sent: Tuesday, November 2, 2021 2:05 PM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Subject: Receipt of NMED-BC116676

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Our ref: NMED-BC116676

2nd Nov 2021

Dear Dr. Grande,

Thank you for submitting your manuscript, "Shedding of Infectious SARS-CoV-2 Despite Vaccination". We expect to have our internal review completed shortly. At that time we will email you the status of

your manuscript. Please quote the manuscript number NMED-BC116676 in future correspondence.

Thank you for considering Nature Medicine as a place to publish and if you have

questions please do not hesitate to contact me. Our internal review usually

takes less than two weeks; if you do not hear from us, feel free to drop me a

note over email and I will get back to you as soon as I can.

As you may know, we are trying to improve the quality and transparency of

methods and statistics reporting in our papers

 $(\underline{http://www.nature.com/nm/journal/v19/n5/full/nm0513-508.html}).$

To that end, we ask that you complete two items: an editorial policy checklist that verifies compliance with all required editorial policies and a reporting summary that collects information on experimental design and reagents.

• Reporting summary:

https://www.nature.com/documents/nr-reporting-summary.zip

• Editorial policy checklist:

https://www.nature.com/documents/nr-editorial-policy-checklist.zip

Please note that we will only use this checklist if the editors decide to send your article for external review. However, to avoid any unnecessary delays in the handling of your papers, we encourage you to fill the checklist during the journal's internal review of the paper.

You may check the status of your manuscript by selecting the "Check manuscript

status" link under the following URL:

https://mts-nmed.nature.com/cgi-bin/main.plex? el=A7H4BBKi4A5EaJO4F4A9ftddmZaOdWF5RnkMpwM3elXwZ

Clicking on this link will automatically send you to the web page.

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contributions.

For your reference, please note that all published original research manuscripts, Reviews and Perspectives must contain a declaration of any

financial and non-financial competing interests. The declaration is required only when a paper is

being accepted. Full details of the policy can be found at "http://www.nature.com/nature/submit/policies/competing/index.html"

Yours sincerely,

Editorial Assistant Nature Medicine medicine@us.nature.com

Our flexible approach during the COVID-19 pandemic

If you need more time at any stage of the peer-review process, please do let us know. While our systems will continue to remind you of the

original timelines, we aim to be as flexible as possible during the current pandemic.

This email has been sent through the Springer Nature Tracking System NY-610A-NPG&MTS

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 From:
 Thomas Friedrich

 To:
 Grande, Katarina

 Cc:
 DAVID H O"CONNOR

Subject: Re: FW: Your PLOS Medicine Submission (PMEDICINE-D-21-04683) - [EMID:a9f2a3d642ffe1bc]

Date: Thursday, November 11, 2021 10:51:38 AM

Great, thanks Kat.

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tefriedrich
@tef-lab
www.vetmed.wisc.edu/friedrichlab

Grande, Katarina wrote on 2021-11-11 10:36:

Let's see if I can find time today to rebuild a Plos Pathogens submission; shouldn't be too difficult since I have all the material from yesterday.

From: Thomas Friedrich < tfriedri@wisc.edu>
Sent: Thursday, November 11, 2021 10:35 AM

To: Grande, Katarina < KGrande@publichealthmdc.com>
Cc: 'DAVID H O'CONNOR' < dhoconno@wisc.edu>

Subject: Re: FW: Your PLOS Medicine Submission (PMEDICINE-D-21-04683) - [EMID:a9f2a3d642ffe1bc]

Caution: This email was sent from an external source. Avoid unknown links and attachments

I would rather not, but could be convinced not to care

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

Grande, Katarina wrote on 2021-11-11 10:33:

It looks like the automatic transfer option is PLOS One. Should we start there, for ease?

From: DAVID H O'CONNOR <u><dhoconno@wisc.edu></u>
Sent: Thursday, November 11, 2021 10:28 AM
To: Thomas Friedrich <u><tfriedri@wisc.edu></u>

Cc: Grande, Katarina < KGrande@publichealthmdc.com>

Subject: Re: FW: Your PLOS Medicine Submission (PMEDICINE-D-21-04683) - [EMID:a9f2a3d642ffe1bc]

Caution: This email was sent from an external source. Avoid unknown links and attachments

Yep. What Tom said. Can you transfer from PLOS Medicine to PLOS Pathogens via the web interface?

dave

Dave O'Connor | UW Medical Foundation Professor

dhoconno@wisc.edu | ☎ +1 http://dho.pathology.wisc.edu

I choose to work flexibly & send emails outside normal office hours. No need to respond to my emails outside yours.

On Nov 11, 2021, 9:57 AM -0600, Thomas Friedrich < tfriedri@wisc.edu >, wrote:

I would try Plos Pathogens first and again highlight PLOS's ostensible no-scooping policy. After that PLOS ONE.

Mostly I am pissed off at CDC's inane clearance policy and retrograde policy on preprints, as well as at NEJM for sitting on the paper for 6 weeks.

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

DAVID H O'CONNOR wrote on 2021-11-11 09:32:

Maybe PLOS Pathogens?

dave

Dave O'Connor | UW Medical Foundation Professor dhoconno@wisc.edu | 🖸 +1

http://dho.pathology.wisc.edu

I choose to work flexibly & send emails outside normal office hours. No need to respond to my emails outside yours.

On Nov 11, 2021, 9:10 AM -0600, Grande, Katarina ≤KGrande@publichealthmdc.com≥, wrote:

And here it (rejection notice) is!

Do we end our journey here, folks? Are these data too 'old' at this point from a pandemic perspective? Has this finding been published enough already, from the perspectives of editors? Even though we acknowledge and cite findings since our study, maybe the journal community has fully shifted from wanting to focus on viral load proxies to the conversations around waning immunity, location of virus in nasal passageways, likelihood of getting infected in the first place if vaccinated, etc. etc. Again, we include all these nuances, but alas. Thoughts?

-Kat

----Original Message-----

From: em.pmedicine.0.77446e.85884cb9@editorialmanager.com

<em.pmedicine.0.77446e.85884cb9@editorialmanager.com> On Behalf Of PLOS

Medicine

Sent: Thursday, November 11, 2021 8:12 AM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Subject: Your PLOS Medicine Submission (PMEDICINE-D-21-04683) -

[EMID:a9f2a3d642ffe1bc]

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Dear Dr. Grande,

Thank you very much for submitting your manuscript entitled "Shedding of Infectious SARS-CoV-2 Despite Vaccination" (PMEDICINE-D-21-04683) for consideration at PLOS Medicine.

As with all manuscripts submitted to the journal, yours was considered in light of other papers that we receive, and our aims for the journal. We are looking for papers of wide general interest which would lead to a substantial advance in clinical management or public health policy, or which provide a substantial new insight into the pathogenesis of disease, with a clear path toward clinical application. Within these categories, we prioritize research on conditions that contribute to a substantial proportion of the global burden of disease.

Now that we have had a chance to evaluate your paper, I regret to tell you that we do not think it is appropriate for the journal given current editorial criteria and our expectations regarding the extent of conceptual or practical advance that we anticipate being of interest to our broad readership.

While we cannot therefore consider your manuscript further for publication in PLOS Medicine, we suggest transferring your manuscript to PLOS ONE instead (www.plosone.org).

PLOS ONE is a peer-reviewed journal that accepts original research that contributes to the base of academic knowledge. The review process at PLOS ONE focuses on scientific validity, strong methodology and high ethical standards, and the journal's inclusive scope and broad reach means that research published in PLOS ONE will be read, cited and used by researchers across many disciplines.

Please remember to ensure that all authors are aware of and agree to the transfer of this submission, and that submissions can only be considered by one journal at a time.

If you would like to submit your work to PLOS ONE, please click the following link: https://urldefense.proofpoint.com/v2/url?u=https-

3A www.editorialmanager.com pmedicine l.asp-3Fi-3D712184-26l-

3DWRWADMXC&d=DwIGaQ&c=byefhD2ZumMFFQYPZBagUCDuBiM9Q9twmxaBM0hCgII&r=zyp-4-WV7kOLmgSbRwbjUT7zXI88RkfDqC-

J0FyhCFc&m=ANWtspF2OmBAqD QBoxfPv-

PbK6wbZegJHiOnFFZcfg&s=goMSNcf1Aq4-898WVDWmt-

1pZDw7RF8a6lngNnHQ4 Q&e=

Please note that the journals are editorially independent and we therefore cannot guarantee the outcome if you choose to pursue a transfer.

Should you choose to transfer your submission to PLOS ONE, you will receive a confirmation email within 24-48 hours of accepting the transfer. Your submission details and manuscript files will be transferred automatically; however, because all PLOS journals vary in submission requirements, once in the PLOS ONE Editorial Manager site, you will be asked to provide additional information before you can finalize your new submission to PLOS ONE. If you have any questions, please feel free to contact the journal at plosone@plos.org.

Thank you for giving us the opportunity to consider your work.

Sincerely,

Richard Turner, PhD Senior Editor, PLOS Medicine

plosmedicine@plos.org

In compliance with data protection regulations, you may request that we remove your In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: <a href="https://urldefense.proofpoint.com/v2/url?u=https-3A_www.editorialmanager.com_pmedicine_login.asp-3Fa-3Dr&d=DwIGaQ&c=byefhD2ZumMFFQYPZBagUCDuBiM9Q9twmxaBM0hCgII&r=zyp-4-WV7kOLmgSbRwbjUT7zXI88RkfDqC-J0FyhCFc&m=ANWtspF2OmBAqD_QBoxfPv-PbK6wbZegJHiOnFFZcfg&s=LwbKJSvS0j1nup1b0e2TM4H8HAd8eWehu8LzouUjA-p&s=1_Places_context_the publication office if you have any questions.

o&e=). Please contact the publication office if you have any questions.

 From:
 Thomas Friedrich

 To:
 DAVID H O"CONNOR

 Cc:
 Grande, Katarina

Subject: Re: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

Date: Monday, October 25, 2021 10:21:54 AM

Attachments: <u>image.png</u>

Taking the JAMA editor off. :)

I fully agree on bringing it back to Google Docs.

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

DAVID H O'CONNOR wrote on 2021-10-25 09:55:

A point on process - I really think we should bring it back into gDocs. Doing this in Word was a huge PITA and required excessive formatting to get right at the end. Would be much better to edit collaboratively in gDocs and export to Word at the very end.

dave

Dave O'Connor | UW Medical Foundation Professor dhoconno@wisc.edu | +1 http://dho.pathology.wisc.edu

I choose to work flexibly & send emails outside normal office hours. No need to respond to my emails outside yours.

On Oct 25, 2021, 9:29 AM -0500, Grande, Katarina <<u>KGrande@publichealthmdc.com</u>>, wrote:

Thanks, Jody, we appreciate your response. Given this, we'd like to withdraw our submission from consideration.

Thanks again for your time, we hope you have a nice week!

-Katarina

From: Jody Zylke Jody Zylke@jamanetwork.org

Sent: Saturday, October 23, 2021 5:11 AM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Subject: RE: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite

Vaccination)

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Yes, all the JAMA Network journals have the same policies.

Jody

From: Grande, Katarina < KGrande@publichealthmdc.com>

Sent: Friday, October 22, 2021 11:45 AM

To: Jody Zylke <<u>Jody.Zylke@jamanetwork.org</u>>

Cc: 'DAVID H O'CONNOR' < dhoconno@wisc.edu; Thomas Friedrich

<tfriedri@wisc.edu>

Subject: RE: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite

Vaccination)

[Warning External Email]

Thanks for your response, Dr. Zylke. We're struggling with this since this endeavor was such a massive collaborative effort! Does JAMA Open Network have the same 7 author limit for a Research Letter submission?

Thanks again for your time!

-Katarina

KATARINA GRANDE, MPH (pronouns: she/her/hers)

Public Health Supervisor/COVID-19 Data Team Lead | Public Health Madison & Dane County

2300 South Park St, Rm 2010, Madison, WI 53713

Phone: (608) 243-0409 | Cell: | Fax: (608) 266-4858

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This email, including any attachments, may contain confidential or protected health information which is only for the intended recipient. If you received this email in error, please delete and notify the sender immediately. Emails sent or received by our agency are subject to open records requests and could be released to the public, unless there is an exception allowed by law.

<image002.png>

From: Jody.Zylke@jamanetwork.org>

Sent: Thursday, October 21, 2021 5:02 PM

To: Grande, Katarina < <u>KGrande@publichealthmdc.com</u>>

Subject: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Dear Ms Grande:

Thanks for submitting a research letter to JAMA. The study is interesting and I would be willing to send it for peer review. However, research letters are limited to 7 authors, and we cannot make an exception.

Would you be willing to decrease the number of authors to 7? If not, we will not be able to consider your manuscript.

Sincerely,

Jody W Zylke, MD Deputy Editor, JAMA Email: <u>Jody.Zylke@jamanetwork.org</u>

Subject: Re: NEJM figure updates

Date: Wednesday, September 29, 2021 10:26:30 PM

Attachments: EOC Riemersma Viral loads in vaccinees NEJM revised 2021-09-29.docx

Dave and Kasen,

Attached is a draft revised version of the NEJM letter.

Kasen, I would appreciate it if you could give a quick read, especially to the Figure 1 legend, to make sure I have correctly described how the samples were chosen.

I decided to omit the supplemental figure showing infectious titer as a function of Ct because we don't have a best-fit line or r-squared value. We should calculate these for when we show that plot in future, though -- Kasen can do it if he has time, or else we can ask Luis to do that.

Thanks,

-T

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

wrote on 2021-09-29 20:36:

All right, I've attached the updated figures and the table of titer data that Dave can share. The figure files are also in the TCF shared google drive in the same directory listed in my previous email. To avoid confusion, Dave should probably remove the older (2-freeze-thaw) titer data in the excel file he's currently sharing since it's no longer in the manuscript.

Let me know if you have any questions or if anything needs to be changed.

Cheers, Kasen

On Wed, Sep 29, 2021 at 6:55 PM Thomas Friedrich < tfriedri@wisc.edu > wrote: Okay, thanks. Sorry about this.

Also, please check to make sure the axes are not cut off in the figure you place in Illustrator. It looked like the very top of the 5 in the 10⁵ on the y axis and the very last zero on the x-axis were every-so-slightly cropped.

Sorry again to bug you about this. After we get this back in things should be less hectic. But, given that we have an opportunity to essentially revise the paper before the editor looks at it, I want to be sure we get it back in asap. I worry that the editor will decide to read it right away, having been pinged by the assistant, so I want to be sure he sees these data.

Thanks again,

wrote:

Hey Tom,

Sorry about that, I had not seen your previous emails. You are correct, I used the two-freeze-thaw data. I will correct the figures with the newer -one-freeze-thaw data tonight. I will do so after Mary is done with her computer late this evening, and I will email you when the main figure and the supplemental figure files have been updated.

Kasen

On Wed, Sep 29, 2021 at 6:24 PM Thomas Friedrich < tfriedri@wisc.edu wrote:
 _
Hi Kasen
<u> </u>
Sorry to bother you, but I wanted to make sure you received the messages below. Can you please check the revised figure and make sure that it contains the correct plaque assay data? I think the figure you made actually uses the data from the samples that had undergone 2 freeze-thaw cycles
We had hoped to get the revised paper to NEJM today, but I think we are still good if we can submit it tomorrow morning. The assistant editor said she was going to flag it for the editor's attention
Thanks,
-T
<u> </u>
*From: *Thomas Friedrich < <u>tfriedri@wisc.edu</u> <mailto:<u>tfriedri@wisc.edu>> *Date: *Wednesday, 29 September 2021 at 10:57 *To: * </mailto:<u>
<pre> <mailto:< td=""></mailto:<></pre>

Here is the pdf of the panel I was thinking of. Note the much smaller number of negative samples.____

Thomas Friedrich Professor Dept. of Pathobiological Sciences University of Wisconsin School of Veterinary Medicine @tcfriedrich @tcf-lab www.vetmed.wisc.edu/friedrichlab <http://www.vetmed.wisc.edu/friedrichlab> Thomas Friedrich wrote on 2021-09-29 10:54: Hi Kasen. Thanks for putting together the revised figure, but I think you may have the incorrect panel. The data you shared earlier from the single freeze-thaw showed only 4 samples from each group (vaccinated vs unvaccinnated) that had no detectable plaques. Here there are many samples in each group for which there are no plaques. Can you please confirm this? I am hoping to get an updated paper back to NEJM by close of business today, so I can perhaps swap in the correct panel in Illustrator if you can help me find/generate it. Thanks, -Tom Thomas Friedrich Professor Dept. of Pathobiological Sciences University of Wisconsin School of Veterinary Medicine @tcfriedrich @tcf-lab www.vetmed.wisc.edu/friedrichlab http://www.vetmed.wisc.edu/friedrichlab>

	
	<mailto:< td=""></mailto:<>
wrote on 2021-09-28 21:11:	
Hey Tom,	

I updated the NEJM figure by replacing the old culture plot with the titer data. I wasn't sure if you wanted to try squeezing the titer-by-ct plot into the main figure, so I just made it as a new supplemental figure 3. The .ai files and associated .png plots are stored in Drive/Shared Drives/TCF lab/Former Lab

T	s/Riemersma_Kasen/SARS2_Sequencing/Ct_values_vax_unvax/NEJM/Figures_NEJM. he updated main figure is 'NEJM_Figure1_v3' and the new applemental is 'NEJM_SupplementalFigure3'
fi st m	et me know if you have any questions, or if you want the gures formatted differently. I don't have the adobe uite on my new work computer, so I will only be able to take edits in the evening when I can steal Mary's omputer
- C	- — heers,
	asen
<	Hey Tom,
	I will work on updating the NEJM figure with the virus titer and titer-by-ct plots tonight since I'll need to use Mary's computer to do so. Re: plot formatting, I adjust the dimensions of each plot when exporting from R, so will just need to match the dimensions of the newer plots with the NEJM plots. For the titer data, which specimens should I include: specimens from the study period that underwent multiple freeze-thaws, or newer specimens that underwent one freeze-thaw?
	That's crazy (and incredibly frustrating) that the editor hasn't looked at it! Have you contacted them to ask what's up?
	Kasen
<mailto:<u>t</mailto:<u>	> On Sep 28, 2021, at 11:13 AM, Thomas Friedrich < tfriedri@wisc.edu friedri@wisc.edu>> wrote: > > Hey Kasen.

>
> > I would like to ask for a little help in updating the figure for the NEJM
paper I would like to replace the panel showing virus isolation with the one you generated comparing virus titers. I would also like to show your plot of infectious
titer as a function of Ct value. I am not sure how you generated the
Illustrator file, but whatever you did, you did very well at making the data points the same size and the
axes about the same scale in each panel. I cannot do
that with the pdf files you attached in your email.
> > If you'd have a few moments to talk me through the figure-making
process you used, and perhaps to just update this figure, I would really appreciate
it.
>
> Dave and I are hoping to submit an updated version to NEJM as soon as possible I think we have an opportunity to do this, because somehow the editor has not looked at it yet!
>
> Thanks,
> >-T
> -1
> Thomas Friedrich
> . n. c
> Professor> Dept. of Pathobiological Sciences
> University of Wisconsin
> School of Veterinary Medicine
> @tcfriedrich
> @tcf-lab
 www.vetmed.wisc.edu/friedrichlab
Shttp://www.vethled.wise.edu/friedreniae/

Kasen K. Riemersma, DVM, PhD
Postdoctoral Research Associate, Friedrich Lab
School of Veterinary Medicine
University of Wisconsin, Madison
<mailto:< td=""></mailto:<>

Kasen K. Riemersma, DVM, PhD
Postdoctoral Research Associate, Friedrich Lab
School of Veterinary Medicine
University of Wisconsin, Madison

<mailto

--

Kasen K. Riemersma, DVM, PhD Postdoctoral Research Associate, Friedrich Lab School of Veterinary Medicine University of Wisconsin, Madison From: Thomas Friedrich

To: <u>Segaloff, Hannah E - DHS</u>

Cc: Kasen Riemersma; DAVID H O"CONNOR

Subject: Re: NEJM letter author list

Date: Tuesday, August 17, 2021 11:28:29 AM

Great, thanks Hannah.

-T

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 17 Aug 2021, at 11:08, Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov > wrote:

Thanks Tom,

I'd like to add a middle initial, which is E.

I should have a CDC affiliation: We can use "Epidemic Intelligence Service, CDC"

I'll send this in back to clearance.

Best,

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Tuesday, August 17, 2021 10:31 AM

To: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov **Cc:** Kasen Riemersma < riemersma@wisc.edu ; DAVID H O'CONNOR

Subject: Re: NEJM letter author list

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah.

Thanks for asking this — it caused me to notice that we had not added you to the author list! I know we removed you from it before submitting to medrxiv, so I have added you back. I will paste the list below, if that is sufficient. Should your affiliation be listed as Wisconsin DHS, as it is here, or CDC? If CDC, please let me know exactly how it should be shown — we can only list one affiliation per author. Also, please let me know if we should add a middle initial for you.

Thanks!

-Tom

Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Kasen K. Riemersma, DVM, PhD¹; Brittany E. Grogan, MPH²; Amanda Kita-Yarbro, MPH²; Peter J. Halfmann, PhD¹; Hannah Segaloff³; Anna Kocharian, MS³; Kelsey R. Florek, PhD⁴; Ryan Westergaard, MD, PhD⁵; Allen Bateman, PhD⁴; Gunnar E. Jeppson, BS⁶; Yoshihiro Kawaoka, DVM, PhD¹; David H. O'Connor, PhD¹ˆ; Thomas C. Friedrich, PhD¹ˆ; Katarina M. Grande, MPH²ˆ

These authors contributed equally. Correspondence can be addressed to:

Katarina Grande KGrande@publichealthmdc.com

Thomas Friedrich tfriedri@wisc.edu

David O'Connor dhoconno@wisc.edu

¹ Department of Pathobiological Sciences, University of Wisconsin-Madison, Madison, WI, USA

² Public Health Madison & Dane County, Madison, WI, USA

³Wisconsin Department of Health Services

⁴Wisconsin State Laboratory of Hygiene

⁵ Department of Medicine, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin

⁶ Exact Sciences, Madison, WI, USA

⁷ Department of Pathology and Laboratory Medicine, University of Wisconsin-Madison, Madison, WI, USA.

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 17 Aug 2021, at 10:02, Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov > wrote:

Can one of you send me a version of the manuscript with the final author list on it? They want that before it goes further in clearance and I want to make sure I have it in the desired order.

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov From: Thomas Friedrich
To: DAVID H O"CONNOR

Cc: Kasen Riemersma; YOSHIHIRO KAWAOKA; Peter Halfmann; Katarina Grande

Subject: Re: New England Journal of Medicine - 21-14060

Date: Tuesday, September 7, 2021 9:39:19 AM

Like Dave, I can see this going either way. Perhaps we could do a set of specimens from within the same time period that is covered in the submitted paper, and then also a more recent batch? This would cover our bases. However, I don't want to burden Peter too much, so I think he and Yoshi should comment also.

Best,

-Tom

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

Dave O'Connor wrote on 2021-09-07 08:42:

Hi all,

I could see it going either way. I don't think we need to add them to the existing dataset. It might even be better to use recent samples because it shows that the trend is stable over time. But I don't feel strongly about it.

dave

Kasen Riemersma wrote on 9/7/21 8:40 AM:

Hi all,

I can definitely provide more samples for Peter to test. Peter, once I know how many you can process, I should be able to send them over quickly.

Tom, if these culture data may be added to our study, I'm inclined to select specimens from the same study period instead of more recent specimens. Do you agree?

Cheers, Kasen

From: Thomas Friedrich tfriedri@wisc.edu
Date: Sunday, September 5, 2021 at 12:43 PM

To: YOSHIHIRO KAWAOKA yoshihiro.kawaoka@wisc.edu **Cc:** DAVID H O'CONNOR dhoconno@wisc.edu, Peter Halfmann

CC. DAVID IT O CONNON <u>Sunoconno@wisc.cddz</u>, i cici riaimiaini

 $\underline{<} \underline{\text{peter.halfmann@wisc.edu}>}, \textbf{Katarina Grande} \underline{<} \underline{\text{kgrande@publichealthmdc.com}>}, \textbf{Kasen}$

Riemersma@wisc.edu>

Subject: Re: New England Journal of Medicine - 21-14060

Hi all.

Okay, I agree with all this. In our emails last week, I was not sure whether you guys wanted to respond to Vincent as soon as possible. I completely agree that we would need to generate new

titration data with samples that have not undergone multiple freeze-thaw cycles. Luckily we are getting a large number of samples from Exact each week. Kasen, can we identify a set of fresh samples that can be aliquoted for Peter to test? Peter, what is a good number of samples for you to receive? Best, -Tom YOSHIHIRO KAWAOKA wrote on 2021-09-03 19:33: If we are going to respond to Vincent by sharing our new data, we should do the virus isolation with new samples that have not been thawed several times. I am concerned about the data showing that the number of no-virus-recovery samples from vaccinated individuals is higher than that from unvaccinated individuals. He will criticize this point if we send him the current data. Best, Yoshi From: DAVID H O'CONNOR dhoconno@wisc.edu Sent: Saturday, September 4, 2021 8:11 AM **To:** Thomas Friedrich ctfriedri@wisc.edu **Cc:** Peter Halfmann <peter.halfmann@wisc.edu>; YOSHIHIRO KAWAOKA <yoshihiro.kawaoka@wisc.edu>; Katarina Grande <kgrande@publichealthmdc.com> **Subject:** Re: New England Journal of Medicine - 21-14060 Hi Tom, I updated Medrxiv with the NEJM submission. I didn't update with this week's data. I suggest waiting until we get a disposition on the NEJM paper before updating Medrxiv again. In terms of Vincent, I'm fine if someone else wants to connect with him and Daniel on the data. I'm not enthusiastic about doing it myself. dave I often work on email outside of work hours, but you don't have to! If you're receiving this outside of your work hours, I don't expect a response until you are back in the office. http://dho.pathology.wisc.edu 608.890.0845

From: Thomas Friedrich < tfriedri@wisc.edu>

Sent: Friday, September 3, 2021 18:04

To: DAVID H O'CONNOR < dhoconno@wisc.edu>

Cc: Peter Halfmann < peter.halfmann@wisc.edu >; YOSHIHIRO KAWAOKA

<yoshihiro.kawaoka@wisc.edu>; Katarina Grande <KGrande@publichealthmdc.com>

Subject: Re: New England Journal of Medicine - 21-14060

Thanks Dave.

Did we update the medrxiv paper with the titration data? If so I can update my Twitter thread on the paper and include it. As you guys have said, even through the samples have undergone multiple freeze-thaw cycles, it is clear that titers are not systematically lower in vaccinees vs. unvaccinated.

Would you guys also email Daniel and Vincent directly to call their attention to these data?

-T

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 3 Sep 2021, at 17:15, DAVID H O'CONNOR < dhoconno@wisc.edu wrote:

What will come first, an NEJM decision on a 400 word letter or Nonetheless, I pinged the editor (see below) and offered the titer data should it be helpful.

dave

--

I often work on email outside of work hours, but you don't have to! If you're receiving this outside of your work hours, I don't expect a response until you are back in the office.

http://dho.pathology.wisc.edu

608.890.0845

From: Letter < letter@nejm.org>
Sent: Friday, September 3, 2021 14:05

To: DAVID H O'CONNOR < dhoconno@wisc.edu>

Subject: RE: New England Journal of Medicine - 21-14060

Hello Dr. O'Connor,

Thank you for your email. Your letter is currently with the editor and a decision regarding possible publication has not yet been made. You will be informed of the final editorial decision via e-mail.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: NEJM Editorial < editorial@nejm.org>
Sent: Friday, September 3, 2021 2:58 PM

To: Letter < letter@nejm.org>

Subject: FW: New England Journal of Medicine - 21-14060

From: Dave O'Connor dhoconno@wisc.edu>
Sent: Friday, September 3, 2021 10:17 AM
To: NEJM Editorial editorial@nejm.org>

Subject: Re: New England Journal of Medicine - 21-14060

To whom it may concern,

I am writing on behalf of our co-authors to ask if there are any updates on the status of the 400 word correspondence we submitted to NEJM on August 23. We are keenly aware that this is timely data given the current landscape of SARS-CoV-2 infection despite vaccination.

One small note: some vocal scientists have criticized our work on social media. The primary claim they make is that virus culture in low Ct samples does not mean that there is similar amounts of replication-competent virus in these samples. Subsequent to our August 23 submission, we re-thawed these samples and showed that virus titers are similar in those who are unvaccinated and infected despite infection (see attached), generally tracking with PCR RNA levels. We would likely want to include a version of this plot in a revised NEJM correspondence to silence this inaccurate criticism.

Thanks in advance for your consideration,

dave

New England Journal of Medicine wrote on 8/23/21 1:39 PM:

Dear Ms. Grande and co-authors,

Thank you for submitting your manuscript, "Shedding of Infectious SARS-CoV-2 Despite Vaccination" to the New England Journal of Medicine.

Your manuscript has been forwarded to members of our editorial staff, who will make an initial evaluation and decide whether it merits further consideration. You will be notified of the decision as soon as possible.

Your manuscript ID is 21-14060.

Please mention the above manuscript ID in all future correspondence or when calling the office for questions. If there are any changes in your street address or e-mail address, please log in to ScholarOne

and te.

You may also view the status of your manuscript at any time by checking For Authors section of the site.

We are undertaking evaluation of your manuscript with the understanding that neither the substance of the article nor the figures or tables have been published or will be submitted for publication elsewhere during the period of review.

Please provide the editors with copies of other manuscripts by you or your coauthors addressing similar or related research questions that are in preparation or under consideration at other journals. This does not apply to abstracts published in connection with scientific meetings or to news reports based on presentations at such meetings.

The Journal's policy is explained more fully at https://www.nejm.org/about-nejm/editorial-policies.

Please call us at 617-734-9800 if you have any questions.

Sincerely,

New England Journal of Medicine 10 Shattuck Street Boston, MA 02115 (617) 734-9800 Fax: (617) 739-9864 http://www.nejm.org

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From: DAVID H O"CONNOR

To: <u>Letter</u>

Cc: Thomas Friedrich

Subject: Re: New England Journal of Medicine - 21-14060 **Date:** Thursday, September 30, 2021 7:03:28 AM

Attachments: EOC Riemersma Viral loads in vaccinees NEJM revised 2021-09-29.docx

Hi Vivian,

Please find attached an updated version of our NEJM submission. The key change (denoted with track changes in case it is helpful) is that the virus culture data is now shown with quantitative titers.

Thanks again in advance for your consideration,

dave

Letter wrote on 9/28/21 2:35 PM:

That would be fine.

Best,

Vivian Vu

Editorial Assistant

New England Journal of Medicine

From: Dave O'Connor dhoconno@wisc.edu
Sent: Tuesday, September 28, 2021 12:30 PM

To: Letter letter@neim.org

Cc: Thomas Friedrich

Subject: Re: New England Journal of Medicine - 21-14060

Sure, can we get it to you by COB tomorrow? It will take a day or so to remake the figures and update the text.

dave

Letter wrote on 9/28/21 10:58 AM:

Hello Dr. O'Connor,

You can send the manuscript to me via email as a word doc. I can upload it to your submission. This way, you will not need to start a new

submission. Let me know what you prefer.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: Dave O'Connor <u><dhoconno@wisc.edu></u> Sent: Tuesday, September 28, 2021 11:56 AM

To: Letter letter@neim.org

Cc: Thomas Friedrich <a href="mailto:<a hre

Subject: Re: New England Journal of Medicine - 21-14060

Hi Vivian,

In the month that we've been under review, we've collected additional data that strengthens the paper. We didn't anticipate this kind of lengthy delay in reviewing a short note. Is there any easy way that we can add this new data to the manuscript without having it compromise our position in the queue, especially if the editor has not yet read the version that is currently queued up?

If not, no worries, but we figure it wouldn't hurt to ask.

Thanks.

dave

Letter wrote on 9/28/21 9:43 AM:

Hello Dr. O'Connor,

We are still waiting for a decision from the editor. He is one of the editors chiefly handling Covid-19 submissions at the Journal and his response time is slower than usual due to the volume of submissions. I apologize for the delay. I have sent an additional reminder to the editor for a decision. You'll receive an email from us with a decision as soon as possible.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: Dave O'Connor dhoconno@wisc.edu
Sent: Monday, September 27, 2021 3:59 PM

To: Letter letter@nejm.org

Cc: Thomas Friedrich <a href="mailto:<a hre

Subject: Re: New England Journal of Medicine - 21-14060

Hi Vivian,

Thanks for checking in with the editor about two weeks ago. Given that our short letter has now been with the editor under internal review for more than a month (August 23), I'm hoping this bodes will for a favorable outcome.

Thanks again for any updates you can provide,

dave

Dave O'Connor wrote on 9/14/21 4:01 PM:

Thanks Vivian for sending the reminder. Please let us know if you need additional information from us.

Best,

dave

Letter wrote on 9/14/21 3:32 PM:

Hello Dr. O'Connor,

Thank you for your email.
Unfortunately a decision has not be made regarding your letter. An additional reminder has been sent

to the editor for a decision. An exact date for a decision cannot be provided given the increased volume in covid-related submissions but know that we strive to give authors as timely a decision as possible. We apologize for the delay, and thank you for your interest in the Journal.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: Dave O'Connor dhoconno@wisc.edu

Sent: Tuesday, September 14,

2021 4:26 PM

To: Letter <a href="mailto:sleet] letter@nejm.org

Cc: Thomas Friedrich

Subject: Re: New England Journal

of Medicine - 21-14060

HI Vivian,

I apologize for asking again, but it has now been another week and a half that the 400 word letter has been with the editor. Do you have an update on when we might receive a final editorial decision?

Thanks again,

dave

Letter wrote on 9/3/21 2:05 PM:

Hello Dr. O'Connor,

Thank you for your email. Your letter is currently with the editor and a decision regarding possible publication has not yet been made. You will be informed of the final editorial decision via e-mail.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: NEJM Editorial <e ditorial@nejm.org

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Sent: Friday, September 3, 2021 2:58 PM

To: Letter

<letter@nejm.org>
Subject: FW: New
England Journal of
Medicine - 21-14060

From: Dave
O'Connor
<dhoconno@wisc.ed

<u>u</u>>

Sent: Friday, September 3, 2021

10:17 AM

To: NEJM Editorial editorial@nejm.org

>

Subject: Re: New England Journal of Medicine - 21-14060

To whom it may concern,

I am writing on behalf of our coauthors to ask if there are any updates on the status of the 400 word correspondence we submitted to NEJM on August 23. We are keenly aware that this is timely data given the current landscape of SARS-CoV-2 infection despite vaccination.

One small note: some vocal scientists have criticized our work on social media. The primary claim they make is that virus culture in low Ct samples does not mean that there is similar amounts of replicationcompetent virus in these samples. Subsequent to our August 23 submission, we rethawed these samples and showed that virus titers are similar in those who are unvaccinated and infected despite infection (see attached), generally tracking with PCR RNA levels. We would likely want to include a version of this plot in a revised NEJM correspondence to silence this inaccurate criticism.

Thanks in advance for your consideration,

dave

New England Journal of Medicine wrote on 8/23/21 1:39 PM:

Dear

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Ms.
Grande
and
co-
author
Thank
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l of Medici ne.

Your manusc ript has been forwar ded to member s of our editor ial staff, who will make an initia l evalua tion and decide whethe r it merits furthe consid eratio n. You will be notifi ed of the decisi on as soon as possib le.

Your manusc ript ID is 21-14060.

Please mentio n the above manusc ript ID in all future corres ponden ce or when callin g the office for questi ons. Ιf

there are any change s in your street addres s or e-mail addres s, please log in to Schola rOne Manusc ripts at https: //mc05 .manus criptc entral .com/n ejm and edit your ūser inform ation as approp riate. You may also view the status of your manusc ript at any time by checki ng For Author s sectio n of the site. We are undert aking evalúa tion of your manusc ript with the unders tandin g that neithe

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nce of the articl e nor the figure s or tables have been publis hed or will be submit ted for public ation elsewh ere during the period of review Please provid e the editor s with copies of other manusc ripts by you or your coauth ors addres sing simila r or relate d resear ch questi ons that are in prepar ation or under consid eratio n at other journa ls. This does not apply to abstra cts publis hed in

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tion with scient ific meetin gs or ŧο news report S based on presen tation s at such meetin gs.

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Please call us at 617-734-9800 if you have any questions.

Sincer ely,

New Englan d Journa 1 of Medici ne 10 Shattu ck Street Boston , MA 02115 (617) 734-9800 Fax: (617) 739-9864 http:/ /www.n ejm.or

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Shedding of Infectious SARS-CoV-2 Despite Vaccination

Kasen K. Riemersma, DVM, PhD¹; Brittany E. Grogan, MPH²; Amanda Kita-Yarbro, MPH²; Peter J. Halfmann, PhD¹; Hannah E. Segaloff, PhD³; Anna Kocharian, MS⁴; Kelsey R. Florek, MPH, PhD⁵; Ryan Westergaard, MD, PhD⁶; Allen Bateman, PhD⁵; Gunnar E. Jeppson, BS⁷; Yoshihiro Kawaoka, DVM, PhD¹; David H. O'Connor, PhD⁸, Thomas C. Friedrich, PhD¹, Katarina M. Grande, MPH²

Katarina Grande KGrande@publichealthmdc.com

¹ Department of Pathobiological Sciences, University of Wisconsin-Madison, Madison, WI, USA

² Public Health Madison & Dane County, Madison, WI, USA

³ Epidemic Intelligence Service, CDC, Atlanta, GA, USA

³ Wisconsin Department of Health Services, Madison, WI, USA

⁵ Wisconsin State Laboratory of Hygiene, Madison, WI, USA

⁶ Department of Medicine, University of Wisconsin School of Medicine and Public Health, Madison, WI, USA

⁷ Exact Sciences, Madison, WI, USA

⁸ Department of Pathology and Laboratory Medicine, University of Wisconsin-Madison, Madison, WI, USA

[^]These authors contributed equally. Correspondence can be addressed to:

Main text (3959 words; limit 400)

The SARS-CoV-2 Delta variant might cause high viral loads, is highly transmissible, and contains mutations that confer partial immune escape ^{1,2}. Outbreak investigations suggest that vaccinated persons can spread Delta ^{3,4}. We compared RT-PCR cycle threshold (Ct) data from 699 swab specimens collected in Wisconsin 29 June through 31 July 2021 and tested with a qualitative assay by a single contract laboratory. Specimens came from residents of 36 counties, most in southern and southeastern Wisconsin, and 81% of cases were not associated with an outbreak. During this time, estimated prevalence of Delta variants in Wisconsin increased from 69% to over 95%. Vaccination status was determined via self-reporting and state immunization records (Supplemental Figure 1).

We observed low Ct values (<25) in 212 of 310 fully vaccinated (68%; Figure 1A) and 246 of 389 (63%) unvaccinated individuals. Testing a subset of <u>such</u> low-Ct samples revealed <u>infectious that</u> <u>infectious</u> SARS-CoV-2 <u>was present at similar levels in vaccinated and unvaccinated persons in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people (Figure 1B).</u>

Low Ct values were detected in vaccinated people regardless of symptoms at the time of testing (Figure 1C). Ct values <25 were detected in 7 of 24 unvaccinated (29%; CI: 13-51%) and 9 of 11 fully vaccinated asymptomatic individuals (82%; CI: 48-97%), and 158 of 232 unvaccinated (68%, CI: 62-74%) and 156 of 225 fully vaccinated (69%; CI: 63-75%) symptomatic individuals. Time from symptom onset to testing did not vary by vaccination status (p=0.40; Supplemental Figure 2). Infectious virus was detected in the sole specimen tested from an asymptomatic fully vaccinated individual. Although few asymptomatic individuals were sampled, these results indicate that even asymptomatic, fully vaccinated people might shed infectious virus.

Combined with other studies ^{2–5}, these data indicate that <u>both</u> vaccinated and unvaccinated individuals infected with the Delta variant might transmit infection. Importantly, we show that infectious SARS-CoV-2 is frequently found even in vaccinated persons when specimen Ct values are low. The inclusion of viruses from Pango lineages B.1.617.2, AY.2, and AY.3, and multiple counties without a linking

outbreak, indicate that Delta-lineage SARS-CoV-2 can achieve low Ct values consistent with transmissibility in fully vaccinated individuals across a range of settings. Vaccinated and unvaccinated persons should get tested when symptomatic or after close contact with someone with suspected or confirmed COVID-19. Continued adherence to non-pharmaceutical interventions during periods of high community transmission to mitigate spread of COVID-19 remain important for both vaccinated and unvaccinated individuals.

Figure

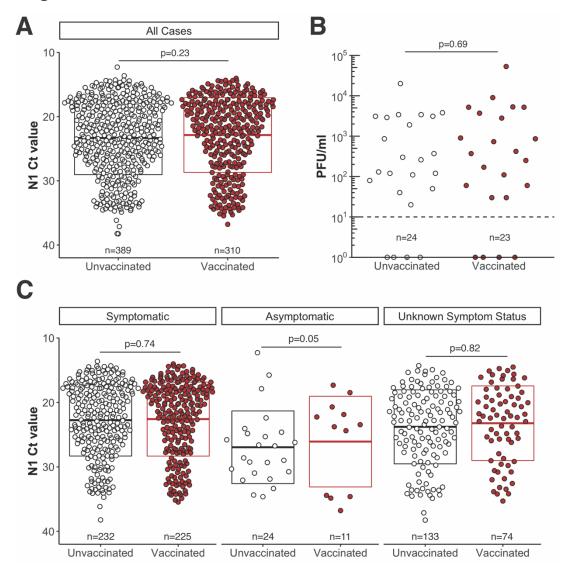
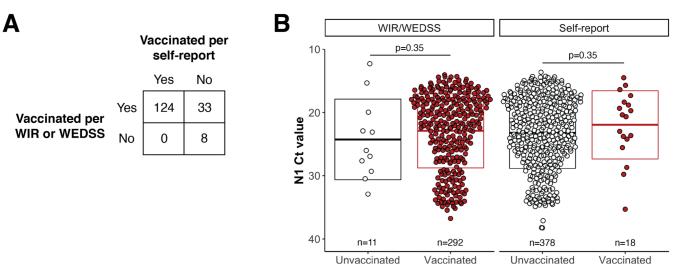


Figure 1. Individuals infected with SARS-CoV-2 despite full vaccination have low Ct values and shed infectious virus. A. Ct values for SARS-CoV-2-positive specimens grouped by vaccination status. RT-PCR was performed by Exact Sciences Corporation, responsible for over 10% of all PCR tests in Wisconsin during this period, using a qualitative diagnostic assay targeting the SARS-CoV-2 N gene (oligonucleotides identical to CDC's N1 primer and probe set) that has been authorized for emergency use by FDA (https://www.fda.gov/media/138328/download). B. Infectiousness was determined for We performed plaque assays on Vero E6 TMPRSS2 cells on a subset of N1 Ct-matched specimens with Ct <25_ by inoculation onto Vero E6 TMPRSS2 cells and determining presence of cytopathic effects (CPE) after 5 days in culture. Specimens -were selected by N1 Ct-matching between fully vaccinated and not fully unvaccinated persons, then specimens from persons with unknown vaccination status were excluded from the analysis. Circles indicate presence of CPE; 'X' indicates no CPE detected Infectious titers are expressed as plaque-forming units (pfu) per milliliter specimen. Specimens underwent a freeze-thaw cycle prior to virus titration. C. N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for individuals who were symptomatic or asymptomatic, or those whose symptom status was not determined, at the time of testing. In A and C,

boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values by independent two-group Mann-Whitney U tests.

Supplemental materials

Supplemental figure 1



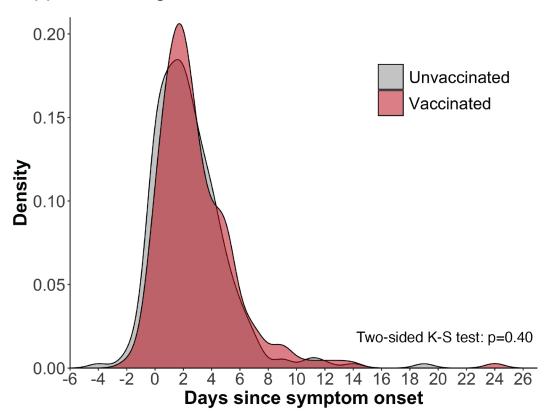
Supplemental figure 1. Concordance between self-reported vaccination status and the Wisconsin Immunization Registry (WIR) or Wisconsin Electronic Disease Surveillance System (WEDSS). For all individuals, vaccination status was determined using WIR/WEDSS electronic registries when data were available. Individuals were identified as unvaccinated at the time of testing if WIR/WEDSS data indicated receipt of a first SARS-CoV-2 vaccine dose after the test date.

Individuals were considered fully vaccinated based on WIR/WEDSS data if the registries indicated receipt of a final vaccine dose at least 14 days prior to testing. For individuals whose vaccination status could not be verified in WIR/WEDSS, self-reported data collected at the time of testing were used. Individuals were considered unvaccinated based on self-report only if there was an explicit declaration of unvaccinated status in the self-reported data. Individuals were considered fully vaccinated based on self-report if they fulfilled all of the following criteria: (1) indicated that they had received a COVID vaccine prior to testing; (2) indicated that they did not require another vaccine dose; and (3) reported a date of last vaccine dose that was at least 14 days prior to testing.

Specimens lacking data on vaccination status were excluded from the study. Specimens from partially vaccinated individuals (incomplete vaccine series, or <14 days post-final dose) were also excluded. Fully vaccinated status was determined by WIR/WEDSS for 292 specimens and by self-reported data for 18. Unvaccinated status was determined by WIR/WEDSS for 11 and by self-reported data by 378. **A.** Of the 699 specimens with vaccination status available from at least one source, 165 specimens had data available from both sources. For self-reporting, under-reporting of full vaccination status (33/157) was more common than over-reporting (0/124). **B.** N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for individuals whose vaccination status was determined by WIR/WEDDS or by self-reported data. Boxplots represent mean N1 Ct values +/- one standard

deviation. P-values were calculated by comparing mean Ct values by independent two-group Mann-Whitney U tests.

Supplemental figure 2



Supplemental figure 2. Density distributions of unvaccinated and vaccinated specimen collection dates by day since symptom onset. Day 0 on the x-axis denotes self-reported day of symptom onset. Negative values for days indicate specimen collection prior to symptom onset. Symptom onset data were available for n=263 unvaccinated cases and n=232 vaccinated cases.

Conflict of interest

The authors declare no conflicting interests.

Ethics statement

Per the University of Wisconsin-Madison IRB, this project qualifies as public health surveillance activities as defined in the Common Rule, 45 CFR 46.102(I)(2). As such, the project is not deemed to be research regulated under the Common Rule and therefore, does not require University of Wisconsin-Madison IRB review and oversight.

The opinions expressed by authors contributing to this journal do not necessarily reflect the opinions of the Centers for Disease Control and Prevention or the institutions with which the authors are affiliated.

Data availability

Data and processing workflows are available at https://go.wisc.edu/p22l16. To protect potentially personally identifiable information, the publicly available dataset contains only PCR Ct values, vaccine status, symptom status, and days from symptom onset to testing for each specimen.

References

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 Delta variant vaccine-breakthrough infections: a multi-center cohort study [Internet]. bioRxiv.

 2021;Available from: http://medrxiv.org/lookup/doi/10.1101/2021.07.28.21261295

From: Thomas Friedrich
To: YOSHIHIRO KAWAOKA

Cc: DAVID H O"CONNOR; Peter Halfmann; Katarina Grande; Kasen Riemersma

Subject: Re: New England Journal of Medicine - 21-14060

Date: Sunday, September 5, 2021 12:43:43 PM

Hi all.

Okay, I agree with all this. In our emails last week, I was not sure whether you guys wanted to respond to Vincent as soon as possible. I completely agree that we would need to generate new titration data with samples that have not undergone multiple freeze-thaw cycles.

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Kasen, can we identify a set of fresh samples that can be aliquoted for Peter to test?

Peter, what is a good number of samples for you to receive?

Best,

-Tom

YOSHIHIRO KAWAOKA wrote on 2021-09-03 19:33:

If we are going to respond to Vincent by sharing our new data, we should do the virus isolation with new samples that have not been thawed several times. I am concerned about the data showing that the number of no-virus-recovery samples from vaccinated individuals is higher than that from unvaccinated individuals. He will criticize this point if we send him the current data.

Best, Yoshi

From: DAVID H O'CONNOR <a href="mailto:sde-du-conno@wisc.edu-conno.edu-

Sent: Saturday, September 4, 2021 8:11 AM **To:** Thomas Friedrich tfriedri@wisc.edu

<yoshihiro.kawaoka@wisc.edu>; Katarina Grande <kgrande@publichealthmdc.com>

Subject: Re: New England Journal of Medicine - 21-14060

Hi Tom,

I updated Medrxiv with the NEJM submission. I didn't update with this week's data. I suggest waiting until we get a disposition on the NEJM paper before updating Medrxiv again.

In terms of Vincent, I'm fine if someone else wants to connect with him and Daniel on the data. I'm not enthusiastic about doing it myself.

dave

--

I often work on email outside of work hours, but you don't have to! If you're receiving this outside of your work hours, I don't expect a response until you are back in the office.

http://dho.pathology.wisc.edu

608.890.0845

From: Thomas Friedrich < tfriedri@wisc.edu>
Sent: Friday, September 3, 2021 18:04

To: DAVID H O'CONNOR < dhoconno@wisc.edu>

Cc: Peter Halfmann < peter.halfmann@wisc.edu>; YOSHIHIRO KAWAOKA

<yoshihiro.kawaoka@wisc.edu>; Katarina Grande <KGrande@publichealthmdc.com>

Subject: Re: New England Journal of Medicine - 21-14060

Thanks Dave.

Did we update the medrxiv paper with the titration data? If so I can update my Twitter thread on the paper and include it. As you guys have said, even through the samples have undergone multiple freeze-thaw cycles, it is clear that titers are not systematically lower in vaccinees vs. unvaccinated.

Would you guys also email Daniel and Vincent directly to call their attention to these data?

-T

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 3 Sep 2021, at 17:15, DAVID H O'CONNOR < dhoconno@wisc.edu> wrote:

What will come first, an NEJM decision on a 400 word letter or Nonetheless, I pinged the editor (see below) and offered the titer data should it be helpful.

dave

--

I often work on email outside of work hours, but you don't have to! If you're receiving this outside of your work hours, I don't expect a response until you are back in the office.

http://dho.pathology.wisc.edu

608.890.0845

From: Letter < letter@nejm.org>
Sent: Friday, September 3, 2021 14:05

To: DAVID H O'CONNOR < dhoconno@wisc.edu>

Subject: RE: New England Journal of Medicine - 21-14060

Hello Dr. O'Connor,

Thank you for your email. Your letter is currently with the editor and a decision regarding possible publication has not yet been made. You will be informed of the final editorial decision via e-mail.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: NEJM Editorial < editorial@nejm.org Sent: Friday, September 3, 2021 2:58 PM

To: Letter < letter@neim.org>

Subject: FW: New England Journal of Medicine - 21-14060

From: Dave O'Connor < dhoconno@wisc.edu Sent: Friday, September 3, 2021 10:17 AM

To: NEJM Editorial editorial@neim.org

Subject: Re: New England Journal of Medicine - 21-14060

To whom it may concern,

I am writing on behalf of our co-authors to ask if there are any updates on the status of the 400 word correspondence we submitted to NEJM on August 23. We are keenly aware that this is timely data given the current landscape of SARS-CoV-2 infection despite vaccination.

One small note: some vocal scientists have criticized our work on social media. The primary claim they make is that virus culture in low Ct samples does not mean that there is similar amounts of replication-competent virus in these samples. Subsequent to our August 23 submission, we re-thawed these samples and showed that virus titers are similar in those who are unvaccinated and infected despite infection (see

attached), generally tracking with PCR RNA levels. We would likely want to include a version of this plot in a revised NEJM correspondence to silence this inaccurate criticism.

Thanks in advance for your consideration,

dave

New England Journal of Medicine wrote on 8/23/21 1:39 PM:

Dear Ms. Grande and co-authors,

Thank you for submitting your manuscript, "Shedding of Infectious SARS-CoV-2 Despite Vaccination" to the New England Journal of Medicine.

Your manuscript has been forwarded to members of our editorial staff, who will make an initial evaluation and decide whether it merits further consideration. You will be notified of the decision as soon as possible.

Your manuscript ID is 21-14060.

Please mention the above manuscript ID in all future correspondence or when calling the office for questions. If there are any changes in your street address or e- e Manuscripts at and edit your

y also view the status of your manuscript at any time by checking For Authors section of the site.

We are undertaking evaluation of your manuscript with the understanding that neither the substance of the article nor the figures or tables have been published or will be submitted for publication elsewhere during the period of review.

Please provide the editors with copies of other manuscripts by you or your coauthors addressing similar or related research questions that are in preparation or under consideration at other journals. This does not apply to abstracts published in connection with scientific meetings or to news reports based on presentations at such meetings.

The Journal's policy is explained more fully at https://www.nejm.org/about-nejm/editorial-policies.

Please call us at 617-734-9800 if you have any questions.

Sincerely,

New England Journal of Medicine 10 Shattuck Street Boston, MA 02115 (617) 734-9800 Fax: (617) 739-9864 http://www.nejm.org

--

http://dho.pathology.wisc.edu @dho • 608-890-0845

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delete the original message from all computer systems. Thank you.

From: Thomas Friedrich

To: <u>mishra.sanjay@outlook.com</u>

Subject: Re: Request to interview from National Geographic

Date: Friday, August 13, 2021 11:32:48 AM

Sounds good — thanks. Will talk to you at 3:30 Central unless things go sideways.

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 13 Aug 2021, at 11:20, mishra.sanjay@outlook.com wrote:

Dear Tom

I really appreciate your reply. I sent you a meeting invite for 3:30 pm Central. If for some reason, something comes up, please feel free to push the meeting later to your convenience.

I look forward to talk to you soon.

Regards

Sanjay

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Friday, August 13, 2021 11:13 AM

To: mishra.sanjay@outlook.com

Subject: Re: Request to interview from National Geographic

Hi Sanjay.

I am in a daylong meeting that is supposed to last until at least 2:30 Central.

Could we perhaps Zoom at 3:30? Please feel free to send me a calendar invite if that is possible for you.

-T

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 13 Aug 2021, at 10:22, mishra.sanjay@outlook.com wrote:

Dear Tom

Can I talk to you sometime today? I have already talked to Kasem and Katrina, but I will love to talk to you still even for 10 min (over phone or Zoom, whatever you prefer).

I am available most of the day except 1 pm - 3:30 pm Central.

Sanjay

Sanjay Mishra, MS, PhD
Nashville, TN 37221; USA
mishra.sanjay@outlook.com | @Ecquis | +1 (615) 829 6563
LinkedIn | Google Scholar | Contently | Skype

From: Thomas Friedrich

Sent: Thursday, August 12, 2021 3:20 PM

To: mishra.sanjay@outlook.com

Cc: <u>Kasen Riemersma</u>; <u>DAVID H O'CONNOR</u>; <u>Katarina Grande</u> **Subject:** Re: Request to interview from National Geographic

Hi Sanjay.

A follow up tomorrow sounds good. I am in meetings most of the rest of today anyway.

Best,

-Tom

Thomas Friedrich

Professor Dept. Pathobiological Sciences University of Wisconsin School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 12 Aug 2021, at 15:00, mishra.sanjay@outlook.com wrote:

Dear All

I really appreciate your reply. I will love to talk to you today, but I am still negotiating with my editors on how important and urgent your work is.

Can I reach out tomorrow, because I will hate to take your busy time in interviewing, but not being able to write about it.

I will love to talk to you today, if you prefer! Please advise.

Sanjay

Sanjay Mishra, MS, PhD
Nashville, TN 37221; USA
mishra.sanjay@outlook.com | @Ecquis | +1 (615) 829 6563
LinkedIn | Google Scholar | Contently | Skype

From: <u>Kasen Riemersma</u>

Sent: Thursday, August 12, 2021 2:56 PM

To: DAVID H O'CONNOR; KGrande@publichealthmdc.com

Cc: <u>'Sanjay Mishra'</u>; <u>Thomas Friedrich</u>

Subject: Re: Request to interview from National Geographic

I am unfortunately unavailable until tomorrow, but could chat anytime from 10-2 CDT then.

Kasen

From: DAVID H O'CONNOR < dhoconno@wisc.edu>

Date: Thursday, August 12, 2021 at 2:37 PM

To: KGrande@publichealthmdc.com < kgrande@publichealthmdc.com >

Cc: 'Sanjay Mishra' <<u>mishra.sanjay@outlook.com</u>>, Kasen Riemersma <<u>riemersma@wisc.edu</u>>, Thomas Friedrich

<tfriedri@wisc.edu>

Subject: Re: Request to interview from National

Geographic

I can chat after 4:30 CDT, or go ahead without me!

dave

KGrande@publichealthmdc.com wrote on 8/12/21 2:36 PM:

Hi Dr. Mishra,

Thanks for reaching out. I could jump on a call after 3:30pm. I'm cc'ing my co-authors, who are the true scientists on the paper—I'm the applied public health person of the bunch. So depending on your angle, it may be helpful to link with them, or see if we could jump on a call together.

-Katarina

KATARINA GRANDE, MPH (pronouns:

she/her/hers)

Public Health Supervisor/COVID-19 Data Team Lead

| Public Health Madison & Dane County 2300 South Park St, Rm 2010, Madison, WI 53713

Phone: (608) 243-0409 | Cell: |

Fax: (608) 266-4858

Healthy People. Healthy Places.

<image001.png>

This email, including any attachments, may contain confidential or protected health information which is only for the intended recipient. If you received this email in error, please delete and notify the sender immediately. Emails sent or received by our agency are subject to open records requests and could be released to the public, unless there is an exception allowed by law.

<image002.png>

From: Sanjay Mishra

<mishra.sanjay@outlook.com>

Sent: Thursday, August 12, 2021 2:07 PM

To: Grande, Katarina

<KGrande@publichealthmdc.com>

Subject: Request to interview from National

Geographic

Importance: High

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Dear Katarina

I read your preprint posted earlier today with alarm: "Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021"
Can I urgently talk to you since I am pitching this as story to my editor at National Geographic, as a follow up to my recent stories on Delta variant, value of masking and breakthrough infections:

In National Geographic:

- Why is Delta more infectious and deadly? New research holds answers. (August 6, 2021)
- 2. How dangerous is the new Delta Plus variant? Here's what we know. (July 2, 2021)
- 3. The Delta variant is serious.

 Here's why it's on the rise.

 (June 16, 2021); updated:
 - a. The Delta variant is spreading fast, especially where vaccination rates are low (July 8, 2021)
- 4. This 'double mutant' variant is adding fuel to India's COVID-19 crisis(April 28, 2021)

In The Conversation:

1. What is a breakthrough infection? 6 questions

answered about catching COVID-19 after vaccination (July 28, 2021)

2. Can people vaccinated against COVID-19 still spread the coronavirus?(May 25, 2021)

I and the readers of National Geographic will highly appreciate it

Sanjay Mishra, MS, PhD
Nashville, TN 37221; USA
mishra.sanjay@outlook.com | @Ecquis | +1
(615) 829 6563
LinkedIn | Google Scholar | Contently | Skype

__

http://dho.pathology.wisc.edu @dho • 608-890-0845 From: Thomas Friedrich

To: Segaloff, Hannah E - DHS

Cc: Kasen Riemersma; DAVID H O"CONNOR; Katarina Grande

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Date: Thursday, August 19, 2021 3:05:30 PM

Attachments: Riemersma Viral loads in vaccinees NEJM revised CLEAN 2021-08-19.docx

Riemersma Viral loads in vaccinees NEJM revised tracked 2021-08-19.docx

Hi Hannah.

Attached please find clean (well, clean-ish) and tracked versions of the revised manuscript. We addressed all the comments and made the changes requested. I hope this can be approved quickly.

Note: As you know, to edit collaboratively, we uploaded the Word doc with CDC comments to Google Drive. I re-downloaded the edited version as a Word doc — this is the "clean" version and preserves CDC comments and our responses. To make the "tracked" version I had to compare that downloaded document to the Word doc you forwarded from CDC. When I did that I noticed that it duplicated several comments from CDC folk. For the sake of readability I tried to delete duplicates, but there are still a lot of comments in a small space. It also appears that replies within comments were not recognized, so now they just appear as comments on top of other comments. I hope that all makes sense.

If these copies do not come through, you can download them from the shared Google drive here:

Best.

-Tom

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 19 Aug 2021, at 09:41, Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov > wrote:

Hi All,

Here are the first round of comments. We should get all responses within 24 to 48 hours of our submission. It looks like this needs to be approved by Lab TF, cross clearance and the response.

Let me know if I can help with comments.

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent 216@cdc.gov >

Sent: Thursday, August 19, 2021 9:24 AM

To: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < adz0@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent216@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah,

Please address the mandatory comments and return for re-review.

Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < qdz0@cdc.gov>

Sent: Wednesday, August 18, 2021 9:18 AM

To: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent216@cdc.gov **Subject:** Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hello,

Thank you for the quick work getting this approved for DIM expedited clearance. I haven't had a manuscript in expedited clearance before. Does it have the same steps as standard? How much time should I anticipate for the clearance process?

Thank you! Hannah

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) <aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 11:51 AM

To: Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov; CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent216@cdc.gov; Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) < kya6@cdc.gov>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD) < bbl7@cdc.gov; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < qdz0@cdc.gov; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < iki5@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

NP! Glad we were able to turn this around so quickly.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Lab TF Communications Mailbox: eocevent503@cdc.gov
Cell:

From: Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov>

Sent: Tuesday, August 17, 2021 12:47 PM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) qqv9@cdc.gov">; CDC IMS 2019 NCOV Response Lab TF Clearance eocevent216@cdc.gov>; Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) kva6@cdc.gov>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD) < bb17@cdc.gov; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < qdz0@cdc.gov; Moon, Jonathan L.

(CDC/DDID/NCEZID/DSR) <iki5@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Thanks Shelbi!

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 12:43 PM

To: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent 216@cdc.gov >; Kools,

John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov; Dunworth, Soumya

(CDC/DDPHSS/CSELS/OD) < kya6@cdc.gov>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD) < bb/>
bb/7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov >; Segaloff, Hannah

(CDC/DDPHSS/CSELS/DSEPD) < adz0@cdc.gov>; Moon, Jonathan L.

(CDC/DDID/NCEZID/DSR) < iki5@cdc.gov >

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Afternoon,

This has been approved for expedited clearance.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 12:40 PM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Thank you. I approve expedited clearance.

Stephanie

Stephanie R. Bialek MD MPH

Deputy Incident Manager

COVID-19 Response

CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 12:16 PM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Hey Stephanie,

Please see attached for the updated draft.

Thanks.

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 11:05 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < <u>zqg7@cdc.gov</u>>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Sure thing, working on the updated draft now.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:56 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < <u>xhg9@cdc.gov</u>>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Yes, please request an updated draft with Hannah's name on it and then I approve it going for expedited clearance.

Stephanie
Stephanie R. Bialek MD MPH
Deputy Incident Manager
COVID-19 Response
CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:56 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < <u>xhg9@cdc.gov</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hey Stephanie,

From correspondence with ADS and STLT Hannah was inadvertently left off the manuscript but WI has confirmed that she is a co-author but her name is not on this draft. Should we request an updated draft with Hannah information on there as the co-author?

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:51 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < <u>zqg7@cdc.gov</u>>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Hey,

I am working on getting clarification as we speak, update to follow.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < regg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:49 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov >; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Hannah Segaloff EISO is listed on the clearance request form as an author but not on the manuscript. Can you clarify that she indeed and author? If so, then my approval for expedited clearance stands.

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:40 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < <u>zqg7@cdc.gov</u>>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < <u>xhg9@cdc.gov</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thanks for the speedy response!

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:39 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

I approve.

Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) <qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:38 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < <u>zqg7@cdc.gov</u>>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Morning Stephanie,

Happy Tuesday! We would like to request DIM1 expedited approval for the attached manuscript. Please refer to the email thread below.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent 216@cdc.gov >

Sent: Tuesday, August 17, 2021 10:32 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < qqv9@cdc.gov; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent216@cdc.gov> **Subject:** Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hi Shelbi and Jarrett,

Should I begin clearance on this item or wait until you receive the DIM approval?

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST
Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov>

Sent: Tuesday, August 17, 2021 9:59 AM

To: CDC IMS 2019 NCOV Response Lab TF Clearance <<u>eocevent216@cdc.gov</u>>; Davis, Shelbi (CDC/DDID/NCIRD/DVD) <<u>qqv9@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) <<u>xhg9@cdc.gov</u>>

Cc: Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) < kya6@cdc.gov">; Limbago, Brandi (CDC/DDID/NCIRD/OD) < bbl7@cdc.gov>; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < iki5@cdc.gov>; Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI) < gif7@cdc.gov>; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < qdz0@cdc.gov>

Subject: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Good Morning,

You may have heard but our task force was asked by STLT, and we agreed, to sponsor this manuscript through clearance. The authors are targeting NEJM and are requesting our task force to request IM approval for expedited clearance. Our main POC for this manuscript is our CDC EISO Hannah Segaloff (Cc'd). Let me know if you have any questions.

Hannah- our clearance team can help shepherd your paper through clearance. I would anticipate our laboratory SMEs to have some questions for your team.

Best regards,

John Kools

ADS, Laboratory & Testing Task Force
CDC COVID-19 Response
Phone: 404-217-7258

From: Rose, Dale A. (CDC/DDID/NCEZID/DPEI) < ido8@cdc.gov>

Sent: Tuesday, August 17, 2021 4:51 AM

To: Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov>

Subject: FW: Follow up on your results

Morning John! Thanks for taking this on. We had intensive discussions with WI, IM, and MMWR last week about this. There's strong interest in supporting and moving this forward quickly in clearance, including securing approval for expedited clearance so it can quickly make it to NEJM for consideration. If you anticipate any issues with the content or timing, please do let me know as our TF is in routine conversation with the state epi and want to make sure we're aligned in our discussions.

Much appreciated, and I hope you are well!

Best, Dale

Dale Rose, Ph.D.
STLT Support Task Force

Cell: 404.840.9507

From: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI) < gif7@cdc.gov>

Sent: Monday, August 16, 2021 3:35 PM

To: Segaloff, Hannah (CDC <u>dhs.wisconsin.gov</u>) < <u>hannah.segaloff@dhs.wisconsin.gov</u>>; Rose, Dale A. (CDC/DDID/NCEZID/DPEI) < <u>ido8@cdc.gov</u>>; Westergaard, Ryan (CDC <u>dhs.wisconsin.gov</u>) < <u>ryan.westergaard@dhs.wisconsin.gov</u>>; Bisgard, Kris (CDC/DDPHSS/CSELS/DSEPD) < <u>kmb6@cdc.gov</u>>

Cc: Ricaldi Camahuali, Jessica (CDC/DDID/NCEZID/DPEI) < mpi7@cdc.gov"> ; Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov"> ; Limbago, Brandi (CDC/DDID/NCIRD/OD) < bb17@cdc.gov> ; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < kit5@cdc.gov> ; CDC IMS 2019 NCOV Response STLT ADS < eocevent410@cdc.gov> ; CDC IMS 2019 NCOV Response Lab Task Force < eocevent177@cdc.gov>

Subject: Re: Follow up on your results

Dear Hannah,

Thank you for these additional documents. Due to this manuscript's focus on laboratory data, our Laboratory and Testing Task Force colleagues have agreed to be the sponsoring task force for CDC COVID-19 Response clearance. John Kools is the Lab TF ADS and can assist with next steps.

Best Regards,

Anna

Anna Llewellyn, PhD
Associate Director for Science
State, Tribal, Local, and Territorial Support Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Office: 404-639-1538 | Cell: 678-887-5058
eocevent410@cdc.gov

From: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov >

Sent: Monday, August 16, 2021 3:13 PM

To: Rose, Dale A. (CDC/DDID/NCEZID/DPEI) < ido8@cdc.gov>; Westergaard, Ryan (CDC dhs.wisconsin.gov) < ryan.westergaard@dhs.wisconsin.gov>; Bisgard, Kris (CDC/DDPHSS/CSELS/DSEPD) < kmb6@cdc.gov>

Cc: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI) < gif7@cdc.gov>; Ricaldi Camahuali,

Jessica (CDC/DDID/NCEZID/DPEI) < mpi7@cdc.gov>

Subject: RE: Follow up on your results

Thank you. I have attached the concept proposal that was approved from the original MMWR submission as well as a clearance request form.

Sincerely, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov <Reimersma_Viral loads in vaccinees_
NEJM_editedauthorlist_LABTFCOMMENTS.docx>

From: tfriedri@wisc.edu
To: Kasen Riemersma

Cc: Segaloff, Hannah E - DHS; DAVID H O"CONNOR; Katarina Grande; Westergaard, Ryan P - DHS

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Date: Saturday, August 21, 2021 4:30:13 PM

Hi all.

Thanks to Hannah

Sent from my iPhone

On Aug 21, 2021, at 15:30, Kasen Riemersma <riemersma@wisc.edu> wrote:

Hey Hannah,

The folder with the publicly shared dataset is currently restricted to UW addresses which is why it's denying you, but the files in the folder haven't been updated yet anyways. I've attached the updated dataset here. I tried to just include the data needed to address the questions so that it's easier to parse, but let me know if you need any other info. Also, I think the column names should be straightforward, but let me know if you have any questions.

Thanks for addressing the reviewer comments!

Kasen

From: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov>

Date: Saturday, August 21, 2021 at 2:26 PM

To: DAVID H O'CONNOR <dhoconno@wisc.edu>, Kasen Riemersma <riemersma@wisc.edu>, Thomas

Friedrich <tfriedri@wisc.edu>

Cc: Katarina Grande <kgrande@publichealthmdc.com>, Westergaard, Ryan P - DHS

<ryan.westergaard@dhs.wisconsin.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

I don't seem to have access to the data that was used for this. Can someone grant me access? It may just be google acting up but my request to view the shared folder keeps was denied.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services

Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: DAVID H O'CONNOR <dhoconno@wisc.edu>

Sent: Saturday, August 21, 2021 12:47 PM

To: Segaloff, Hannah E - DHS hannah.segaloff@dhs.wisconsin.gov; Kasen Riemersma riemersma@wisc.edu; Thomas Friedrich tfriedri@wisc.edu>

Cc: Katarina Grande <kgrande@publichealthmdc.com>; Westergaard, Ryan P - DHS

<ryan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah,

I'm still not sure I understand. Why are there new comments now after we responded to the ones that were issued yesterday? If there are edits that can fit in the 400 word limit that's fine but I worry that the request for

more information is at odds with the word count.

Do you want to take a crack at these edits since you know how to write these things on the way that the clearance process expects?

Cheers,

Dave

Get Outlook for iOS

From: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov>

Sent: Saturday, August 21, 2021 11:49:15 AM

To: Kasen Riemersma < riemersma@wisc.edu >; Thomas Friedrich < tfriedri@wisc.edu >

Cc: DAVID H O'CONNOR dhoconno@wisc.edu; Katarina Grande kgrande@publichealthmdc.com; Westergaard,

Ryan P - DHS < ryan.westergaard@dhs.wisconsin.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hi All,

This was not cleared by the JIC- they want to see the new version before clearance. However, comments don't seem too extensive.

I can work on the comments about the statewide perspective.

Best,

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Kasen Riemersma < riemersma@wisc.edu>

Sent: Friday, August 20, 2021 4:32 PM

To: Thomas Friedrich < tfriedri@wisc.edu; Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov
CC: DAVID H O'CONNOR < dhoconno@wisc.edu; Katarina Grande < kgrande@publichealthmdc.com; Westergaard, Ryan P - DHS < ryan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Thanks, Hannah!

Kasen

From: Thomas Friedrich < tfriedri@wisc.edu > Date: Friday, August 20, 2021 at 4:25 PM

To: Segaloff, Hannah E - DHS < Hannah.Segaloff@dhs.wisconsin.gov >

Cc: DAVID H O'CONNOR <<u>dhoconno@wisc.edu</u>>, Kasen Riemersma <<u>riemersma@wisc.edu</u>>, Katarina Grande <<u>kgrande@publichealthmdc.com</u>>, Westergaard, Ryan P - DHS <<u>ryan.westergaard@dhs.wisconsin.gov</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Sweet, thanks Hannah!

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 20 Aug 2021, at 16:24, Segaloff, Hannah E - DHS hannah.segaloff@dhs.wisconsin.gov> wrote:

It's back in. Fingers crossed that we get this back quickly. It looks like the on call clearance coordinator has email check-ins over the weekend at 10am and 3pm so those are the times that you are likely to hear Saturday or Sunday.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases
Wisconsin Department of Health Services
Currently Teleworking
Cell:
Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Friday, August 20, 2021 4:18 PM

To: DAVID H O'CONNOR < dhoconno@wisc.edu>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Oops, just saw this. I think we should go with Hannah's version since she addresses the question about the CDC ethics statement.

-T

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tefriedrich
@tef-lab
www.vetmed.wisc.edu/friedrichlab

On 20 Aug 2021, at 16:14, DAVID H O'CONNOR < dhoconno@wisc.edu > wrote:

Looks fine to me Hannah. Thanks for taking care of the edits.

dave

Segaloff, Hannah E - DHS wrote on 8/20/21 4:12 PM:

Sorry for the repeat emails. I can just send this version back if you all agree since changes were so minor.

-Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking Cell:

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Thomas Friedrich tfriedri@wisc.edu

Sent: Friday, August 20, 2021 3:44 PM

To: Segaloff, Hannah E - DHS segaloff@dhs.wisconsin.gov

Cc: Kasen Riemersma riemersma@wisc.edu; DAVID H

O'CONNOR chicken; Katarina

Grande kgrande@publichealthmdc.com; Westergaard, Ryan P -

DHS cryan.westergaard@dhs.wisconsin.gov

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the

Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah.

Do you have any updates on the CDC clearance process? Can you see if others have been able to look at the paper?

Thanks,

-T

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tefriedrich
@tef-lab
www.vetmed.wisc.edu/friedrichlab

On 19 Aug 2021, at 18:51, Thomas Friedrich <<u>tfriedri@wisc.edu</u>> wrote:

Okay, fingers crossed!

Sent from my iPhone

On Aug 19, 2021, at 18:02, Segaloff, Hannah E - DHS hannah.segaloff@dhs.wisconsin.gov wrote:

Though on second thought I can see that the STLT TF is reviewing now- so maybe this is moving faster than I thought.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Thursday, August 19, 2021 5:44 PM

To: Segaloff, Hannah E - DHS

< hannah.segaloff@dhs.wisconsin.gov>

Cc: Kasen Riemersma < riemersma@wisc.edu>;
DAVID H O'CONNOR < dhoconno@wisc.edu>;
Katarina Grande < kgrande@publichealthmdc.com>
Subject: Re: Shedding of Infectious SARS-CoV-2
Despite Vaccination when the Delta Variant is

Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Thanks Hannah.

I really hope they can return comments tomorrow so we can submit.

Do

you think that is at all possible?

Best,

Tom

Sent from my iPhone

On Aug 19, 2021, at 15:20, Segaloff, Hannah E - DHS hannah.segaloff@dhs.wisconsin.gov wrote:

Thanks Tom,

I will send these along and the note. I'm hoping we can switch over to a Google drive format for comments.

Best, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking Cell:

Hannah.Segaloff@dhs.wisconsin.gov

From: Thomas Friedrich < tfriedri@wisc.edu>

Sent: Thursday, August 19, 2021 3:05

PM

To: Segaloff, Hannah E - DHS

< hannah.segaloff@dhs.wisconsin.gov>

Cc: Kasen Riemersma

<<u>riemersma@wisc.edu</u>>; DAVID H O'CONNOR <<u>dhoconno@wisc.edu</u>>;

Katarina Grande

< kgrande@publichealthmdc.com>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah.

Attached please find clean (well, clean-ish) and tracked versions of the revised manuscript. We addressed all the comments and made the changes requested. I hope this can be approved quickly.

Note: As you know, to edit collaboratively, we uploaded the Word doc with CDC comments to Google Drive. I re-downloaded the edited version as a Word doc — this is the "clean" version and preserves CDC comments and our responses. To make the "tracked" version I had to compare that downloaded document to the Word doc you forwarded from CDC. When I did that I noticed that it duplicated several comments from CDC folk. For the sake of readability I tried to delete duplicates, but there are still a lot of comments in a small space. It also appears that replies within comments were not recognized, so now they just appear as comments on top of other comments. I hope that all makes sense.

If these copies do not come through, you can download them from the shared Google drive here:

Best,

-Tom

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tefriedrich
@tef-lab
www.vetmed.wisc.edu/friedrichlab

On 19 Aug 2021, at 09:41, Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov > wrote:

Hi All,

Here are the first round of comments. We should get all responses within 24 to 48 hours of our submission. It looks like this needs to be approved by Lab TF, cross clearance and the response. Let me know if I can help with comments.

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases
Wisconsin Department of Health

Services Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov Odz0@cdc.gov

From: CDC IMS 2019 NCOV Response Lab TF Clearance

<eocevent216@cdc.gov>
Sent: Thursday, August
19, 2021 9:24 AM
To: Segaloff, Hannah
(CDC/DDPHSS/CSELS/DSEPD)

Cc: CDC IMS 2019 NCOV
Response Lab TF
Clearance

<eocevent216@cdc.gov>
Subject: Re: Shedding of

Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah,

Please address the mandatory comments and return for rereview.

Shedding of
Infectious SARS-CoV-2
Despite Vaccination
when the Delta Variant
is Prevalent

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD)

<<u>qdz0@cdc.gov</u>>

Sent: Wednesday, August 18, 2021 9:18 AM To: CDC IMS 2019 NCOV Response Lab TF Clearance <eocevent216@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2
Despite Vaccination when the Delta Variant is
Prevalent

Hello,

Thank you for the quick work getting this approved for DIM expedited clearance. I haven't had a manuscript in expedited clearance before. Does it have the same steps as standard? How much time should I anticipate for the clearance process?

Thank you! Hannah

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 11:51 AM

To: Kools, John J.

(CDC/DDID/NCEZID/OD)

<<u>czk7@cdc.gov</u>>; CDC

IMS 2019 NCOV Response

Lab TF Clearance

<eocevent216@cdc.gov>;

Dunworth, Soumya

(CDC/DDPHSS/CSELS/OD)

<kya6@cdc.gov>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD)

<<u>bbl7@cdc.gov</u>>; Gartin,

Jarrett

(CDC/DDID/NCIRD/OD)

(CTR) <xhg9@cdc.gov>;

Segaloff, Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<adz0@cdc.gov>; Moon,

Jonathan L.

(CDC/DDID/NCEZID/DSR)

<iki5@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

NP! Glad we were able to turn this around so quickly.

Thanks, Shelbi Davis Communication Lead Health Communication Specialist Laboratory and Testing Task
Force
COVID-19 Emergency
Response
Centers for Disease Control
and Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov
Cell:

_

From: Kools, John J. (CDC/DDID/NCEZID/OD)

<czk7@cdc.gov>

Sent: Tuesday, August 17,

2021 12:47 PM **To:** Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<<u>qqv9@cdc.gov</u>>; CDC

IMS 2019 NCOV Response

Lab TF Clearance

<eocevent216@cdc.gov>;

Dunworth, Soumya

(CDC/DDPHSS/CSELS/OD)

<kya6@cdc.gov>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD)

< bbl7@cdc.gov >; Gartin,

Jarrett

(CDC/DDID/NCIRD/OD)

(CTR) < xhg9@cdc.gov>;

Segaloff, Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<qdz0@cdc.gov>; Moon,

Jonathan L.

(CDC/DDID/NCEZID/DSR)

<iki5@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thanks Shelbi!

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) <aav9@cdc.gov>

Sent: Tuesday, August 17,

2021 12:43 PM

To: CDC IMS 2019 NCOV

Response Lab TF

Clearance

<<u>eocevent216@cdc.gov</u>>;

Kools, John J.

(CDC/DDID/NCEZID/OD)

<<u>czk7@cdc.gov</u>>;

Dunworth, Soumya

(CDC/DDPHSS/CSELS/OD)

<<u>kya6@cdc.gov</u>>

Cc: Limbago, Brandi
(CDC/DDID/NCIRD/OD)

bbl7@cdc.gov>; Gartin,
Jarrett
(CDC/DDID/NCIRD/OD)
(CTR) <xhg9@cdc.gov>;
Segaloff, Hannah
(CDC/DDPHSS/CSELS/DSEPD)
<qdz0@cdc.gov>; Moon,
Jonathan L.
(CDC/DDID/NCEZID/DSR)
<iki5@cdc.gov>
Subject: Fw: Shedding of

Subject: Fw: Shedding of Infectious SARS-CoV-2
Despite Vaccination when the Delta Variant is
Prevalent

Afternoon,

This has been approved for expedited clearance.

Thanks,
Shelbi Davis
Communication Lead
Health
Communication Specialist
Laboratory and Testing Task
Force
COVID-19 Emergency
Response
Centers for Disease Control
and Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov
Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < 2qg7@cdc.gov>

Sent: Tuesday, August 17, 2021 12:40 PM To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) <qqv9@cdc.gov>

Cc: Fisher, Angela H.
(CDC/DDPHSS/CSELS/OD)
<iwg7@cdc.gov>; Gartin,
Jarrett
(CDC/DDID/NCIRD/OD)
(CTR) <xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2
Despite Vaccination when the Delta Variant is
Prevalent

Thank you. I approve expedited clearance. Stephanie

Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<aav9@cdc.gov>

Sent: Tuesday, August 17,

2021 12:16 PM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov>; Gartin,

Jarrett

(CDC/DDID/NCIRD/OD)

(CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hey Stephanie,

Please see attached for the updated draft.

Thanks,

Shelbi Davis

Communication Lead

Health

Communication Specialist Laboratory and Testing Task

Force

COVID-19 Emergency

Response

Centers for Disease Control

and Prevention

Lab TF Communications

Mailbox: eocevent503@cdc.gov

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17,

2021 11:05 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin,

Jarrett

(CDC/DDID/NCIRD/OD)

(CTR) < xhg9@cdc.gov> Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Sure thing, working on the updated draft now.

Thanks, Shelbi Davis Communication Lead Health Communication Specialist Laboratory and Testing Task Force COVID-19 Emergency Response Centers for Disease Control and Prevention Lab TF Communications Mailbox: eocevent503@cdc.gov Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:56 AM To: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov> Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov>; Gartin,

Jarrett

(CDC/DDID/NCIRD/OD) (CTR) <xhg9@cdc.gov> Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Yes, please request an updated draft with Hannah's name on it and then I approve it going for expedited clearance. Stephanie Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17,

2021 10:56 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin,

Jarrett

(CDC/DDID/NCIRD/OD)

(CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hey Stephanie,

From correspondence with ADS and STLT Hannah was inadvertently left off the manuscript but WI has confirmed that she is a coauthor but her name is not on this draft. Should we request an updated draft with Hannah information on there as the co-author?

Thanks,
Shelbi Davis
Communication Lead
Health
Communication Specialist
Laboratory and Testing Task
Force
COVID-19 Emergency
Response
Centers for Disease Control
and Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov
Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17,

2021 10:51 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<<u>zqg7@cdc.gov</u>>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov>; Gartin,

Jarrett

(CDC/DDID/NCIRD/OD)

(CTR) <xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Неу,

I am working on getting clarification as we speak, update to follow.

Thanks,
Shelbi Davis
Communication Lead
Health
Communication Specialist
Laboratory and Testing Task
Force
COVID-19 Emergency
Response
Centers for Disease Control
and Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov
Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:49 AM

To: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<<u>qqv9@cdc.gov</u>>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin,

Jarrett

(CDC/DDID/NCIRD/OD)

(CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2
Despite Vaccination when the Delta Variant is
Prevalent

Hannah Segaloff EISO is listed on the clearance request form as an author but not on the manuscript. Can you clarify that she indeed and author? If so, then my approval for expedited clearance stands.

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17,

2021 10:40 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin,

Jarrett

(CDC/DDID/NCIRD/OD)

(CTR) <xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Thanks for the speedy response!

Thanks,

Shelbi Davis

Prevalent

Communication Lead

Health

Communication Specialist

Laboratory and Testing Task

Force

COVID-19 Emergency

Response

Centers for Disease Control

and Prevention

Lab TF Communications

Mailbox: eocevent503@cdc.gov Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17,

2021 10:39 AM **To:** Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov >; Gartin,

Jarrett

(CDC/DDID/NCIRD/OD)

(CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

I approve.

Stephanie R. Bialek MD

MPH

Deputy Incident Manager

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17,

2021 10:38 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin,

Jarrett

(CDC/DDID/NCIRD/OD)

(CTR) <xhg9@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Morning Stephanie,

Happy Tuesday! We would like to request DIM1 expedited approval for the attached manuscript. Please refer to the email thread below.

Thanks,
Shelbi Davis
Communication Lead
Health
Communication Specialist
Laboratory and Testing Task
Force
COVID-19 Emergency
Response
Centers for Disease Control
and Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov
Cell:

From: CDC IMS 2019 NCOV Response Lab TF Clearance

<eocevent216@cdc.gov>

Sent: Tuesday, August 17, 2021 10:32 AM To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) <qqv9@cdc.gov>; Gartin,

Jarrett

(CDC/DDID/NCIRD/OD)

(CTR) < xhg9@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance

<eocevent216@cdc.gov>
Subject: Fw: Shedding of Infectious SARS-CoV-2
Despite Vaccination when the Delta Variant is
Prevalent

Hi Shelbi and Jarrett,

Should I begin clearance on this item or wait until you receive the DIM approval?

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Kools, John J. (CDC/DDID/NCEZID/OD) <czk7@cdc.gov>

Sent: Tuesday, August 17,

2021 9:59 AM

To: CDC IMS 2019 NCOV Response Lab TF

Clearance

<eocevent216@cdc.gov>;

Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>; Gartin,

Jarrett

(CDC/DDID/NCIRD/OD)

(CTR) < xhg9@cdc.gov>

Cc: Dunworth, Soumya (CDC/DDPHSS/CSELS/OD)

<kya6@cdc.gov>;

Limbago, Brandi

(CDC/DDID/NCIRD/OD)

<<u>bbl7@cdc.gov</u>>; Moon,

Jonathan L.

(CDC/DDID/NCEZID/DSR)

<<u>iki5@cdc.gov</u>>;

Llewellyn, Anna C.

(CDC/DDID/NCEZID/DPEI) < gif7@cdc.gov>; Segaloff,

Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<<u>qdz0@cdc.gov</u>>

Subject: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Good Morning,

You may have heard but our task force was asked by STLT, and we agreed, to sponsor this manuscript through clearance. The authors are targeting NEJM and are requesting our task force to request IM approval for expedited clearance. Our main POC for this manuscript is our CDC EISO Hannah Segaloff (Cc'd). Let me know if you have any questions.

Hannah- our clearance team can help shepherd your paper through clearance. I would anticipate our laboratory SMEs to have some questions for your team.

Best regards,

John

John Kools ADS, Laboratory & Testing Task Force CDC COVID-19 Response Phone: 404-217-7258

From: Rose, Dale A. (CDC/DDID/NCEZID/DPEI)

<ido8@cdc.gov>
Sent: Tuesday, August 17,

2021 4:51 AM **To:** Kools, John J.
(CDC/DDID/NCEZID/OD)
<czk7@cdc.gov>

Cubicate CM. Calla

Subject: FW: Follow up on

your results

Morning John! Thanks for taking this on. We had intensive discussions with WI, IM, and MMWR last week about this. There's strong interest in supporting and moving this forward quickly in clearance, including securing approval for expedited clearance so it can quickly make it to NEJM for consideration. If you anticipate any issues with the content or timing, please do let me know as our TF is in routine conversation with the state epi and want to make sure we're aligned in our discussions.

Much appreciated, and I hope you are well!

Best, Dale

Dale Rose, Ph.D.
STLT Support Task Force

Cell: 404.840.9507

From: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI)

<gif7@cdc.gov>

Sent: Monday, August 16,

2021 3:35 PM **To:** Segaloff, Hannah

(CDC dhs.wisconsin.gov)

hannah.segaloff@dhs.wisconsin.gov>;

Rose, Dale A.

(CDC/DDID/NCEZID/DPEI)

<<u>ido8@cdc.gov</u>>;

Westergaard, Ryan

(CDC dhs.wisconsin.gov)

<ryan.westergaard@dhs.wisconsin.gov>;

Bisgard, Kris

(CDC/DDPHSS/CSELS/DSEPD)

< kmb6@cdc.gov>

Cc: Ricaldi Camahuali,

Jessica

(CDC/DDID/NCEZID/DPEI) <mpi7@cdc.gov>; Kools, John J. (CDC/DDID/NCEZID/OD) <czk7@cdc.gov>; Limbago, Brandi (CDC/DDID/NCIRD/OD)
bbl7@cdc.gov>; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < iki5@cdc.gov>; CDC IMS 2019 NCOV Response STLT ADS <eocevent410@cdc.gov>; CDC IMS 2019 NCOV Response Lab Task Force <eocevent177@cdc.gov> Subject: Re: Follow up on your results

Dear Hannah,

Thank you for these additional documents. Due to this manuscript's focus on laboratory data, our Laboratory and Testing Task Force colleagues have agreed to be the sponsoring task force for CDC COVID-19 Response clearance. John Kools is the Lab TF ADS and can assist with next steps.

Best Regards,

Anna

Anna Llewellyn, PhD
Associate Director for
Science
State, Tribal, Local, and
Territorial Support Task
Force
COVID-19 Emergency
Response
Centers for Disease Control
and Prevention
Office: 404-639-1538 | Cell:
678-887-5058
eocevent410@cdc.gov

~

From: Segaloff, Hannah E - DHS

 $<\!\!\underline{hannah.segaloff@dhs.wisconsin.gov}\!\!>$

Sent: Monday, August 16,

2021 3:13 PM

To: Rose, Dale A. (CDC/DDID/NCEZID/DPEI)

<ido8@cdc.gov>;

Westergaard, Ryan

(CDC dhs.wisconsin.gov)

<ryan.westergaard@dhs.wisconsin.gov>;

Bisgard, Kris

(CDC/DDPHSS/CSELS/DSEPD)

<<u>kmb6@cdc.gov</u>>

Cc: Llewellyn, Anna C.

(CDC/DDID/NCEZID/DPEI)

<<u>gif7@cdc.gov</u>>; Ricaldi

Camahuali, Jessica

(CDC/DDID/NCEZID/DPEI)

<mpi7@cdc.gov>

Subject: RE: Follow up on

your results

Thank you. I have attached the concept proposal that was approved from the original MMWR submission as well as a clearance request form.

Sincerely, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking Cell: Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

<Reimersma_Viral loads in vaccinees_ NEJM_editedauthorlist_LABTFCOMMENTS.docx>

http://dho.pathology.wisc.edu @dho • 608-890-0845

<N1_Ct_updated_Hannah.csv>

From: Thomas Friedrich

To: <u>mishra.sanjay@outlook.com</u>

Cc: Katarina Grande; DAVID H O"CONNOR; Kasen Riemersma

Subject: Re: [Nat Geo] Evidence mounts that people with breakthrough infections can spread Delta easily

Date: Friday, August 20, 2021 12:34:27 PM

Thanks Sanjay — the story looks great! I am glad to see Kasen and Kat featured.

Best,

-Tom

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 20 Aug 2021, at 12:12, mishra.sanjay@outlook.com wrote:

Dear Katrina, Kasen, Tom

My article is online now: https://www.nationalgeographic.com/science/article/evidence-mounts-that-people-with-breakthrough-infections-can-spread-delta-easily

Dear Tom,

I apologize none of your wonderful quotes made it to the final story. Editors are tough critics.

I really appreciate your time and help in getting this story out. I can only hope that these articles make even a tiny difference in convincing some fence sitters and help others to stay cautious.

Sanjay

From: Grande, Katarina

Sent: Thursday, August 12, 2021 2:36 PM

To: 'Sanjay Mishra'

Cc: <u>DAVID H O'CONNOR</u>; <u>'Kasen Riemersma'</u>; <u>Thomas Friedrich</u> **Subject:** RE: Request to interview from National Geographic

Hi Dr. Mishra,

Thanks for reaching out. I could jump on a call after 3:30pm. I'm cc'ing my co-authors, who are the true scientists on the paper—I'm the applied public health person of the bunch. So depending on your angle, it may be helpful to link with them, or see if we could jump on a call together.

KATARINA GRANDE, MPH (pronouns: she/her/hers)

Public Health Supervisor/COVID-19 Data Team Lead | Public Health Madison & Dane County

2300 South Park St, Rm 2010, Madison, WI 53713

Phone: (608) 243-0409 | Cell: | Fax: (608) 266-4858

Healthy People. Healthy Places.

<image001.png>

This email, including any attachments, may contain confidential or protected health information which is only for the intended recipient. If you received this email in error, please delete and notify the sender immediately. Emails sent or received by our agency are subject to open records requests and could be released to the public, unless there is an exception allowed by law.

<image002.png>

From: Sanjay Mishra < mishra.sanjay@outlook.com >

Sent: Thursday, August 12, 2021 2:07 PM

To: Grande, Katarina < KGrande@publichealthmdc.com KGrande@publichealthmdc.com KGrande@publichealthmdc.com KGrande@publichealthmdc.com KGRANGE <a href="mailto:Subject: Request to interview from National Geographic To interview from National Geographic To interview from National Geographic To interview from National Geographic To interview from National Geographic To interview from National Geographic To interview from National Geographic To interview from National Geographic To interview from National Geographic To interview from National Geographic To interview from National Geographic To interview from National Geographic To interview from National Geographic To interview from National Geographic To interview from National Geographic To interview from National Geographic To interview from National Geographic To interview from National Ge

Importance: High

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Dear Katarina

I read your preprint posted earlier today with alarm: "Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021"

Can I urgently talk to you since I am pitching this as story to my editor at National Geographic, as a follow up to my recent stories on Delta variant, value of masking and breakthrough infections:

In National Geographic:

- 1. Why is Delta more infectious and deadly? New research holds answers. (August 6, 2021)
- 2. How dangerous is the new Delta Plus variant? Here's what we know. (July 2, 2021)
- 3. The Delta variant is serious. Here's why it's on the rise. (June 16, 2021); updated:
 - a. The Delta variant is spreading fast, especially where vaccination rates are low (July 8, 2021)
- 4. This 'double mutant' variant is adding fuel to India's COVID-19 crisis (April 28, 2021)

In The Conversation:

- 1. What is a breakthrough infection? 6 questions answered about catching COVID-19 after vaccination (July 28, 2021)
- 2. Can people vaccinated against COVID-19 still spread the coronavirus? (May 25, 2021)

I and the readers of National Geographic will highly appreciate it

Sanjay Mishra, MS, PhD
Nashville, TN 37221; USA
mishra.sanjay@outlook.com | @Ecquis | +1 (615) 829 6563
LinkedIn | Google Scholar | Contently | Skype

From: Sabine Tian/MDPI
To: THOMAS FRIEDRICH

Subject: [Vaccines, IF 4.422] - Ask for the Status of Your Manuscript "Shedding of Infectious SARS-CoV-2 Despite

Vaccination"

Date: Monday, December 20, 2021 9:06:25 PM

Dear Dr. Friedrich,

Hope my email finds you well. This is Sabine Tian of journal Vaccines (ISSN 2076-393X, IF 4.422, https://www.mdpi.com/journal/vaccines).

We are writing to ask if you have finished your following paper published in Preprint platform or if it has been submitted to any journals.

"Shedding of Infectious SARS-CoV-2 Despite Vaccination"

If not, we would like to invite you to submit this paper to the Special Issue in our journal Vaccines. It is our great honor to read this paper and think it is suitable for our journal (If you are interested, please contact me for the suitable special issue).

I attached more information at the end of this email. In case of any questions, please feel free to contact me.

We would be honored to receive a positive reply from you and look forward to your feedback on our proposal. Thank you for your support.

Kind regards,
Sabine Tian/MDPI
Section Managing Editor
E-Mail: sabine.tian@mdpi.com

Some Special Issues

COVID-19 Vaccines and Vaccination

Knowledge and Beliefs on Vaccines

Research on Monoclonal Antibodies and Antibody Engineering Mechanisms of Mucosal Immonoregulation and Allergy

Cancer Immunotherapy and Vaccines Research

A Century of Vaccine Adjuvants: from 1920 to 2020 and Beyond Nucleic Acid Vaccine

Research on MHC background and TCR diversity in Vaccinology Frontiers in Cross-Protective Vaccines

Veterinary Parasitic Vaccines: Current Status and Future Directions Frontiers in Flavivirus Vaccines

...and so on (Can contact me to recommend).

According to our average record in 2020, a first decision based on thorough review was provided to authors around 12.9 days after submissions, and papers were published after acceptance in 3 days.

^{*}Rapid Process*

^{*}Flexible Opportunity & Contribution Form*

We would be honored to gain your kind feedback on the exact topic or organization of your contribution. If you have not enough time yourself, we would be happy if you would like members of your staff, post-docs or students to write the paper. You are warmly welcome to contribute in any form of scientific communication (original research article, review, short communication, case reports, etc.).

Publishing Fee

Vaccines is fully open access. An Article Processing Charge (APC) of CHF 2000 currently applies to all accepted papers. Open access (unlimited and free access by readers) increases publicity and promotes more frequent citations, as indicated by several studies. Open access is supported by the authors and their institutes.

Journal Introduction

/Vaccines/ (ISSN 2076-393X, http://www.mdpi.com/journal/vaccines) is an international, peer-reviewed, quick-refereeing open access journal published online by MDPI, Basel, Switzerland. /Vaccines/ is indexed by SCIE, PubMed (NLM), etc. The Impact Factor is 4.422

.....

Hope your family and you are fine during COVID-19 and everything will be back to normal soon.

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From: medicine@us.nature.com

To: Peter Halfmann

Subject: NMED-BC116676 Receipt of New Paper by Nature Medicine

Date: Tuesday, November 2, 2021 2:05:07 PM

Dear Dr Halfmann,

Please note that you are listed as a co-author on the manuscript "Shedding of Infectious SARS-CoV-2 Despite Vaccination" (reference number: NMED-BC116676), which was recently submitted to Nature Medicine.

The corresponding author is solely responsible for communicating with the journal and managing communication between co-authors. Please contact the corresponding author directly with any queries you may have related to this manuscript.

You can now use a single sign-on for all your accounts, view the status of all your manuscript submissions and reviews, access usage statistics for your published articles and download a record of your refereeing activity for the Nature journals. Please check your account regularly and ensure that we have your current contact information.

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">these

instructions. Please note that it must be linked prior to acceptance, it will not be possible to add/modify ORCIDs at proof, and you may not receive further notification before an accept decision is made. Please ensure the ORCID is linked to your account associated with this manuscript, and not to any other account you may have on our system.

Login =

If you have any issues attaching an ORCID to your Manuscript Tracking System account, please contact the <u>Platform Support Helpdesk</u>.

Many thanks,

Editorial Assistant Nature Medicine medicine@us.nature.com

Our flexible approach during the COVID-19 pandemic

If you need more time at any stage of the peer-review process, please do let us know. While our systems will continue to remind you of the original timelines, we aim to be as flexible as possible during the current pandemic.

This email has been sent through the Springer Nature Tracking System NY-610A-NPG&MTS

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Privacy Policy | Update Profile

From: <u>em.ppathogens.0.77467c.eff3e03c@editorialmanager.com</u> on behalf of <u>PLOS Pathogens</u>

To: Peter Halfmann

Subject: PLOS Pathogens: Please confirm your authorship - [EMID:d9ac2fd5588cc51c]

Date: Thursday, November 11, 2021 4:58:55 PM

Dear Halfmann,

You are receiving this email because Ms. Katarina M Grande listed you as an author on the manuscript titled "Shedding of Infectious SARS-CoV-2 Despite Vaccination," recently submitted to PLOS Pathogens.

All co-authors MUST confirm their authorship before a manuscript can be accepted for publication.

Click this link to CONFIRM your authorship and/or add your ORCID to this submission now:

The Corresponding Author has entered your name into our online submission system as indicated below. Please ensure your name is entered correctly, as this impacts indexing. If your name is not entered correctly, please confirm your authorship and then email the journal office at plospathogens@plos.org.

First Name: Peter Middle Name: J. Last Name: Halfmann

Alternatively, if you are not aware of this submission, or if you should not be listed as a co-author, then please contact the journal office at plospathogens@plos.org.

We appreciate your timely response. The abstract follows below, for your reference.

Kind regards,

PLOS Pathogens Staff plospathogens@plos.org

Manuscript Title:

Shedding of Infectious SARS-CoV-2 Despite Vaccination

Article Type: Research Article

Authors:

Katarina Maria Grande; Kasen K. Riemersma; Brittany E. Grogan; Amanda Kita-Yarbro; Peter J. Halfmann; Hannah E. Segaloff; Anna Kocharian; Kelsey R. Florek; Ryan Westergaard; Allen Bateman; Gunnar E. Jeppson; Yoshihiro Kawaoka; David H. O'Connor; Thomas C. Friedrich

Abstract:

The SARS-CoV-2 Delta variant is highly transmissible and contains mutations that confer partial immune escape. We compared RT-PCR cycle threshold (Ct) data from 699 test-positive anterior nasal swab specimens from fully vaccinated (n = 310) or unvaccinated (n=389) individuals. We observed low Ct values (<25) in 212 of 310 fully vaccinated (68%) and 246 of 389 (63%) unvaccinated individuals. Testing a subset of these low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people. To determine whether infectious virus titers differed in vaccinated and unvaccinated persons, we performed plaque assays on an additional set of 48 samples with Ct <25, finding no difference in infectious virus titer between groups.

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: https://www.editorialmanager.com/ppathogens/login.asp?a=r). Please contact the publication office if you have any questions.

From: em.ppathogens.0.77467c.eff3e03c@editorialmanager.com on behalf of PLOS Pathogens

To: <u>Peter Halfmann</u>

Subject: PLOS Pathogens: Submission confirmation for PPATHOGENS-D-21-02286 - [EMID:afbd2b2acb21bb18]

Date: Thursday, November 11, 2021 4:58:54 PM

You are being carbon copied ("cc:'d") on an e-mail "To" "Katarina M Grande" kgrande@publichealthmdc.com

CC: "Kasen K. Riemersma" riemersma@wisc.edu, "Brittany E. Grogan"

bgrogan@publichealthmdc.com, "Amanda Kita-Yarbro" akita@publichealthmdc.com, "Peter J. Halfmann" peter.halfmann@wisc.edu, "Hannah E. Segaloff"

hannah.segaloff@dhs.wisconsin.gov, "Anna Kocharian" anna.kocharian@dhs.wisconsin.gov, "Kelsey R. Florek" kelsey.florek@slh.wisc.edu, "Ryan Westergaard"

ryan.westergaard@dhs.wisconsin.gov, "Allen Bateman" acbateman@wisc.edu, "Gunnar E. Jeppson" gjeppson@exactsciences.com, "Yoshihiro Kawaoka" yoshihiro.kawaoka@wisc.edu, "David H. O'Connor" dhoconno@wisc.edu, "Thomas C. Friedrich" tfriedri@wisc.edu

Dear Ms. Grande,

Your submission entitled "Shedding of Infectious SARS-CoV-2 Despite Vaccination" has been received by PLOS Pathogens. You will be able to check on the progress of your paper by logging on to Editorial Manager as an author. The URL is https://www.editorialmanager.com/ppathogens/.

Best,

PLOS Pathogens Staff plospathogens@plos.org

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Remove my information/details). Please contact the publication office if you have any questions.

 From:
 Peter Halfmann

 To:
 Kasen Riemersma

 Cc:
 YOSHIHIRO KAWAOKA

Subject: RE: New England Journal of Medicine - 21-14060

Date: Wednesday, September 15, 2021 12:39:00 PM

We got that sample; from what the wells look like there was (bacterial) contamination so I don't to say it was negative.

From: Kasen Riemersma < riemersma@wisc.edu>
Sent: Wednesday, September 15, 2021 12:37 PM
To: Peter Halfmann < peter.halfmann@wisc.edu>
Cc: YOSHIHIRO KAWAOKA < yoshihiro.kawaoka@wisc.edu>
Subject: Re: New England Journal of Medicine - 21-14060

Thanks, Peter! Was the specimen whose titer was "ND" missing from the drop off?

Cheers, Kasen

Sent from my iPhone

On Sep 15, 2021, at 12:31 PM, Peter Halfmann < peter.halfmann@wisc.edu > wrote:

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http://dho.pathology.wisc.edu

608.890.0845

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608.890.0845

From: Letter < letter@nejm.org > Sent: Friday, September 3, 2021 14:05

To: DAVID H O'CONNOR < dhoconno@wisc.edu>

Subject: RE: New England Journal of Medicine - 21-14060

Hello Dr. O'Connor,

Thank you for your email. Your letter is currently with the editor and a decision regarding possible publication has not yet been made. You will be informed of the final editorial decision via e-mail.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: NEJM Editorial < editorial@nejm.org Sent: Friday, September 3, 2021 2:58 PM

To: Letter < letter@nejm.org>

Subject: FW: New England Journal of Medicine - 21-14060

From: Dave O'Connor < dhoconno@wisc.edu Sent: Friday, September 3, 2021 10:17 AM
To: NEJM Editorial < editorial@nejm.org>

Subject: Re: New England Journal of Medicine - 21-14060

To whom it may concern,

I am writing on behalf of our co-authors to ask if there are any updates on the status of the 400 word correspondence we submitted to NEJM on August 23. We are keenly aware that this is timely data given the current landscape of SARS-CoV-2 infection despite vaccination.

One small note: some vocal scientists have criticized our work on social media. The primary claim they make is that virus culture in low Ct samples does not mean that there is similar amounts of replication-competent virus in these samples. Subsequent to our August 23 submission, we rethawed these samples and showed that virus titers are similar in those who are unvaccinated and infected despite infection (see attached), generally tracking with PCR RNA levels. We would likely want to include a version of this plot in a revised NEJM correspondence to silence this inaccurate criticism.

Thanks in advance for your consideration,

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New England Journal of Medicine wrote on 8/23/21 1:39 PM:

Dear Ms. Grande and co-authors,

Thank you for submitting your manuscript, "Shedding of Infectious SARS-CoV-2 Despite Vaccination" to the New England Journal of Medicine.

Your manuscript has been forwarded to members of our editorial staff, who will make an initial evaluation and decide whether it merits further consideration. You will be notified of the decision as soon as possible.

Your manuscript ID is 21-14060.

Please mention the above manuscript ID in all future correspondence or when calling the office for questions. If there are any changes in your street address or e-mail address, please log in to

appropriate. You may also view the status of your manuscript at any time by checking For Authors section of the site.

We are undertaking evaluation of your manuscript with the understanding that neither the substance of the article nor the figures or tables have been published or will be submitted for publication elsewhere during the period of review.

Please provide the editors with copies of other manuscripts by you or your coauthors addressing similar or related research questions that are in preparation or under consideration at other journals. This does not apply to abstracts published in connection with scientific meetings or to news reports based on presentations at such meetings.

The Journal's policy is explained more fully at https://www.nejm.org/about-nejm/editorial-policies.

Please call us at 617-734-9800 if you have any questions.

Sincerely,

New England Journal of Medicine 10 Shattuck Street Boston, MA 02115 (617) 734-9800 Fax: (617) 739-9864 http://www.nejm.org

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http://dho.pathology.wisc.edu @dho • 608-890-0845

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<Copy of Specimens for culture 20210910 PH.xlsx>

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Your manuscript ID is 21-14060.

Please mention the above manuscript ID in all future correspondence or when calling the office for questions. If there are any changes in your street address or e-mail address, please log in

appropriate. You may also view the status of your manuscript at any time by checking For Authors section of the site.

We are undertaking evaluation of your manuscript with the understanding that neither the substance of the article nor the figures or tables have been published or will be submitted for publication elsewhere during the period of review.

Please provide the editors with copies of other manuscripts by you or your coauthors addressing similar or related research questions that are in preparation or under consideration at other journals. This does not apply to abstracts published in connection with scientific meetings or to news reports based on presentations at such meetings.

The Journal's policy is explained more fully at https://www.nejm.org/about-nejm/editorial-policies.

Please call us at 617-734-9800 if you have any questions.

Sincerely,

New England Journal of Medicine 10 Shattuck Street Boston, MA 02115 (617) 734-9800 Fax: (617) 739-9864 http://www.nejm.org

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To: Thomas Friedrich; DAVID H O"CONNOR

Cc: <u>Kasen Riemersma; YOSHIHIRO KAWAOKA; Katarina Grande</u>
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Date: Tuesday, September 7, 2021 9:46:24 AM

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Subject: Re: New England Journal of Medicine - 21-14060

Thanks Dave.

Did we update the medrxiv paper with the titration data? If so I can update my Twitter thread on the paper and include it. As you guys have said, even through the samples have undergone multiple freeze-thaw cycles, it is clear that titers are not systematically lower in vaccinees vs. unvaccinated.

Would you guys also email Daniel and Vincent directly to call their attention to these data?

-T

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 3 Sep 2021, at 17:15, DAVID H O'CONNOR < dhoconno@wisc.edu wrote:

What will come first, an NEJM decision on a 400 word letter or Kat's return from Iceland? Nonetheless, I pinged the editor (see below) and offered the titer data should it be helpful.

dave

--

I often work on email outside of work hours, but you don't have to! If you're receiving this outside of your work hours, I don't expect a response until you are back in the office.

http://dho.pathology.wisc.edu

608.890.0845

From: Letter < letter@nejm.org > Sent: Friday, September 3, 2021 14:05

To: DAVID H O'CONNOR < dhoconno@wisc.edu>

Subject: RE: New England Journal of Medicine - 21-14060

Hello Dr. O'Connor,

Thank you for your email. Your letter is currently with the editor and a decision regarding possible publication has not yet been made. You will be informed of the final editorial decision via e-mail.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: NEJM Editorial < editorial@nejm.org Sent: Friday, September 3, 2021 2:58 PM

To: Letter < letter@nejm.org>

Subject: FW: New England Journal of Medicine - 21-14060

From: Dave O'Connor < dhoconno@wisc.edu Sent: Friday, September 3, 2021 10:17 AM To: NEJM Editorial < editorial@nejm.org

Subject: Re: New England Journal of Medicine - 21-14060

To whom it may concern,

I am writing on behalf of our co-authors to ask if there are any updates on the status of the 400 word correspondence we submitted to NEJM on August 23. We are keenly aware that this is timely data given the current landscape of SARS-CoV-2 infection despite vaccination.

One small note: some vocal scientists have criticized our work on social media. The primary claim they make is that virus culture in low Ct samples does not mean that there is similar amounts of replication-competent virus in these samples. Subsequent to our August 23 submission, we re-thawed these samples and showed that virus titers are similar in those who are unvaccinated and infected despite infection (see attached), generally tracking with PCR RNA levels. We would likely want to include a version of this plot in a revised NEJM correspondence to silence this inaccurate criticism.

Thanks in advance for your consideration,

dave

New England Journal of Medicine wrote on 8/23/21 1:39 PM:

Dear Ms. Grande and co-authors,

Thank you for submitting your manuscript, "Shedding of Infectious SARS-CoV-2 Despite Vaccination" to the New England Journal of Medicine.

Your manuscript has been forwarded to members of our editorial staff, who will make an initial evaluation and decide whether it merits further consideration. You will be notified of the decision as soon as possible.

Your manuscript ID is 21-14060.

Please mention the above manuscript ID in all future correspondence or when calling the office for questions. If there are any changes in your street address or e-mail address, please log in to ScholarOne

and te.

You may also view the status of your manuscript at any time by checking For Authors section of the site.

We are undertaking evaluation of your manuscript with the understanding that neither the substance of the article nor the figures or tables have been published or will be submitted for publication elsewhere during the period of review.

Please provide the editors with copies of other manuscripts by you or your coauthors addressing similar or related research questions that are in preparation or under consideration at other journals. This does not apply to abstracts published in connection with scientific meetings or to news reports based on presentations at such meetings.

The Journal's policy is explained more fully at https://www.nejm.org/about-nejm/editorial-policies.

Please call us at 617-734-9800 if you have any questions.

Sincerely,

New England Journal of Medicine 10 Shattuck Street Boston, MA 02115 (617) 734-9800 Fax: (617) 739-9864 http://www.nejm.org

--

http://dho.pathology.wisc.edu @dho • 608-890-0845

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To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 22, 2021 2:30:54 PM

A bit of insight: I spoke to a journalist who told me how our paper is being weaponized by the far right. It might be that journals don't want to publish it and deal with the potential backlash.



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From: Brittany Grogan (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 8:28:52 AM

We don't, Katarina, but it's something I can pull together manually, just have to download some files from WEDSS. I can work on developing a masterlist of booster breakthroughs today that we can use in the meantime until DHS adds those to our daily files!

To be consistent with "regular" breakthroughs, do we want to consider a 'booster breakthrough' as an episode date (i.e. earliest date between symptom onset or test collection date) 14 or more days after the booster shot? CDC said on a call last week that they're finding it takes about 7 days to see a benefit from the booster, and I know that the Israel data Davesent us shows more of a benefit at 12 days vs. 7 days. I'll reach out to Anna to see if DHS is planning on presenting booster breakthrough data and if so, what interval they will use to define it.



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To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 9:24:55 AM

14 days is the definition I'd use if possible. Otherwise you run the risk of underestimating booster effectiveness.

It would be excellent to start cross-checking these cases against viral load. I feel like I've asked this before, but is PHMDC also planning to break out booster vs. non-booster infection and severe case rates?



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From: Brittany Grogan (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 1:46:54 PM

Sounds good, I added a file to Teams with all of our booster breakthroughs so far where the lab was processed by Exact or UW. There are 43 on the list with the majority being from November.



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From: Thomas Friedrich (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 12:28:36 PM

Thanks Prittanyand Katarina. I think it is worth analyzing breakthrough viral loads stratified by booster vs. no booster in general, and in preparation of potential reviewer requests for more recent data. We can certainly sequence breakthroughs along with everything else. Luis is the person to coordinate with, yes.



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To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 1:57:33 PM

Just to be clear, breakthrough equals >= 14 days after final dose?



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From: Brittany Grogan (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 2:18:42 PM

Correct; we have 80 total since 8/13/21. 56 of those are from November, compared to a total of 3,693 total cases so far in November. On last week's data snapshot we reported that so far 1/3 of Dane County residents who have completed the initial vaccine series have received a booster or third dose.



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To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 3:03:54 PM

So if roughly 72% of Dane County is fully vaccinated, that means that roughly 24% have been boosted (.72 * .3)

This would mean that if the vaccine was having no effect, you'd expect 886 of these November cases to be in vaccinees (3693 *.24). An actual number of 56 doesn't seem that bad - about 6% as likely to be infected after boosting than if unvaccinated.

Unless I can't do math anymore, which is entirely possible:)



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From: Dave OConnor (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Relevant paper in Nature Medicine

Date: Thursday, December 2, 2021 9:48:16 AM

So, like, we were right?



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From: Brittany Grogan (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Thursday, December 2, 2021 9:11:04 PM

Dave FYI we have included booster case rate data in our snapshot that was released this evening! We only release hospitalization and death data by vaccination status once a month, so we'll release that in the same format (not vaxxed/vaxxed initial series/vaxxed + boosted) in two weeks, for both October and November.



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From: Katarina Grande (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Relevant paper in Nature Medicine

Date: Tuesday, December 7, 2021 4:34:34 PM

yep. well done!



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From: Katarina Grande (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 22, 2021 1:33:18 PM

agreed, very annoying. same status today.



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From: Brittany Grogan (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 11:10:34 AM

② Davel'll chat with ② Katarinaand the rest of the data team at our meeting tomorrow morning, but I think that yes, we can certainly explore breaking out unvaccinated vs vaccinated non-booster vs vaccinated booster, perhaps even on this week's data snapshot.

Should we send a list of booster breakthroughs for potential sequencing? It's been a couple months since I've sent a request for sequencing; is this something I would send to Luis?



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From: Katarina Grande (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 22, 2021 4:17:44 PM

Great point!



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From: Thomas Friedrich (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Wednesday, November 24, 2021 2:52:36 PM

Any further updates <a> Ratarina?

One question for you and <a> Dave -- we have continued to collect data on Ct value and vaccination status. We could update the figures if this version does not get sent out for review...



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To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Wednesday, November 24, 2021 2:59:46 PM

Great point P Thomas



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To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 22, 2021 3:08:44 PM

Probably a "lost" cause, but I'm not sure I'd welcome the term "lost." A paper that has been seen by more than 100,000 people is arguably the most impactful thing I've ever been involved with. Even if it means that it just becomes an opportunity to educate about what the data says and why the weaponization is wrong.



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To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Wednesday, November 24, 2021 3:00:10 PM

We could also start looking at third vaccine breakthroughs to see if there is any difference in VL in those cases.



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From: Thomas Friedrich (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Wednesday, November 24, 2021 3:00:33 PM

That is a great point yourself, <a> Dave .



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From: Katarina Grande (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 8:11:47 AM

Current status is now "under review."

Brittany, do we have the data file we need from DHS to gauge what our booster/3rd dose BTs are looking like right now?



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From: Katarina Grande (Basecamp)

To: Peter Halfmann

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 22, 2021 2:37:09 PM

Ok, that's helpful context. Unfortunate! Wonder if there is a different frame we could build out in a submission that would help with this. Or is it a lost cause at this point...



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From: YOSHIHIRO KAWAOKA

DAVID H O"CONNOR; KGrande@publichealthmdc.com To:

Peter Halfmann; Thomas Friedrich Cc:

Subject: RE: FW: Preprint: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent -

Wisconsin, July 2021

Monday, August 16, 2021 9:15:00 AM Date:

Attachments: image001.png image002.png

Daniel Griffin!

From: DAVID H O'CONNOR <dhoconno@wisc.edu>

Sent: Monday, August 16, 2021 10:41 PM To: KGrande@publichealthmdc.com

Cc: YOSHIHIRO KAWAOKA <yoshihiro.kawaoka@wisc.edu>; Peter Halfmann

<peter.halfmann@wisc.edu>; Thomas Friedrich <tfriedri@wisc.edu>

Subject: Re: FW: Preprint: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent - Wisconsin, July 2021

Hi Kat.

I already responded to him yesterday!

dave

KGrande@publichealthmdc.com wrote on 8/16/21 8:37 AM:

Hi Yoshi and Peter,

Would you please response to Daniel when you have a moment? I believe the answer to the question is "nope, no real time monitoring or quantification as of now, but it is something we're working on." But in case Daniel has more technical questions, best if you answer. Thanks!

-Kat

KATARINA GRANDE, MPH (pronouns: she/her/hers)

Public Health Supervisor/COVID-19 Data Team Lead | Public Health Madison & Dane County

2300 South Park St, Rm 2010, Madison, WI 53713

Phone: (608) 243-0409 | Cell: (608) 640-9430 | Fax: (608) 266-4858

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From: Griffin, Daniel square;<a href="mailto:squa

Sent: Saturday, August 14, 2021 9:44 PM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Subject: Preprint: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the

Delta Variant is Prevalent - Wisconsin, July 2021

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Dr Grande,

I hope this email finds you well. I was hoping to a ask a few questions about the preprint Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021.

You report "Infectious SARS-CoV-2 was isolated from 14 of 16 specimens (88%) from unvaccinated individuals and 37 of 39 specimens (95%) from vaccinated people.'

In figure 2 According to figure 2 Infectiousness was determined by the presence of cytopathic effects (CPE) after 5 days of replication in Vero E6 TMPRSS2 cells with visually apparent CPE under a light microscope. Any real time monitoring or quantification?

Sincerely,

Daniel Griffin, MD PhD CTropMed CTH

Chief, Division of Infectious Disease - ProHEALTH, an OPTUM Company Senior Fellow for Infectious Disease - UHG Research and Development Clinical Instructor of Medicine - Columbia University College of Physicians and Surgeons

Department of Medicine-Division of Infectious Diseases President -Parasites Without Borders 1 Dakota Drive Suite 205 New Hyde Park, NY 11042 Office Tel: (516)-656-6500

Cell:

Email: danielgriffinmd@gmail.com

www.parasiteswithoutborders.com www.microbe.tv Twitter @DanielGriffinMD

__

http://dho.pathology.wisc.edu @dho • 608-890-0845 From: Katarina Grande (Basecamp)
To: YOSHIHIRO KAWAOKA

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 22, 2021 1:33:18 PM

agreed, very annoying. same status today.



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From: Brittany Grogan (Basecamp)
To: YOSHIHIRO KAWAOKA

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 8:28:51 AM

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From: Brittany Grogan (Basecamp)
To: YOSHIHIRO KAWAOKA

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 11:10:43 AM

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Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 9:24:58 AM

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From: Thomas Friedrich (Basecamp)
To: YOSHIHIRO KAWAOKA

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 12:28:34 PM

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From: Brittany Grogan (Basecamp)
To: YOSHIHIRO KAWAOKA

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 1:47:05 PM

Sounds good, I added a file to Teams with all of our booster breakthroughs so far where the lab was processed by Exact or UW. There are 43 on the list with the majority being from November.



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Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 1:57:34 PM

Just to be clear, breakthrough equals >= 14 days after final dose?



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From: Brittany Grogan (Basecamp)
To: YOSHIHIRO KAWAOKA

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 2:18:37 PM

Correct; we have 80 total since 8/13/21. 56 of those are from November, compared to a total of 3,693 total cases so far in November. On last week's data snapshot we reported that so far 1/3 of Dane County residents who have completed the initial vaccine series have received a booster or third dose.



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Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 3:03:53 PM

So if roughly 72% of Dane County is fully vaccinated, that means that roughly 24% have been boosted (.72 * .3)

This would mean that if the vaccine was having no effect, you'd expect 886 of these November cases to be in vaccinees (3693 *.24). An actual number of 56 doesn't seem that bad - about 6% as likely to be infected after boosting than if unvaccinated.

Unless I can't do math anymore, which is entirely possible:)



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Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Relevant paper in Nature Medicine

Date: Thursday, December 2, 2021 9:48:17 AM

So, like, we were right?



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From: Brittany Grogan (Basecamp)
To: YOSHIHIRO KAWAOKA

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Thursday, December 2, 2021 9:11:07 PM

Dave FYI we have included booster case rate data in our snapshot that was released this evening! We only release hospitalization and death data by vaccination status once a month, so we'll release that in the same format (not vaxxed/vaxxed initial series/vaxxed + boosted) in two weeks, for both October and November.



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From: <u>Dave OConnor (Basecamp)</u>
To: <u>YOSHIHIRO KAWAOKA</u>

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 22, 2021 3:08:44 PM

Probably a "lost" cause, but I'm not sure I'd welcome the term "lost." A paper that has been seen by more than 100,000 people is arguably the most impactful thing I've ever been involved with. Even if it means that it just becomes an opportunity to educate about what the data says and why the weaponization is wrong.



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From: Katarina Grande (Basecamp)
To: YOSHIHIRO KAWAOKA

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 22, 2021 2:37:11 PM

Ok, that's helpful context. Unfortunate! Wonder if there is a different frame we could build out in a submission that would help with this. Or is it a lost cause at this point...



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From: <u>Katarina Grande (Basecamp)</u>
To: <u>YOSHIHIRO KAWAOKA</u>

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 22, 2021 4:17:46 PM

Great point!



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Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 22, 2021 2:30:51 PM

A bit of insight: I spoke to a journalist who told me how our paper is being weaponized by the far right. It might be that journals don't want to publish it and deal with the potential backlash.



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Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Wednesday, November 24, 2021 2:59:45 PM

Great point <a> Thomas



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Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Wednesday, November 24, 2021 3:00:06 PM

We could also start looking at third vaccine breakthroughs to see if there is any difference in VL in those cases.



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From: Thomas Friedrich (Basecamp)
To: YOSHIHIRO KAWAOKA

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Wednesday, November 24, 2021 3:00:38 PM

That is a great point yourself, <a> Dave .



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From: Katarina Grande (Basecamp)
To: YOSHIHIRO KAWAOKA

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Monday, November 29, 2021 8:11:48 AM

Current status is now "under review."

Brittany, do we have the data file we need from DHS to gauge what our booster/3rd dose BTs are looking like right now?



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?



From: Thomas Friedrich (Basecamp)
To: YOSHIHIRO KAWAOKA

Subject: Re: (m: Shedding of Infectious SARS-CoV-2 Despite Vaccination) Manuscript update

Date: Wednesday, November 24, 2021 2:52:30 PM

Any further updates <a> Ratarina?

One question for you and <a> Dave -- we have continued to collect data on Ct value and vaccination status. We could update the figures if this version does not get sent out for review...



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From: Thomas Friedrich
To: Peter Halfmann

Cc: DAVID H O"CONNOR; Kasen Riemersma; YOSHIHIRO KAWAOKA; Katarina Grande

Subject: Re: New England Journal of Medicine - 21-14060

Date: Tuesday, September 7, 2021 9:49:04 PM

Okay, Kasen, can you and Luis identify 2 batches of 24 samples for Peter to test Thursday and Friday?

T

Sent from my iPhone

On Sep 7, 2021, at 12:02, Peter Halfmann peter.halfmann@wisc.edu> wrote:

We can do 24 samples on Thursday and another 24 samples on Friday.

On Sep 7, 2021, at 9:39 AM, Thomas Friedrich < tfriedri@wisc.edu > wrote:

Like Dave, I can see this going either way. Perhaps we could do a set of specimens from within the same time period that is covered in the submitted paper, and then also a more recent batch? This would cover our bases. However, I don't want to burden Peter too much, so I think he and Yoshi should comment also.

Best,

-Tom

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tefriedrich
@tef-lab
www.vetmed.wisc.edu/friedrichlab

Dave O'Connor wrote on 2021-09-07 08:42:

Hi all,

I could see it going either way. I don't think we need to add them to the existing dataset. It might even be better to use recent samples because it shows that the trend is stable over time. But I don't feel strongly about it.

dave

Kasen Riemersma wrote on 9/7/21 8:40 AM:

Hi all,

I can definitely provide more samples for Peter to test. Peter, once I know how many you can process, I should be able to send them over quickly.

Tom, if these culture data may be added to our study, I'm inclined to select specimens from the same study period instead of more recent specimens. Do you agree?

Cheers, Kasen

From: Thomas Friedrich <tfriedri@wisc.edu>

Date: Sunday, September 5, 2021 at 12:43 PM To: YOSHIHIRO KAWAOKA <<u>yoshihiro.kawaoka@wisc.edu></u> **Cc:** DAVID H O'CONNOR <a href="mailto:sde-<peter.halfmann@wisc.edu>, Katarina Grande kgrande@publichealthmdc.com, Kasen Riemersma kgrande@publichealthmdc.com, Kasen Riemersma kgrande@publichealthmdc.com, Subject: Re: New England Journal of Medicine - 21-14060 Hi all. Okay, I agree with all this. In our emails last week, I was not sure whether you guys wanted to respond to Vincent as soon as possible. I completely agree that we would need to generate new titration data with samples that have not undergone multiple freeze-thaw cycles. Luckily we are getting a large number of samples from Exact each week. Kasen, can we identify a set of fresh samples that can be aliquoted for Peter to test? Peter, what is a good number of samples for you to receive? Best, -Tom YOSHIHIRO KAWAOKA wrote on 2021-09-03 19:33: If we are going to respond to Vincent by sharing our new data, we should do the virus isolation with new samples that have not been thawed several times. I am concerned about the data showing that the number of no-virus-recovery samples from vaccinated individuals is higher than that from unvaccinated individuals. He will criticize this point if we send him the current data. Best, Yoshi From: DAVID H O'CONNOR <a href Sent: Saturday, September 4, 2021 8:11 AM **To:** Thomas Friedrich <a href Cc: Peter Halfmann peter.halfmann@wisc.edu>; YOSHIHIRO KAWAOKA <yoshihiro.kawaoka@wisc.edu>; Katarina Grande <kgrande@publichealthmdc.com> Subject: Re: New England Journal of Medicine - 21-14060 Hi Tom, I updated Medrxiv with the NEJM submission. I didn't update with this week's data. I suggest waiting until we get a disposition on the NEJM paper before updating Medrxiv again. In terms of Vincent, I'm fine if someone else wants to connect with him and Daniel on the data. I'm not enthusiastic about doing it myself. dave

I often work on email outside of work hours, but you don't have to! If you're receiving this outside of your work hours, I don't expect a

response until you are back in the office.

http://dho.pathology.wisc.edu

608.890.0845

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Friday, September 3, 2021 18:04

To: DAVID H O'CONNOR < dhoconno@wisc.edu>

Cc: Peter Halfmann < peter.halfmann@wisc.edu >; YOSHIHIRO KAWAOKA

<yoshihiro.kawaoka@wisc.edu>; Katarina Grande

< KGrande@publichealthmdc.com>

Subject: Re: New England Journal of Medicine - 21-14060

Thanks Dave.

Did we update the medrxiv paper with the titration data? If so I can update my Twitter thread on the paper and include it. As you guys have said, even through the samples have undergone multiple freeze-thaw cycles, it is clear that titers are not systematically lower in vaccinees vs. unvaccinated.

Would you guys also email Daniel and Vincent directly to call their attention to these data?

-T

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 3 Sep 2021, at 17:15, DAVID H O'CONNOR < dhoconno@wisc.edu wrote:

What will come first, an NEJM decision on a 400 word letter or Nonetheless, I pinged the editor (see below) and offered the titer data should it be helpful.

dave

--

I often work on email outside of work hours, but you don't have to! If you're receiving this outside of your work hours, I don't expect a response until you are back in the office.

http://dho.pathology.wisc.edu 608.890.0845 From: Letter < letter@nejm.org>
Sent: Friday, September 3, 2021 14:05

To: DAVID H O'CONNOR < dhoconno@wisc.edu>

Subject: RE: New England Journal of Medicine - 21-14060

Hello Dr. O'Connor,

Thank you for your email. Your letter is currently with the editor and a decision regarding possible publication has not yet been made. You will be informed of the final editorial decision via e-mail.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: NEJM Editorial <<u>editorial@nejm.org</u>>
Sent: Friday, September 3, 2021 2:58 PM

To: Letter < letter@nejm.org>

Subject: FW: New England Journal of Medicine - 21-14060

From: Dave O'Connor < dhoconno@wisc.edu>
Sent: Friday, September 3, 2021 10:17 AM
To: NEJM Editorial < editorial@nejm.org>

Subject: Re: New England Journal of Medicine - 21-14060

To whom it may concern,

I am writing on behalf of our co-authors to ask if there are any updates on the status of the 400 word correspondence we submitted to NEJM on August 23. We are keenly aware that this is timely data given the current landscape of SARS-CoV-2 infection despite vaccination.

One small note: some vocal scientists have criticized our work on social media. The primary claim they make is that virus culture in low Ct samples does not mean that there is similar amounts of replication-competent virus in these samples. Subsequent to our August 23 submission, we rethawed these samples and showed that virus titers are similar in those who are unvaccinated and infected despite infection (see attached), generally tracking with PCR RNA levels. We would likely want to include a version of this plot in a revised NEJM correspondence to silence this inaccurate criticism.

Thanks in advance for your consideration,

dave

New England Journal of Medicine wrote on 8/23/21 1:39 PM:

Dear Ms. Grande and co-authors,

Thank you for submitting your manuscript, "Shedding of Infectious SARS-CoV-2 Despite Vaccination" to the New England Journal of Medicine.

Your manuscript has been forwarded to members of our editorial staff, who will make an initial evaluation and decide whether it merits further consideration. You will be notified of the decision as soon as possible.

Your manuscript ID is 21-14060.

Please mention the above manuscript ID in all future correspondence or when calling the office for questions. If there are any changes in your street address or e-mail address, please log in to ScholarOne Manuscripts at https://mco5.manuscriptcentral.com/neim and edit your user information as appropriate. You may also view the status of your manuscript at any time by checking For Authors section of the site.

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Please call us at 617-734-9800 if you have any questions.

Sincerely,

New England Journal of Medicine 10 Shattuck Street Boston, MA 02115 (617) 734-9800 Fax: (617) 739-9864 http://www.nejm.org

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From: <u>Dave O"Connor</u>

To: <u>Chris Barncard</u>; <u>Grande, Katarina</u>; <u>Thomas Friedrich</u>

Cc: Finke, Morgan R.; Kelly Tyrrell

Subject: Attention rodeo redux

Date: Tuesday, August 10, 2021 7:21:31 PM

Attachments: <u>Viral loads in vaccinees Medrxiv 10 Aug 2021-3.pdf</u>

Chris, Morgan, Kelly -

Quick heads up that we just updated our preprint on infection despite vaccination. Here is the new version. I expect that, like the last version, it might get some attention. A key criticism of our work last week was that it was underpowered and that PCR Ct did not equate to replication-competent virus. Fine. So we added 400+ more individuals and, with Yoshi's lab's help, showed that nearly all of the high viral load samples we tested contained live, replication-competent virus. I really wish Nate Silver had taken my bet; I'd be \$100 richer.

dave

Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021

Kasen K. Riemersma, DVM, PhD¹; Brittany E. Grogan, MPH²; Amanda Kita-Yarbro, MPH²; Peter Halfmann, PhD¹; Anna Kocharian, MS³; Kelsey R. Florek, PhD⁴; Ryan Westergaard, MD, PhD³, Allen Bateman, PhD⁴; Gunnar E. Jeppson, BS⁶; Yoshihiro Kawaoka, DVM, PhD¹; David H. O'Connor, PhD³; Thomas C. Friedrich, PhD¹; Katarina M. Grande, MPH²

Abstract

The SARS-CoV-2 Delta variant and its sublineages (B.1.617.2, AY.1, AY.2, AY.3; [1]) can cause high viral loads, are highly transmissible, and contain mutations that confer partial immune escape [2,3]. Using PCR threshold cycle (Ct) data from a single large contract laboratory, we show that individuals in Wisconsin, USA had similar viral loads in nasal swabs, irrespective of vaccine status, during a time of high and increasing prevalence of the Delta variant. Infectious SARS-CoV-2 was isolated from 51 of 55 specimens (93%) with Ct <25 from both vaccinated and unvaccinated persons, indicating that most individuals with Ct values in this range (Wilson 95% CI 83%-97%) shed infectious virus regardless of vaccine status. Notably, 68% of individuals infected despite vaccination tested positive with Ct <25, including at least 8 who were asymptomatic at the time of testing. Our data substantiate the idea that vaccinated individuals who become infected with the Delta variant may have the potential to transmit SARS-CoV-2 to others. Vaccinated individuals should continue to wear face coverings in indoor and congregate settings, while also being tested for SARS-CoV-2 if they are exposed or experience COVID-like symptoms.

Main text

We analyzed respiratory specimens from 719 individuals collected between 29 June 2021 and 31 July 2021. Delta and its sublineages accounted for 69% of all Wisconsin sequences in GISAID in the week beginning 27 June 2021; this proportion increased to 95% for the week ending 24 July, the most recent date for which data are available [4]. We recovered viral genome sequences from 122 of the specimens analyzed in this report; 110 of 122 (90%) belonged to Delta lineages. The high and increasing prevalence of Delta-lineage viruses during the study period, and high proportion of Delta-lineage

¹ Department of Pathobiological Sciences, University of Wisconsin-Madison, Madison, WI, USA; ² Public Health Madison & Dane County, Madison, WI, USA; ³ Wisconsin Department of Health Services; ⁴ Wisconsin State Laboratory of Hygiene; ⁵ Department of Medicine, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin; ⁶ Exact Sciences, Madison, WI, USA; ⁷ Department of Pathology and Laboratory Medicine, University of Wisconsin-Madison, Madison, WI, USA.

[^] Author to whom all correspondence should be addressed. E-mail: KGrande@publichealthmdc.com

viruses among our sequenced samples, together suggest that most infections in our dataset were caused by Delta, though this cannot be directly confirmed.

We defined fully vaccinated individuals as those who received a final vaccine dose at least 2 weeks prior to testing positive. Of the 719 individuals, vaccination status at the time of testing was available in the Wisconsin Immunization Registry and Wisconsin Electronic Disease Surveillance System for 322 (293 vaccinated and 29 unvaccinated), while self-reported vaccination status was available for the remaining 397 (18 vaccinated and 379 unvaccinated). We compared Ct values in specimens from these fully vaccinated and unvaccinated individuals at the time of testing (Figure 1). We detected no significant differences in Ct values by vaccination status. Notably, 212 of 311 (68%) of individuals with infection despite full vaccination had extremely low Ct values <25, consistent with high viral loads.

While a given Ct value cannot be used to infer infectiousness, previous studies suggested that infectious SARS-CoV-2 can frequently be recovered from specimens with Ct values of 25-30 or lower [5]. To determine whether high viral loads might indicate the presence of infectious SARS-CoV-2, we attempted to culture infectious virus from a subset of 55 specimens with Ct values <25 (Figure 2). Infectious SARS-CoV-2 was isolated from 14 of 16 specimens (88%) from unvaccinated individuals and 37 of 39 specimens (95%) from vaccinated people, suggesting that Ct <25 is frequently associated with the capacity to shed infectious SARS-CoV-2, even in fully vaccinated persons.

Data on symptom status were available from 516 of the 719 individuals evaluated here, so we further compared Ct values in test-positive specimens according to vaccination and symptom status (Figure 3A). For symptomatic cases, there was no significant difference in the time elapsed between symptom onset and testing for vaccinated vs. unvaccinated individuals (two-sample K-S test, p=0.49; Figure 3B). Full vaccination did not affect Ct values observed in infected individuals, either with or without symptoms, at the time of testing. Among those for whom symptom status is known, 252 of 276 individuals who were not fully vaccinated (91%) reported symptoms at the time of testing, while 228 of 240 people who were fully vaccinated (95%) reported symptoms. Among individuals who were asymptomatic at the time of testing, Ct values <25 were detected in 7 of 24 unvaccinated individuals (29%; CI: 13-51%) and in 8 of 12 individuals who were infected despite being fully vaccinated (67%; CI: 35-90%). Infectious virus was detected in the sole specimen tested from an asymptomatic fully vaccinated individual. Although the number of asymptomatic individuals sampled is small, these results indicate that some individuals who are infected despite vaccination can have high viral loads and shed infectious virus even while being asymptomatic. Additional virus isolation data are needed to determine the frequency of infectious virus shedding in asymptomatic cases.

Our findings are consistent with other recent reports detecting high virus loads in some individuals infected despite vaccination in England [6] and Singapore [7]. Our detection of infectious virus in 93% of samples with Ct <25 indicates that high viral loads are consistent with the potential to transmit SARS-CoV-2, regardless of the individual's vaccination status. Notably, transmission of Delta from vaccinated healthcare workers to their household contacts was recently documented in an investigation of a hospital-associated outbreak in Finland [8]. An outbreak in Barnstable County, MA associated with large gatherings also involved a substantial proportion of fully vaccinated individuals [9]. The co-circulation of viruses belonging to Pango lineages B.1.617.2, AY.2, and AY.3, as well as the broad geographic distribution of our specimens, indicate that the infections analyzed here are not associated with any single large outbreak, and that Delta-lineage SARS-CoV-2 can achieve high viral loads consistent with transmissibility in fully vaccinated individuals across a range of exposure settings. Taken

together, these studies indicate that individuals infected with Delta variants despite vaccination have the capacity to transmit infection to others.

Our study has at least three important limitations. First, we have only one specimen from most individuals, and therefore we cannot know the trajectory of viral loads at the time of testing. Indeed, a study of Delta infection dynamics suggests that viral loads decline more rapidly in vaccinated vs. unvaccinated individuals, as one might expect [7]. However, that study also indicates that viral loads in vaccinated and unvaccinated individuals remain similarly high for 5-6 days after illness onset, before declining more rapidly in vaccinated people. In our study, 91% of specimens from symptomatic cases were collected from 0-6 days after illness onset and the timing of tests relative to illness onset did not differ by vaccination status. These observations suggest that the Ct value comparisons in our study are likely not biased by the time of testing. A second limitation is that there may be differences in the populations of vaccinated and unvaccinated persons seeking testing that bias our results. Vaccinated individuals may not perceive a high risk of COVID-19 disease, and may be less likely to seek testing than unvaccinated people. It is difficult to determine from our data whether vaccinated and unvaccinated people experienced symptoms of similar severity. Thus, we cannot determine the extent to which our sampling failed to detect asymptomatic or paucisymptomatic infections. Such mild infections may be more frequent among vaccinated than unvaccinated individuals infected with Delta. Consistent with this, a recent report from England detected a substantially greater proportion of low-positive tests with Ct values between 35 and 40 in vaccinated individuals than in the unvaccinated [6]. Importantly, our study was not designed to estimate the rate of infection despite vaccination, but rather to determine whether individuals infected despite vaccination could have high viral loads consistent with the potential to transmit SARS-CoV-2. Finally, there is inherent variability in PCR Ct values due to specimen variability that can be impacted by collection technique and other variables outside of our control.

The finding of high SARS-CoV-2 viral loads and replication-competent virus in vaccinated individuals has important implications for risk assessment and mitigation. The impact of Delta variants on vaccine effectiveness is currently being evaluated (see, e.g., [10]). Risk disinhibition may lead vaccinated people to increase behaviors that expose them to SARS-CoV-2 infection, and individuals who are infected despite vaccination could serve as sources of onward transmission to others. Vaccinated individuals, particularly those who may have high levels of community or occupational exposure to SARS-CoV-2, should be encouraged to continue frequent testing, especially when symptomatic, to limit community spread. Continued adherence to non-pharmaceutical interventions, such as masking and distancing, will remain important for both vaccinated and unvaccinated individuals because we cannot predict which vaccinated individuals will experience infections with high viral loads. While vaccines continue to provide outstanding protection against severe disease and mortality, the durability of this protection cannot be reliably predicted. Therefore, it is essential for public health policy to encourage vaccination while also planning for contingencies, including diminished long-term protection.

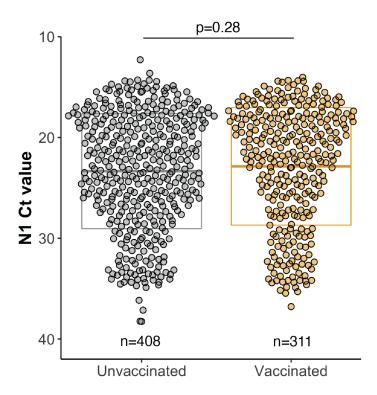


Figure 1. Distributions of SARS-CoV-2 PCR cycle threshold (Ct) values at the time of testing do not differ by vaccination status. N1 PCR Ct values for SARS-CoV-2-positive specimens grouped by vaccination status. Boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values between the groups by Welch two-sample t-test.

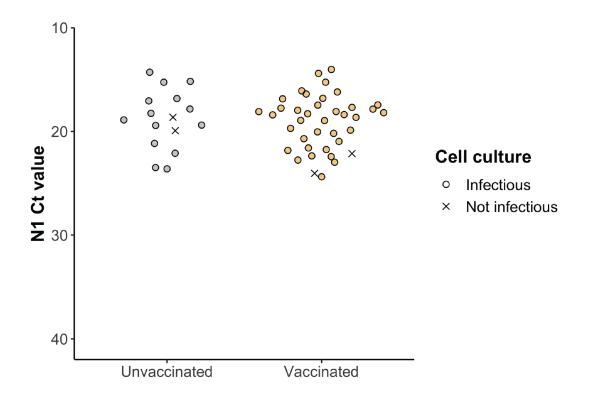


Figure 2. Infectious virus detected in nasal swab specimens from unvaccinated and fully vaccinated cases with Ct values < 25. Infectiousness was determined by the presence of cytopathic effects (CPE) after 5 days of replication in Vero E6 TMPRSS2 cells. Specimens with visually apparent CPE under a light microscope are represented by filled circles, and specimens without apparent CPE are represented by 'X'.

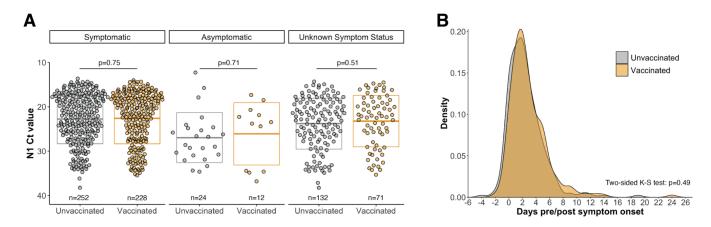


Figure 3. Symptom status does not affect distributions of SARS-CoV-2 PCR cycle threshold (Ct) values at the time of testing in vaccinated vs. unvaccinated persons. A) N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for symptomatic, asymptomatic, and unknown symptom status cases. Boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values between groups by Welch two-sample t-tests. B) Density distributions of unvaccinated and vaccinated specimen collection dates by day since symptom onset. Day 0 on the x-axis denotes self-reported day of symptom onset. Negative values for days indicate specimen collection prior to symptom onset. Symptom onset data were available for n=249 unvaccinated cases and n=222 vaccinated cases.

Acknowledgments

We would like to acknowledge the local health departments in Wisconsin who referred samples for SARS-CoV-2 testing. We gratefully acknowledge Shelby O'Connor and Hannah Segaloff for critical review of the manuscript and helpful discussion. We also acknowledge all Exact Sciences employees who contributed to sample testing. This work was supported by Centers for Disease Control and Prevention contracts 75D30120C09870 and 75D30121C11060 to D.H.O and T.C.F. The authors are also members of the Upper Midwest Regional Accelerator for Genomic Surveillance funded by the Rockefeller Foundation.

Conflict of interest

The authors declare no conflicting interests.

Ethics statement

Per the University of Wisconsin-Madison IRB, this project qualifies as public health surveillance activities as defined in the Common Rule, 45 CFR 46.102(I)(2). As such, the project is not deemed to be research regulated under the Common Rule and therefore, does not require University of Wisconsin-Madison IRB review and oversight.

Data availability

Data and processing workflows are available at https://go.wisc.edu/p22l16. To protect potentially personally identifiable information, the publicly available dataset contains only PCR Ct values, vaccine status, symptom status, and days from symptom onset to testing for each specimen.

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From: <u>Grande, Katarina</u>

To: Thomas Friedrich; DAVID H O"CONNOR

Subject: FW: JAMA21-11227 Receipt of New Manuscript by JAMA

Date: Wednesday, October 20, 2021 1:00:50 PM

Is the highlighted part an issue? Perhaps not since you disclosed in the cover letter?

From: lisa.hardin@jamanetwork.org < lisa.hardin@jamanetwork.org >

Sent: Wednesday, October 20, 2021 12:59 PM

To: Grande, Katarina < KGrande@publichealthmdc.com> **Subject:** JAMA21-11227 Receipt of New Manuscript by JAMA

Caution: This email was sent from an external source. Avoid unknown links and attachments.

October 20, 2021

Dear Ms Grande:

Thank you for submitting your research letter, "Shedding of Infectious SARS-CoV-2 Despite Vaccination," received on October 20, 2021, to JAMA. Your research letter has been assigned the following manuscript number: JAMA21-11227. Please refer to the manuscript number and corresponding author in all subsequent communications.

You may check the status of this letter by selecting the Check Manuscript Status link on the following Web page:

Do not share this encrypted link with others, as it will automatically log you into your account for JAMA's Web-based system.

Every effort will be made to review your research letter quickly and to notify you of our decision as soon as possible. All research letters addressing the SARS-CoV-2 outbreak are being automatically prioritized. Please do not contact the editorial office to request expedited review.

We agree to consider your research letter with the understanding that its content, figures, and tables have not been published or submitted elsewhere in print or electronic format and will not be submitted elsewhere during the period of review by JAMA. If you have not already done so, please provide copies of any manuscripts on closely related topics or with possibly duplicative material that have been previously published or are under consideration for publication elsewhere. The information in your letter should not be distributed or released in hard copy or electronic form, except through presentation at scientific meetings, unless and until the letter is published.

Thank you for your interest in JAMA. If you have any questions about your letter please contact <u>Lisa.Hardin@jamanetwork.org</u> or 312-464-2405.

Sincerely yours,

Jody W. Zylke, MD Deputy Editor, JAMA

Lisa Hardin, MBA, MHA Editorial Assistant II

Email: Lisa.Hardin@jamanetwork.org

Phone: 312.464.2405 Fax: 312.464.5989

Access the following link to view a short video on the JAMA Network editorial process: https://ja.ma/JNEditorialProcess

Confidentiality Note: This communication, including any attachments, is solely for the use of the addressee, may contain privileged, confidential or proprietary information, and may not be redistributed in any way without the sender's consent. Thank you.

 From:
 medicine@us.nature.com

 To:
 DAVID H O"CONNOR

Subject: NMED-BC116676 Receipt of New Paper by Nature Medicine

Date: Tuesday, November 2, 2021 2:05:08 PM

Dear Dr O'Connor,

Please note that you are listed as a co-author on the manuscript "Shedding of Infectious SARS-CoV-2 Despite Vaccination" (reference number: NMED-BC116676), which was recently submitted to Nature Medicine.

The corresponding author is solely responsible for communicating with the journal and managing communication between co-authors. Please contact the corresponding author directly with any queries you may have related to this manuscript.

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Should you wish to publish your ORCID with this manuscript, please use the link below to access your account listed as co-author and attach your ORCID following

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If you have any issues attaching an ORCID to your Manuscript Tracking System account, please contact the <u>Platform Support Helpdesk</u>.

Many thanks,

Editorial Assistant Nature Medicine medicine@us.nature.com

Our flexible approach during the COVID-19 pandemic

If you need more time at any stage of the peer-review process, please do let us know. While our systems will continue to remind you of the original timelines, we aim to be as flexible as possible during the current pandemic.

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From: em.ppathogens.0.77467c.eff3e03c@editorialmanager.com on behalf of PLOS Pathogens

To: DAVID H O"CONNOR

Subject: PLOS Pathogens: Please confirm your authorship - [EMID:a940ee4f0674d1f1]

Date: Thursday, November 11, 2021 4:59:02 PM

Dear O'Connor,

You are receiving this email because Ms. Katarina M Grande listed you as an author on the manuscript titled "Shedding of Infectious SARS-CoV-2 Despite Vaccination," recently submitted to PLOS Pathogens.

All co-authors MUST confirm their authorship before a manuscript can be accepted for publication.

Click this link to CONFIRM your authorship and/or add your ORCID to this submission now:

The Corresponding Author has entered your name into our online submission system as indicated below. Please ensure your name is entered correctly, as this impacts indexing. If your name is not entered correctly, please confirm your authorship and then email the journal office at plospathogens@plos.org.

First Name: David Middle Name: H. Last Name: O'Connor

Alternatively, if you are not aware of this submission, or if you should not be listed as a co-author, then please contact the journal office at plospathogens@plos.org.

We appreciate your timely response. The abstract follows below, for your reference.

Kind regards,

PLOS Pathogens Staff plospathogens@plos.org

Manuscript Title:

Shedding of Infectious SARS-CoV-2 Despite Vaccination

Article Type: Research Article

Authors:

Katarina Maria Grande; Kasen K. Riemersma; Brittany E. Grogan; Amanda Kita-Yarbro; Peter J. Halfmann; Hannah E. Segaloff; Anna Kocharian; Kelsey R. Florek; Ryan Westergaard; Allen Bateman; Gunnar E. Jeppson; Yoshihiro Kawaoka; David H. O'Connor; Thomas C. Friedrich

Abstract:

The SARS-CoV-2 Delta variant is highly transmissible and contains mutations that confer partial immune escape. We compared RT-PCR cycle threshold (Ct) data from 699 test-positive anterior nasal swab specimens from fully vaccinated (n = 310) or unvaccinated (n=389) individuals. We observed low Ct values (<25) in 212 of 310 fully vaccinated (68%) and 246 of 389 (63%) unvaccinated individuals. Testing a subset of these low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people. To determine whether infectious virus titers differed in vaccinated and unvaccinated persons, we performed plaque assays on an additional set of 48 samples with Ct <25, finding no difference in infectious virus titer between groups.

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: https://www.editorialmanager.com/ppathogens/login.asp?a=r). Please contact the publication office if you have any questions.

From: em.ppathogens.0.77467c.eff3e03c@editorialmanager.com on behalf of PLOS Pathogens

To: DAVID H O"CONNOR

Subject: PLOS Pathogens: Submission confirmation for PPATHOGENS-D-21-02286 - [EMID:afbd2b2acb21bb18]

Date: Thursday, November 11, 2021 4:58:54 PM

You are being carbon copied ("cc:'d") on an e-mail "To" "Katarina M Grande" kgrande@publichealthmdc.com

CC: "Kasen K. Riemersma" riemersma@wisc.edu, "Brittany E. Grogan"

bgrogan@publichealthmdc.com, "Amanda Kita-Yarbro" akita@publichealthmdc.com, "Peter J. Halfmann" peter.halfmann@wisc.edu, "Hannah E. Segaloff"

hannah.segaloff@dhs.wisconsin.gov, "Anna Kocharian" anna.kocharian@dhs.wisconsin.gov, "Kelsey R. Florek" kelsey.florek@slh.wisc.edu, "Ryan Westergaard"

ryan.westergaard@dhs.wisconsin.gov, "Allen Bateman" acbateman@wisc.edu, "Gunnar E. Jeppson" gjeppson@exactsciences.com, "Yoshihiro Kawaoka" yoshihiro.kawaoka@wisc.edu, "David H. O'Connor" dhoconno@wisc.edu, "Thomas C. Friedrich" tfriedri@wisc.edu

Dear Ms. Grande,

Your submission entitled "Shedding of Infectious SARS-CoV-2 Despite Vaccination" has been received by PLOS Pathogens. You will be able to check on the progress of your paper by logging on to Editorial Manager as an author. The URL is https://www.editorialmanager.com/ppathogens/.

Best.

PLOS Pathogens Staff plospathogens@plos.org

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Remove my information/details). Please contact the publication office if you have any questions.

From: <u>Grande, Katarina</u>

To: <u>DAVID H O"CONNOR</u>; <u>Thomas Friedrich</u>

Subject: RE: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

Date: Friday, October 22, 2021 2:13:39 PM

Haven't heard back yet!

From: DAVID H O'CONNOR <dhoconno@wisc.edu>

Sent: Friday, October 22, 2021 2:10 PM

To: Thomas Friedrich <tfriedri@wisc.edu>; Grande, Katarina <KGrande@publichealthmdc.com>

Subject: RE: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Did you hear back from JAMA? If they are a hard no, I like the idea of submitting as-is to PLOS Medicine. Well, we should reformat references to PLOS standards, but otherwise submit as-is.

dave

http://dho.pathology.wisc.edu

On Oct 22, 2021, 2:03 PM -0500, Grande, Katarina < KGrande@publichealthmdc.com >, wrote:

That's a good idea. PLOS Med doesn't get cranky about pre-prints. They also have an article type called 'Perspectives," 1000 word limit/12 ref...could be a decent enough fit. Straightforward cover letter draft attached. Login to submission is via ORCID.

From: DAVID H O'CONNOR < dhoconno@wisc.edu>

Sent: Friday, October 22, 2021 1:14 PM

To: Grande, Katarina < KGrande@publichealthmdc.com; Thomas Friedrich < tfriedri@wisc.edu> Subject: Re: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

Caution: This email was sent from an external source. Avoid unknown links and attachments.

PLOS Med as-is, with a cover letter that indicates that we understand it isn't conventional format, but that we think it is the most appropriate one for this type of communication. And maybe something to the effect

of "they have a high visibility journal where the contributions of all co-authors can be appropriately recognized"?

http://dho.pathology.wisc.edu

On Oct 22, 2021, 12:57 PM -0500, Thomas Friedrich < tfriedri@wisc.edu >, wrote:

I agree it is a lousy and arbitrary policy. I would also be annoyed to be taken off a paper -- a bit still today, although less so than 10 years ago. So I am like 51% in favor of withdrawing, I think.

If we withdraw, where should this go instead?

-T

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

Grande, Katarina wrote on 2021-10-22 11:25:

We'll have the same problem with JAMA Open Network it looks like: \leq image.jpg \geq

From: DAVID H O'CONNOR <a href="mailto:sde-chick-no-chick

Sent: Friday, October 22, 2021 11:21 AM **To:** Thomas Friedrich stfriedri@wisc.edu

Cc: Grande, Katarina < KGrande@publichealthmdc.com>

Subject: Re: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite

Vaccination)

Caution: This email was sent from an external source. Avoid unknown links and attachments.

I agree with points 1-3. I think we should see if JAMA Open Network does have the same firm limit then question 3 comes into play. If they will consider it with more authors at JAMA Open Network, I agree we have more decisions to balance.

I personally am at a place in my career where I can be easy going about authorships. But I can imagine that me from ten years ago would be really annoyed if a paper that I was involved with got published in a high impact journal but my contribution was rendered invisible.

Plus, it's a lousy policy.

dave

http://dho.pathology.wisc.edu

On Oct 22, 2021, 11:09 AM -0500, Thomas Friedrich <<u>tfriedri@wisc.edu</u>>, wrote:

I think we can also make an argument to limit to the 7 authors we already have. Before we pull the manuscript, I want to consider this more fully.

- 1. These findings are important and stand a good chance to be accepted in a high-impact journal.
- 2. I think we have an interest in getting this into a journal with a wide audience given the level of interest in the preprint and the degree to which it has been used by anti-vaxxers.
- 3. But, the longer we wait, the more the impact of this study will be reduced. Pulling this submission and submitting to another journal will cost us a week or so, as new editors decide whether to send it out.
- 4. I think we can honestly say that the 7 authors we have currently listed did the most work to generate, analyze, and interpret the data, and also write the manuscript. So we could keep these authors and acknowledge the others.

I am not saying that I am fully swayed by the above points that we should keep the paper at JAMA, but I think we need to carefully weigh these points. It would indeed be a bit uncomfortable to tell people who were authors before that we had to take them off. I think most of them would be more or less okay with it, but some may not.

What do you guys think of this?

-T

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

Thomas Friedrich wrote on 2021-10-22 11:02:

Wait -- quick counterpoint to follow

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

Thomas Friedrich wrote on 2021-10-22 10:58:

I agree that I would rather not take people off the paper at this stage. Let's ask about JAMA Network Open, but I bet the answer will be the same. So then I would think to take it to Plos Med or similar.

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

DAVID H O'CONNOR wrote on 2021-10-22 10:51:

Kat,

Can you ask whether their lower tier journal ("JAMA Network Open") also has the same restriction? As a matter of principle, I'm against the idea of removing authors from papers where people have made significant contributions. I could be overruled if others strenuously disagree, but my inclination is to say no to JAMA before arbitrarily

limiting authors.

I do know that I end up choosing quirky hills of principle to die on sometimes, though, so if this is one of those times, again, others can overrule.

dave

http://dho.pathology.wisc.edu

On Oct 22, 2021, 10:45 AM -0500, Grande, Katarina <<u>KGrande@publichealthmdc.com</u>>, wrote:

They're not budging on our plea to extend beyond 7 authors.

Given the state focus, I'm happy to cede my spot to a state person—could swap one of you to corresponding slot and add in Anna or Ryan?

Could look like?

- 1. Kasen
- 2. Peter
- 3. Hannah
- 4. Yoshi
- 5. Anna/Ryan
- 6. Tom
- 7. Dave

From:

Jody.Zylke@jamanetwork.org
<Jody.Zylke@jamanetwork.org>

Sent: Thursday, October 21, 2021

5:02 PM

To: Grande, Katarina

<KGrande@publichealthmdc.com>

Subject: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination) Caution: This email was sent from an external source. Avoid unknown links and attachments.

Dear Ms Grande:

Thanks for submitting a research letter to JAMA. The study is interesting and I would be willing to send it for peer review. However, research letters are limited to 7 authors, and we cannot make an exception.

Would you be willing to decrease the number of authors to 7? If not, we will not be able to consider your manuscript.

Sincerely,

Jody W Zylke, MD Deputy Editor, JAMA Email: Jody.Zylke@jamanetwork.org From: <u>Grande, Katarina</u>

To: <u>DAVID H O"CONNOR</u>; <u>Thomas Friedrich</u>

Subject: RE: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

Date: Friday, October 22, 2021 2:03:29 PM

Attachments: Plos Med cover letter.docx

That's a good idea. PLOS Med doesn't get cranky about pre-prints. They also have an article type called 'Perspectives," 1000 word limit/12 ref...could be a decent enough fit. Straightforward cover letter draft attached. Login to submission is via ORCID.

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Sent: Friday, October 22, 2021 1:14 PM

To: Grande, Katarina <KGrande@publichealthmdc.com>; Thomas Friedrich <tfriedri@wisc.edu>

Subject: Re: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

Caution: This email was sent from an external source. Avoid unknown links and attachments.

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Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
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School of Veterinary Medicine
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@tcf-lab
www.vetmed.wisc.edu/friedrichlab

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We'll have the same problem with JAMA Open Network it looks like: <image.jpg>

From: DAVID H O'CONNOR <a href

Sent: Friday, October 22, 2021 11:21 AM **To:** Thomas Friedrich stfriedri@wisc.edu

Cc: Grande, Katarina < <u>KGrande@publichealthmdc.com></u>

Subject: Re: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite

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4. I think we can honestly say that the 7 authors we have currently listed did the most work to generate, analyze, and interpret the data, and also write the manuscript. So we could keep these authors and acknowledge the others.

I am not saying that I am fully swayed by the above points that we should keep the paper at JAMA, but I think we need to carefully weigh these points. It would indeed be a bit uncomfortable to tell people who were authors before that we had to take them off. I think most of them would be more or less okay with it, but some may not.

What do you guys think of this?

-T

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
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@tcfriedrich
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www.vetmed.wisc.edu/friedrichlab

Thomas Friedrich wrote on 2021-10-22 11:02:

Wait -- quick counterpoint to follow

Thomas Friedrich

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I agree that I would rather not take people off the paper at this stage. Let's ask about JAMA Network Open, but I bet the answer will be the same. So then I would think to take it to Plos Med or similar.

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I do know that I end up choosing quirky hills of principle to die on sometimes, though, so if this is one of those times, again, others can overrule.

dave

http://dho.pathology.wisc.edu

On Oct 22, 2021, 10:45 AM -0500, Grande, Katarina KGrande@publichealthmdc.com, wrote:

They're not budging on our plea to extend beyond 7 authors.

Given the state focus, I'm happy to cede my spot to a state person—could swap one of you to corresponding slot and add in Anna or Ryan?

Could look like?

- 1. Kasen
- 2. Peter
- 3. Hannah
- 4. Yoshi
- 5. Anna/Ryan
- 6. Tom
- 7. Dave

From: Jody.Zylke@jamanetwork.org <Jody.Zylke@jamanetwork.org>

Sent: Thursday, October 21, 2021

5:02 PM

To: Grande, Katarina

<KGrande@publichealthmdc.com>

Subject: JAMA21-11227 (Shedding of

Infectious SARS-CoV-2 Despite

Vaccination)

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Dear Ms Grande:

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Would you be willing to decrease the number of authors to 7? If not, we will not be able to consider your manuscript.

Sincerely,

Jody W Zylke, MD Deputy Editor, JAMA Email: Jody.Zylke@jamanetwork.org From: Grande, Katarina

To: <u>Thomas Friedrich</u>; <u>DAVID H O"CONNOR</u>

Subject: RE: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

Date: Monday, October 25, 2021 9:20:46 AM

Attachments: <u>image001.png</u>

Agree! And I scanned the authorship section and didn't see any immediate red flags. Let's go here. I can tell JAMA goodbye and cc you all.

From: Thomas Friedrich <tfriedri@wisc.edu> **Sent:** Monday, October 25, 2021 9:20 AM **To:** DAVID H O'CONNOR <dhoconno@wisc.edu>

Cc: Grande, Katarina < KGrande@publichealthmdc.com>

Subject: Re: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

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dave

Dave O'Connor | UW Medical Foundation Professor dhoconno@wisc.edu | 2 +1 http://dho.pathology.wisc.edu

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Is PLOS Med format-neutral?

I know we looked at Lancet, but before we officially go to PLOS Med, is there any other high-impact journal we might want to consider?

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Professor

Dept. of Pathobiological Sciences University of Wisconsin School of Veterinary Medicine @tcfriedrich @tcf-lab www.vetmed.wisc.edu/friedrichlab

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OK, Kat, can you please officially withdraw the paper from consideration at JAMA and we can revise the cover letter for PLOS? Unless you or Tom feel otherwise, I think we should submit as-is to PLOS Med.

dave

Dave O'Connor | UW Medical Foundation Professor dhoconno@wisc.edu | 2 +1 http://dho.pathology.wisc.edu

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On Oct 25, 2021, 8:05 AM -0500, Grande, Katarina <<u>KGrande@publichealthmdc.com</u>>, wrote:

Off to PLOS we go!

From: Jody Zylke <<u>Jody.Zylke@jamanetwork.org</u>>

Sent: Saturday, October 23, 2021 5:11 AM

To: Grande, Katarina

<KGrande@publichealthmdc.com>

Subject: RE: JAMA21-11227 (Shedding of Infectious

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Caution: This email was sent from an external source. Avoid unknown links and attachments.

Yes, all the JAMA Network journals have the same policies.

Jody

From: Grande, Katarina

<KGrande@publichealthmdc.com>

Sent: Friday, October 22, 2021 11:45 AM **To:** Jody Zylke <<u>Jody.Zylke@jamanetwork.org</u>> Cc: 'DAVID H O'CONNOR' < dhoconno@wisc.edu>;

Thomas Friedrich < tfriedri@wisc.edu >

Subject: RE: JAMA21-11227 (Shedding of Infectious

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[Warning External Email]

Thanks for your response, Dr. Zylke. We're struggling with this since this endeavor was such a massive collaborative effort! Does JAMA Open Network have the same 7 author limit for a Research Letter submission?

Thanks again for your time!

-Katarina

KATARINA GRANDE, MPH (pronouns:

she/her/hers)

Public Health Supervisor/COVID-19 Data Team Lead

Public Health Madison & Dane County 2300 South Park St, Rm 2010, Madison, WI 53713

Phone: (608) 243-0409 | Cell: | Fax: (608)

266-4858

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<image002.png>

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Email: Jody.Zylke@jamanetwork.org

From: **DAVID H O"CONNOR**

To: Thomas Friedrich; Grande, Katarina

Subject: RE: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

Date: Monday, October 25, 2021 6:25:04 PM

Attachments: image001.png

Yep!

dave

Dave O'Connor | UW Medical Foundation Professor

dhoconno@wisc.edu |

http://dho.pathology.wisc.edu

I choose to work flexibly & send emails outside normal office hours. No need to respond to my emails outside yours.

On Oct 25, 2021, 5:49 PM -0500, Grande, Katarina < KGrande@publichealthmdc.com>, wrote:

Sorry, got pulled in to infinite meetings today! Will try to highlight a few papers tomorrow didn't Gage's group post one last week finding transmission indeed occurring from vax'ed in Provincetown?

From: Thomas Friedrich < tfriedri@wisc.edu> **Sent:** Monday, October 25, 2021 9:25 AM **To:** DAVID H O'CONNOR <dhoconno@wisc.edu>

Cc: Grande, Katarina < KGrande@publichealthmdc.com>

Subject: Re: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

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Just because it can be 2000 words doesn't mean it needs to have 2000 words.

Exactly.

We will want to edit the abstract you had in the medrxiv version, because IIRC it just repeats a lot of the language in the paper itself.

We should also add a sentence or two to the discussion so we can cite a few more recent papers. Kat, could you possibly take a stab at that? You could even just suggest a few talking points that we could wordsmith collaboratively.

Dave, should we still edit the SharePoint version? -T Thomas Friedrich Professor Dept. of Pathobiological Sciences University of Wisconsin School of Veterinary Medicine @tcfriedrich @tcf-lab www.vetmed.wisc.edu/friedrichlab DAVID H O'CONNOR wrote on 2021-10-25 09:22: Alrighty. Just because it can be 2000 words doesn't mean it needs to have 2000 words. If you look at the Medrxiv version, I had to create an abstract or else they don't accept the submission, so we can use that as a start. I'm on this WHO webinar all morning but could help later. dave Dave O'Connor | UW Medical Foundation Professor dhoconno@wisc.edu | 2 +1 http://dho.pathology.wisc.edu I choose to work flexibly & send emails outside normal office hours. No need to respond to my emails outside yours. On Oct 25, 2021, 9:19 AM -0500, Thomas Friedrich <a wrote: ı

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Subject: RE: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

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Yes, all the JAMA Network journals have the same policies.

Jody

From: Grande, Katarina

Sent: Friday, October 22, 2021

11:45 AM **To:** Jody Zylke

<<u>Jody.Zylke@jamanetwork.org</u>>

Cc: 'DAVID H O'CONNOR'

<<u>dhoconno@wisc.edu</u>>; Thomas Friedrich <<u>tfriedri@wisc.edu</u>> **Subject:** RE: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

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Thanks for your response, Dr. Zylke. We're struggling with this since this endeavor was such a massive collaborative effort! Does JAMA Open Network have the same 7 author limit for a Research Letter submission?

Thanks again for your time!

-Katarina

KATARINA GRANDE, MPH

(pronouns: she/her/hers)

Public Health Supervisor/COVID-19

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<image002.png>

From:

<u>Jody.Zylke@jamanetwork.org</u> <<u>Jody.Zylke@jamanetwork.org</u>>

Sent: Thursday, October 21, 2021

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< KGrande@publichealthmdc.com>

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To: <u>DAVID H O"CONNOR</u>; <u>Thomas Friedrich</u>

Subject: RE: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

Date: Friday, October 22, 2021 11:42:34 AM

Sure, can do and will cc you all.

From: DAVID H O'CONNOR <dhoconno@wisc.edu>

Sent: Friday, October 22, 2021 11:39 AM

To: Thomas Friedrich <tfriedri@wisc.edu>; Grande, Katarina <KGrande@publichealthmdc.com>

Subject: RE: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

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It says that, but does it mean that? Can you ask the editor via email to double-check, just so that we are sure? It will also have the beneficial effect of saying that we are willing to go somewhere besides JAMA with this paper if push comes to shove.

dave

http://dho.pathology.wisc.edu

On Oct 22, 2021, 11:25 AM -0500, Grande, Katarina < KGrande@publichealthmdc.com >, wrote:

We'll have the same problem with JAMA Open Network it looks like:

<image002.jpg>

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Subject: Re: FW: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

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I agree with points 1-3. I think we should see if JAMA Open Network does have the same firm limit then question 3 comes into play. If they will consider it with more authors at JAMA Open Network, I agree we have more decisions to balance.

I personally am at a place in my career where I can be easy going about authorships. But I can imagine that me from ten years ago would be really annoyed if a paper that I was involved with got published in a high impact journal but my contribution was rendered invisible.

Plus, it's a lousy policy.

dave

http://dho.pathology.wisc.edu

On Oct 22, 2021, 11:09 AM -0500, Thomas Friedrich <tfriedri@wisc.edu>, wrote:

I think we can also make an argument to limit to the 7 authors we already have. Before we pull the manuscript, I want to consider this more fully.

- 1. These findings are important and stand a good chance to be accepted in a high-impact journal.
- 2. I think we have an interest in getting this into a journal with a wide audience given the level of interest in the preprint and the degree to which it has been used by antivaxxers.
- 3. But, the longer we wait, the more the impact of this study will be reduced. Pulling this submission and submitting to another journal will cost us a week or so, as new editors decide whether to send it out.
- 4. I think we can honestly say that the 7 authors we have currently listed did the most work to generate, analyze, and interpret the data, and also write the manuscript. So we could keep these authors and acknowledge the others.

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Sincerely,

Jody W Zylke, MD Deputy Editor, JAMA Email: <u>Jody.Zylke@jamanetwork.org</u>

From: Grande, Katarina To: "Chris Miller"

Gilly Regev; DAVID H O"CONNOR Cc: Subject: RE: Interesting Article Collaboration? Date: Wednesday, August 25, 2021 2:01:22 PM

Attachments: image002.png

image003.png

Hi Dr. Miller.

Thanks for your interest and inquiry. We are not interested at this time, but wish you the best on your research endeavor!

-Katarina

KATARINA GRANDE, MPH (pronouns: she/her/hers)

Public Health Supervisor/COVID-19 Data Team Lead | Public Health Madison & Dane County

2300 South Park St, Rm 2010, Madison, WI 53713

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From: Chris Miller <chris@sanotize.com> **Sent:** Tuesday, August 24, 2021 7:26 PM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Cc: Gilly Regev <gilly@sanotize.com> **Subject:** Interesting Article Collaboration?

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Hello Dr Grande.

We read your pre-print article entitled "Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021" with interest. We have developed a nitric oxide based nasal spray (NONS) and currently in Phase III clinical trials. We believe we can make an impact on mild infection and prevention of COVID-19 regardless of the variant of concern. We have shown in a Phase II trial in the UK that NONS

reduces the viral load significantly during the first 24 -72hours.

With the new data emerging and as your article adeptly demonstrates, fully vaccinated, healthy individuals can be highly infectious.

We would be interested to rapidly conduct a study to test our hypothesis that NONS can rapidly reduce the SARS-CoV-2 viral load to below infectious levels.

Would you be interested in being the PI and site for this study?

If so, what might this look like from your perspective from a timing and budget perspective? As you know COVID waits for no one, so your candid response is appreciated. Thanks,

Chris

--

Chris Miller, Ph.D. Co-founder / CSO www.saNOtize.com 8755 Ash St., Suite #1 Vancouver, BC V6P-6T3 Canada

Phone: 778-899-0607 email: chris@sanotize.com

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 From:
 Grande, Katarina

 To:
 Thomas Friedrich

 Cc:
 DAVID H O"CONNOR

 Subject:
 RE: JAMA cover letter

Date: Tuesday, October 19, 2021 10:17:00 AM

Attachments: JAMA cover letter1.pdf

I like that. New letter attached!

From: Thomas Friedrich <tfriedri@wisc.edu> Sent: Tuesday, October 19, 2021 8:41 AM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Cc: Dave O'Connor <dhoconno@wisc.edu>

Subject: Re: JAMA cover letter

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Hey Kat.

Thanks for sending this through. I discussed the author issue briefly with Dave. How about this. Let's say in the cover letter that this work required coordination and analysis of lots of complex data and therefore more than 7 people contributed to these findings. We will leave the author list as-is in the submission and say we wish for all authors to be credited. I drafted a new paragraph in the cover letter Google Doc to reflect this.

Could you take a quick look, and if it looks good to you, sign that one on letterhead?

Meanwhile, I have cued up the submission with the following authors in the form:

- 1. Kasen
- 2. Peter
- 3. Hannah
- 4. Yoshi
- 5. Dave
- 6. Me
- 7. You

How does that sound?

-T

Thomas Friedrich

Professor
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University of Wisconsin
School of Veterinary Medicine
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@tcf-lab
www.vetmed.wisc.edu/friedrichlab

Grande, Katarina wrote on 2021-10-19 08:06:

PDF'ed letter is attached!

7 authors, oh geez. It's a state-wide analysis, so it feels weird to boot out state folks. And the novel part is all about the plaque assays, so it feels weird to boot out the lab folks...

For sure: Kasen Dave Tom Probably:

Hannah Peter Yoshihiro

Maybe: Kat Brittany

Served in a consultant role:

Amanda Anna Ryan Allen

Gunnar

From: Thomas Friedrich <tfriedri@wisc.edu>

To: Grande, Katarina < KGrande@publichealthmdc.com>

Cc: Dave O'Connor < dhoconno@wisc.edu>

Sent: Monday, October 18, 2021 10:34 PM

Subject: Re: JAMA cover letter

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Also, the system only allows me to enter info for 7 authors. We have a total of 14. What to do?

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

Thomas Friedrich wrote on 2021-10-18 22:27:

Hi Kat.

So, turns out JAMA requires a full-on cover letter, even for Research Letters.

I've drafted one for you <u>here</u>. Could you please edit as you see fit, add your contact info including preferred email, phone, and physical address, and then put it on letterhead and return it to me?

Thanks!

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab





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219 October 2021

Dear JAMA editors,

Please consider our article, "Shedding of Infectious SARS-CoV-2 Despite Vaccination," as a Research Letter for publication in JAMA. Our study of nasal swab specimens collected from individuals with community-acquired infections in Wisconsin shows that, at a time of high prevalence of the Delta variant, people infected with SARS-CoV-2 despite being fully vaccinated had levels of viral RNA and of infectious SARS-CoV-2 in nasal secretions that were indistinguishable from those present in unvaccinated individuals. Our study is valuable to JAMA readers because it directly compares infectious virus loads in vaccinated and unvaccinated individuals, demonstrating the potential for those infected despite vaccination to transmit virus to others. Thus, our data help support recommendations that vaccinated individuals continue to practice SARS-CoV-2 risk mitigation and seek booster vaccinations that reduce the risk of infection.

Our study has been posted to medrxiv, but has not been published in a peer-reviewed journal. The medrxiv link is: https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v5

Finally, please note that our manuscript includes 14 authors. We understand that Research Letters are typically limited to 7 authors, and we have listed 7 authors in the online form. However, because this study involved data sharing and analysis across state and local public health agencies in addition to laboratory studies, each of the 14 individuals listed as authors in the manuscript file made contributions to this study that fit the definition of authorship. We therefore ask you to list all authors as shown in the manuscript if this paper should be accepted for publication at JAMA or a sister journal.

Thank you for your consideration of our manuscript.

afor Shoole

Sincerely,

Katarina Grande

Phone:

2300 South Park Street, Room 2010

Madison, WI 53713

From: Lisa Hardin Grande, Katarina To:

Thomas Friedrich; DAVID H O"CONNOR Cc:

Subject: RE: JAMA21-11227 Receipt of New Manuscript by JAMA

Date: Wednesday, October 20, 2021 3:48:10 PM

Attachments: image001.png image002.png

Hello.

You are very welcome.

Lisa

From: Grande, Katarina < KGrande@publichealthmdc.com>

Sent: Wednesday, October 20, 2021 3:09 PM **To:** Lisa Hardin < Lisa. Hardin@jamanetwork.org >

Cc: 'Thomas Friedrich' <tfriedri@wisc.edu>; Dave O'Connor <dhoconno@wisc.edu>

Subject: RE: JAMA21-11227 Receipt of New Manuscript by JAMA

[Warning External Email]

Thank you for the confirmation of receipt, Lisa!

Per our cover letter, "Our study has been posted to medrxiv, but has not been published in a peerreviewed journal. The medrxiv link is:

https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v5" Hopefully that addresses the note regarding publication elsewhere.

Thanks again for your time.

-Katarina

KATARINA GRANDE, MPH (pronouns: she/her/hers)

Public Health Supervisor/COVID-19 Data Team Lead | Public Health Madison & Dane County

2300 South Park St, Rm 2010, Madison, WI 53713

Phone: (608) 243-0409 | Cell: | Fax: (608) 266-4858

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From: lisa.hardin@jamanetwork.org>

Sent: Wednesday, October 20, 2021 12:59 PM

To: Grande, Katarina < KGrande@publichealthmdc.com Subject: JAMA21-11227 Receipt of New Manuscript by JAMA

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October 20, 2021

Dear Ms Grande:

Thank you for submitting your research letter, "Shedding of Infectious SARS-CoV-2 Despite Vaccination," received on October 20, 2021, to JAMA. Your research letter has been assigned the following manuscript number: JAMA21-11227. Please refer to the manuscript number and corresponding author in all subsequent communications.

You may check the status of this letter by selecting the Check Manuscript Status link on the following Web page:

Do not share this encrypted link with others, as it will automatically log you into your account for JAMA's Web-based system.

Every effort will be made to review your research letter quickly and to notify you of our decision as soon as possible. All research letters addressing the SARS-CoV-2 outbreak are being automatically prioritized. Please do not contact the editorial office to request expedited review.

We agree to consider your research letter with the understanding that its content, figures, and tables have not been published or submitted elsewhere in print or electronic format and will not be submitted elsewhere during the period of review by JAMA. If you have not already done so, please provide copies of any manuscripts on closely related topics or with possibly duplicative material that have been previously published or are under consideration for publication elsewhere. The information in your letter should not be distributed or released in hard copy or electronic form, except through presentation at scientific meetings, unless and until the letter is published.

Thank you for your interest in JAMA. If you have any questions about your letter please contact <u>Lisa.Hardin@jamanetwork.org</u> or 312-464-2405.

Sincerely yours,

Jody W. Zylke, MD Deputy Editor, JAMA

Lisa Hardin, MBA, MHA Editorial Assistant II

Email: Lisa.Hardin@jamanetwork.org

Phone: 312.464.2405 Fax: 312.464.5989

Access the following link to view a short video on the JAMA Network editorial process: https://ja.ma/JNEditorialProcess

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From: Grande, Katarina
To: DAVID H O"CONNOR

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Date: Monday, August 23, 2021 1:30:32 PM

Username: Password:

From: Dave O'Connor <dhoconno@wisc.edu>
Sent: Monday, August 23, 2021 1:19 PM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

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Hi Kat,

Do you have login credentials for NEJM? I thought Tom said he shared them with both of us but I can't find them.

Thanks,

dave

Grande, Katarina wrote on 8/23/21 12:06 PM:

Thanks, Hannah!

Dave, you have everything you need to submit to the portal? I can lend a hand if you need anything.

-Kat

From: Segaloff, Hannah E - DHS segaloff@dhs.wisconsin.gov

Sent: Monday, August 23, 2021 11:53 AM

To: Kasen Riemersma <a href="mailto:kasen.edu"

<KGrande@publichealthmdc.com>; DAVID H O'CONNOR <dhoconno@wisc.edu>;

Thomas Friedrich tfriedri@wisc.edu>

Subject: FW: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

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Hi all,

We are cleared! There are some extremely tiny comments to incorporate/consider. Once we submit they just want me to send a final copy for their records. Note that I made two additional small changes (added "qualitative in two places and deleted one word to keep it in the word count) without sending it back to facilitate quick review- so you many want to upload this version.

Thanks for your patience with this painful process!

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent 216@cdc.gov >

Sent: Monday, August 23, 2021 11:47 AM

To: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < adz0@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance <eocevent216@cdc.gov>

Subject: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant

is Prevalent

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Hi Hannah:

The attached document has been cleared by JIC with comments.

Once you have addressed the reviewer's feedback, please send us a clean and final document, so we can provide it to JIC for their records.

JIC OS Content Comment.

 Very informative study. It is approved with minor comments, see attached

Thanks,

Audrey

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM) From: Dave O"Connor
To: Grande, Katarina

 Cc:
 Kasen Riemersma; Thomas Friedrich

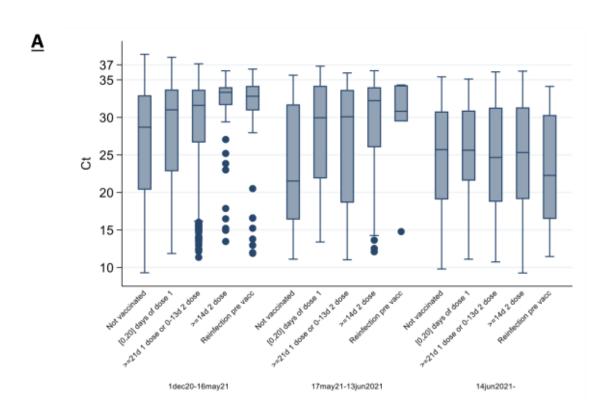
 Subject:
 Re: A question regarding your paper

 Date:
 Wednesday, August 25, 2021 2:17:03 PM

Attachments: image.pnc

Hi Kat,

No, I don't think that data gets captured in the analysis. Though the UK study I shared earlier showed a *lower* Ct in people who were reinfected than in those who were vaccinated, in line with the idea that vaccines provide better immunity than natural infection.



Grande, Katarina wrote on 8/25/21 1:58 PM:

We don't have these data/didn't look at this—anything additional to add in a response to Jon, team?

From: Jon Poling <ipoling@athensneuro.com>
Sent: Wednesday, August 25, 2021 12:43 PM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Subject: A question regarding your paper

Importance: High

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Dear Dr. Grande,

I read with interest your manuscript entitled--Shedding of Infectious SARS-CoV-2 Despite Vaccination. Do you have data on shedding of infectious SARS COV2 in patients who have recovered from prior ancestral COVID19? In other words, does natural mucosal immunity provide better protection against transmissible virus in this wave of Delta or other VOCs? Thank-you in advance for your attention to my question. Regards,

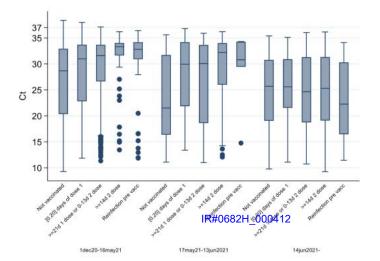
Jon S. Poling MD/PhD
Department Chair of Neurology/Neurosurgery, Piedmont ARMC Hospital
Clinical Asst Professor AU/GRU School of Medicine
Athens Neurological Assoc. PC
Board Certified in Neurology, Neuromuscular Medicine, and Neuroimaging www.athensneuro.com

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From: <u>Dave O"Connor</u>
To: <u>Thomas Friedrich</u>

Cc: KGrande@publichealthmdc.com; Kasen Riemersma

Subject: Re: FW: Cov-2 in vaccinated infectious?

Date: Thursday, September 16, 2021 11:30:28 AM

Me neither - guess he only wrote Kat.

d

Thomas Friedrich wrote on 9/16/21 9:54 AM:



Did anyone respond to Mr. Neeper? I never saw that email before Kat's forward yesterday.

-T

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

Dave O'Connor wrote on 2021-09-15 17:02:



KGrande@publichealthmdc.com wrote on 9/15/21 4:55 PM:

Did this email/question get bounced to you all?

-Kat

From: Michael Neeper <

Sent: Wednesday, September 8, 2021 9:31 AM

To: Grande, Katarina < <u>KGrande@publichealthmdc.com></u>

Subject: Cov-2 in vaccinated infectious?

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Hi Dr. Grande,

In your below-listed article, you state that infectious Cov-2 virus levels were detected in both vaccinated and unvaccinated individuals at similar levels, but the only data presented was that of RT-PCR, which does not reflect infectious virus. Can you show me where I might find data indicating the virus was infectious? How was this determined if these studies were performed?

I am a retired molecular biologist just trying to understand what is going on regarding Covid, not trying to criticize, so please let me know of any evidence that vaccinated individuals carry high levels of infectious virus. Even if it is the publication of others. I am mystified how this virus can be producing infectious particles in the presence of neutralizing antibodies. Thank you,

Michael Neeper

Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021

http://dho.pathology.wisc.edu @dho • 608-890-0845 From: <u>Dave O"Connor</u>
To: <u>Grande, Katarina</u>

 Cc:
 Kasen Riemersma; Thomas Friedrich

 Subject:
 Re: FW: Interesting Article Collaboration?

 Date:
 Wednesday, August 25, 2021 9:08:37 AM

Nope from me too. And I'm guessing that Tom would say the same.

dave

Grande, Katarina wrote on 8/25/21 8:06 AM:

A no from me, but passing along in case of interest!

From: Chris Miller chris@sanotize.com

Sent: Tuesday, August 24, 2021 7:26 PM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Cc: Gilly Regev sqiff Regev <a href="mailto:

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Hello Dr Grande,

We read your pre-print article entitled "Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021" with interest.

We have developed a nitric oxide based nasal spray (NONS) and currently in Phase III clinical trials. We believe we can make an impact on mild infection and prevention of COVID-19 regardless of the variant of concern. We have shown in a Phase II trial in the UK that NONS reduces the viral load significantly during the first 24 -72hours.

With the new data emerging and as your article adeptly demonstrates, fully vaccinated, healthy individuals can be highly infectious.

We would be interested to rapidly conduct a study to test our hypothesis that NONS can rapidly reduce the SARS-CoV-2 viral load to below infectious levels. Would you be interested in being the PI and site for this study?

If so, what might this look like from your perspective from a timing and budget perspective? As you know COVID waits for no one, so your candid response is appreciated.

Thanks, Chris

--

Chris Miller, Ph.D. Co-founder / CSO www.saNOtize.com 8755 Ash St., Suite #1 Vancouver, BC V6P-6T3 Canada Phone: 778-899-0607 email: chris@sanotize.com

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From: Dave O"Connor

To: KGrande@publichealthmdc.com

YOSHIHIRO KAWAOKA; Peter Halfmann; Thomas Friedrich Cc:

Subject: Re: FW: Preprint: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent -

Wisconsin, July 2021

Monday, August 16, 2021 8:41:32 AM Date:

Attachments: image.png

image.png

Hi Kat,

I already responded to him yesterday!

dave

KGrande@publichealthmdc.com wrote on 8/16/21 8:37 AM:

Hi Yoshi and Peter.

Would you please response to Daniel when you have a moment? I believe the answer to the question is "nope, no real time monitoring or quantification as of now, but it is something we're working on." But in case Daniel has more technical questions, best if you answer. Thanks!

-Kat

KATARINA GRANDE, MPH (pronouns: she/her/hers)

Public Health Supervisor/COVID-19 Data Team Lead | Public Health Madison & Dane County

2300 South Park St, Rm 2010, Madison, WI 53713

Phone: (608) 243-0409 | Cell: | Fax: (608) 266-4858

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From: Griffin, Daniel dg2810@cumc.columbia.edu>

Sent: Saturday, August 14, 2021 9:44 PM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Subject: Preprint: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the

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Dr Grande,

I hope this email finds you well. I was hoping to a ask a few questions about the preprint Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021.

You report "Infectious SARS-CoV-2 was isolated from 14 of 16 specimens (88%) from unvaccinated individuals and 37 of 39 specimens (95%) from vaccinated people.'

In figure 2 According to figure 2 Infectiousness was determined by the presence of cytopathic effects (CPE) after 5 days of replication in Vero E6 TMPRSS2 cells with visually apparent CPE under a light microscope. Any real time monitoring or quantification?

Sincerely,

Daniel Griffin, MD PhD CTropMed CTH

Chief, Division of Infectious Disease - ProHEALTH, an OPTUM Company Senior Fellow for Infectious Disease - UHG Research and Development Clinical Instructor of Medicine - Columbia University College of Physicians and Surgeons

Department of Medicine-Division of Infectious Diseases

President -Parasites Without Borders

1 Dakota Drive Suite 205 New Hyde Park, NY 11042

Office Tel: (516)-656-6500

Cell:

Email:

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www.microbe.tv

Twitter @DanielGriffinMD

__

http://dho.pathology.wisc.edu @dho • 608-890-0845 From: <u>Dave O"Connor</u>

To: <u>Segaloff, Hannah E - DHS</u>

Cc: <u>Kasen Riemersma</u>; <u>Katarina Grande</u>; <u>Thomas Friedrich</u>

Subject: Re: FW: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Date: Monday, August 23, 2021 1:25:37 PM

Hi Hannah,

Thanks much - I'll upload as soon as I get the login credentials from Kat (or Tom, if he happens to be eavesdropping from up north).

dave

Segaloff, Hannah E - DHS wrote on 8/23/21 11:52 AM:

Hi all,

We are cleared! There are some extremely tiny comments to incorporate/consider. Once we submit they just want me to send a final copy for their records. Note that I made two additional small changes (added "qualitative in two places and deleted one word to keep it in the word count) without sending it back to facilitate quick review- so you many want to upload this version.

Thanks for your patience with this painful process!

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases
Wisconsin Department of Health Services
Currently Teleworking
Cell:

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: CDC IMS 2019 NCOV Response Lab TF Clearance <eocevent216@cdc.gov>

Sent: Monday, August 23, 2021 11:47 AM

To: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) <qdz0@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance <eocevent216@cdc.gov>

Subject: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant

is Prevalent

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Hi Hannah:

The attached document has been cleared by JIC with comments.

Once you have addressed the reviewer's feedback, please send us a clean and final document, so we can provide it to JIC for their records.

JIC OS Content Comment.

 Very informative study. It is approved with minor comments, see attached

Thanks,

Audrey

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM) From: Dave O"Connor

Cc: Goldberg, Rachel; Grande, Katarin

Subject: Re: Introducing your school K-12 COVID-19 Testing Program Vendor

Date: Tuesday, August 10, 2021 5:51:32 PM

Attachments: Viral loads in vaccinees Medrxiv 10 Aug 2021-3.pdf

Rachel,

To:

Here is the preprint we chatted about earlier. Again, I suggest asking Kat for more details about the symptoms and testing and such. It should be online tomorrow morning, so showing some of this data in your Thursday meeting should be fine.

dave

wrote on 8/10/21 5:07 PM:

Ok, new thought. The ESSER II program: https://dpi.wi.gov/crrsaa/esser-ii

Can we apply to that if we want to do a Dane County program?

Sorry, just thinking out loud here.

shelby

On Aug 10, 2021, at 4:56 PM, SHELBY L O'CONNOR <<u>slfeinberg@wisc.edu</u>> wrote:

HI Rachel —

I was talking to Andy over at EAGLE today and he mentioned to me that they were able to receive funding through the EANS program. (Attached). That looks to be for non-public schools. On page 4, point G, it looks like funds could be used to

G. expanding capacity to administer coronavirus testing to effectively monitor and suppress coronavirus, to conduct surveillance and contact tracing activities, and to support other activities related to coronavirus testing for students, teachers, and staff at the non-public school:

That sounds like surveillance projects could be funded, right? Do you know if there is a parallel source of funding for public schools? I'm wondering if we could try to dip into this pot of money to support air sampling.

Thoughts? Or, am I being crazy?

Shelby

<Wisconsin-EANS-CnA-Redacted.pdf>

On Aug 10, 2021, at 2:50 PM, Goldberg, Rachel < RGoldberg@publichealthmdc.com> wrote:

RACHEL GOLDBERG, MPH (pronouns: she/her/hers)

Public Health Specialist/COVID-19 School & Child Care Liaison | Public Health Madison & Dane

County

210 Martin Luther King Jr. Blvd, Room 507, Madison, WI 53703

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<image003.png>

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<image006.png>

From: Heinrich, Janel < JHeinrich@publichealthmdc.com>

Sent: Thursday, August 5, 2021 2:14 PM

To: Van Horn, Kenneth B < KVanHorn@publichealthmdc.com; Goldberg, Rachel

< RGoldberg@publichealthmdc.com>

Subject: FW: Introducing your school K-12 COVID-19 Testing Program Vendor

From: Dreyer, Amanda C - DHS < amanda.dreyer@dhs.wisconsin.gov>

Sent: Thursday, August 5, 2021 2:10 PM

To: beckert@deerfield.k12.wi.us

Cc: Noah Clinical Laboratory < symport@noahclinicallaboratory.com; Heinrich, Janel

<JHeinrich@publichealthmdc.com>

Subject: Introducing your school K-12 COVID-19 Testing Program Vendor

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Dear Deerfield Community School District,

We'd like to introduce you to **NOAH Clinical Laboratories**, the vendor who will help support your school COVID-19 Testing Program.

Next up, you and your vendor will decide the details of the testing program that meets your needs. You can expect a request for a kickoff meeting for:

- Introductions
- Important information about your school, community, and testing needs
- Testing model(s) you will implement as school begins
 - o Note that DHS shared your initial survey response for testing models with your vendor.
 - Consult with your local public health department will help you implement testing that meets your needs, considering local conditions.
 - o Review the CDC Schools guidance: https://www.cdc.gov/coronavirus/2019ncov/community/schools-childcare/k-12-guidance.html.
- Important details and processes for how to safely and effectively conduct testing, for example:
 - o Identify possible spaces where testing may occur at your school.
 - The days/times when the vendor will have staff on site at your school for testing,
 - o How to facilitate consent.
- Additional questions and next steps

Thank you for your work to help assure the health and safety of your school

community. Thanks to you, we are making COVID-19 testing available to nearly 1 million students, staff, teachers and their families.

<image007.png>Amanda Dreyer
Testing Task Force Lead, COVID-19 Response Team
Deputy Administrator, Division of Enterprise Services

Wisconsin Department of Health Services

C: amanda.dreyer@dhs.wisconsin.gov

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Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021

Kasen K. Riemersma, DVM, PhD¹; Brittany E. Grogan, MPH²; Amanda Kita-Yarbro, MPH²; Peter Halfmann, PhD¹; Anna Kocharian, MS³; Kelsey R. Florek, PhD⁴; Ryan Westergaard, MD, PhD³, Allen Bateman, PhD⁴; Gunnar E. Jeppson, BS⁶; Yoshihiro Kawaoka, DVM, PhD¹; David H. O'Connor, PhD⁻; Thomas C. Friedrich, PhD¹; Katarina M. Grande, MPH²

Abstract

The SARS-CoV-2 Delta variant and its sublineages (B.1.617.2, AY.1, AY.2, AY.3; [1]) can cause high viral loads, are highly transmissible, and contain mutations that confer partial immune escape [2,3]. Using PCR threshold cycle (Ct) data from a single large contract laboratory, we show that individuals in Wisconsin, USA had similar viral loads in nasal swabs, irrespective of vaccine status, during a time of high and increasing prevalence of the Delta variant. Infectious SARS-CoV-2 was isolated from 51 of 55 specimens (93%) with Ct <25 from both vaccinated and unvaccinated persons, indicating that most individuals with Ct values in this range (Wilson 95% CI 83%-97%) shed infectious virus regardless of vaccine status. Notably, 68% of individuals infected despite vaccination tested positive with Ct <25, including at least 8 who were asymptomatic at the time of testing. Our data substantiate the idea that vaccinated individuals who become infected with the Delta variant may have the potential to transmit SARS-CoV-2 to others. Vaccinated individuals should continue to wear face coverings in indoor and congregate settings, while also being tested for SARS-CoV-2 if they are exposed or experience COVID-like symptoms.

Main text

We analyzed respiratory specimens from 719 individuals collected between 29 June 2021 and 31 July 2021. Delta and its sublineages accounted for 69% of all Wisconsin sequences in GISAID in the week beginning 27 June 2021; this proportion increased to 95% for the week ending 24 July, the most recent date for which data are available [4]. We recovered viral genome sequences from 122 of the specimens analyzed in this report; 110 of 122 (90%) belonged to Delta lineages. The high and increasing prevalence of Delta-lineage viruses during the study period, and high proportion of Delta-lineage

¹ Department of Pathobiological Sciences, University of Wisconsin-Madison, Madison, WI, USA; ² Public Health Madison & Dane County, Madison, WI, USA; ³ Wisconsin Department of Health Services; ⁴ Wisconsin State Laboratory of Hygiene; ⁵ Department of Medicine, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin; ⁶ Exact Sciences, Madison, WI, USA; ⁷ Department of Pathology and Laboratory Medicine, University of Wisconsin-Madison, Madison, WI, USA.

[^] Author to whom all correspondence should be addressed. E-mail: KGrande@publichealthmdc.com

viruses among our sequenced samples, together suggest that most infections in our dataset were caused by Delta, though this cannot be directly confirmed.

We defined fully vaccinated individuals as those who received a final vaccine dose at least 2 weeks prior to testing positive. Of the 719 individuals, vaccination status at the time of testing was available in the Wisconsin Immunization Registry and Wisconsin Electronic Disease Surveillance System for 322 (293 vaccinated and 29 unvaccinated), while self-reported vaccination status was available for the remaining 397 (18 vaccinated and 379 unvaccinated). We compared Ct values in specimens from these fully vaccinated and unvaccinated individuals at the time of testing (Figure 1). We detected no significant differences in Ct values by vaccination status. Notably, 212 of 311 (68%) of individuals with infection despite full vaccination had extremely low Ct values <25, consistent with high viral loads.

While a given Ct value cannot be used to infer infectiousness, previous studies suggested that infectious SARS-CoV-2 can frequently be recovered from specimens with Ct values of 25-30 or lower [5]. To determine whether high viral loads might indicate the presence of infectious SARS-CoV-2, we attempted to culture infectious virus from a subset of 55 specimens with Ct values <25 (Figure 2). Infectious SARS-CoV-2 was isolated from 14 of 16 specimens (88%) from unvaccinated individuals and 37 of 39 specimens (95%) from vaccinated people, suggesting that Ct <25 is frequently associated with the capacity to shed infectious SARS-CoV-2, even in fully vaccinated persons.

Data on symptom status were available from 516 of the 719 individuals evaluated here, so we further compared Ct values in test-positive specimens according to vaccination and symptom status (Figure 3A). For symptomatic cases, there was no significant difference in the time elapsed between symptom onset and testing for vaccinated vs. unvaccinated individuals (two-sample K-S test, p=0.49; Figure 3B). Full vaccination did not affect Ct values observed in infected individuals, either with or without symptoms, at the time of testing. Among those for whom symptom status is known, 252 of 276 individuals who were not fully vaccinated (91%) reported symptoms at the time of testing, while 228 of 240 people who were fully vaccinated (95%) reported symptoms. Among individuals who were asymptomatic at the time of testing, Ct values <25 were detected in 7 of 24 unvaccinated individuals (29%; CI: 13-51%) and in 8 of 12 individuals who were infected despite being fully vaccinated (67%; CI: 35-90%). Infectious virus was detected in the sole specimen tested from an asymptomatic fully vaccinated individual. Although the number of asymptomatic individuals sampled is small, these results indicate that some individuals who are infected despite vaccination can have high viral loads and shed infectious virus even while being asymptomatic. Additional virus isolation data are needed to determine the frequency of infectious virus shedding in asymptomatic cases.

Our findings are consistent with other recent reports detecting high virus loads in some individuals infected despite vaccination in England [6] and Singapore [7]. Our detection of infectious virus in 93% of samples with Ct <25 indicates that high viral loads are consistent with the potential to transmit SARS-CoV-2, regardless of the individual's vaccination status. Notably, transmission of Delta from vaccinated healthcare workers to their household contacts was recently documented in an investigation of a hospital-associated outbreak in Finland [8]. An outbreak in Barnstable County, MA associated with large gatherings also involved a substantial proportion of fully vaccinated individuals [9]. The co-circulation of viruses belonging to Pango lineages B.1.617.2, AY.2, and AY.3, as well as the broad geographic distribution of our specimens, indicate that the infections analyzed here are not associated with any single large outbreak, and that Delta-lineage SARS-CoV-2 can achieve high viral loads consistent with transmissibility in fully vaccinated individuals across a range of exposure settings. Taken

together, these studies indicate that individuals infected with Delta variants despite vaccination have the capacity to transmit infection to others.

Our study has at least three important limitations. First, we have only one specimen from most individuals, and therefore we cannot know the trajectory of viral loads at the time of testing. Indeed, a study of Delta infection dynamics suggests that viral loads decline more rapidly in vaccinated vs. unvaccinated individuals, as one might expect [7]. However, that study also indicates that viral loads in vaccinated and unvaccinated individuals remain similarly high for 5-6 days after illness onset, before declining more rapidly in vaccinated people. In our study, 91% of specimens from symptomatic cases were collected from 0-6 days after illness onset and the timing of tests relative to illness onset did not differ by vaccination status. These observations suggest that the Ct value comparisons in our study are likely not biased by the time of testing. A second limitation is that there may be differences in the populations of vaccinated and unvaccinated persons seeking testing that bias our results. Vaccinated individuals may not perceive a high risk of COVID-19 disease, and may be less likely to seek testing than unvaccinated people. It is difficult to determine from our data whether vaccinated and unvaccinated people experienced symptoms of similar severity. Thus, we cannot determine the extent to which our sampling failed to detect asymptomatic or paucisymptomatic infections. Such mild infections may be more frequent among vaccinated than unvaccinated individuals infected with Delta. Consistent with this, a recent report from England detected a substantially greater proportion of low-positive tests with Ct values between 35 and 40 in vaccinated individuals than in the unvaccinated [6]. Importantly, our study was not designed to estimate the rate of infection despite vaccination, but rather to determine whether individuals infected despite vaccination could have high viral loads consistent with the potential to transmit SARS-CoV-2. Finally, there is inherent variability in PCR Ct values due to specimen variability that can be impacted by collection technique and other variables outside of our control.

The finding of high SARS-CoV-2 viral loads and replication-competent virus in vaccinated individuals has important implications for risk assessment and mitigation. The impact of Delta variants on vaccine effectiveness is currently being evaluated (see, e.g., [10]). Risk disinhibition may lead vaccinated people to increase behaviors that expose them to SARS-CoV-2 infection, and individuals who are infected despite vaccination could serve as sources of onward transmission to others. Vaccinated individuals, particularly those who may have high levels of community or occupational exposure to SARS-CoV-2, should be encouraged to continue frequent testing, especially when symptomatic, to limit community spread. Continued adherence to non-pharmaceutical interventions, such as masking and distancing, will remain important for both vaccinated and unvaccinated individuals because we cannot predict which vaccinated individuals will experience infections with high viral loads. While vaccines continue to provide outstanding protection against severe disease and mortality, the durability of this protection cannot be reliably predicted. Therefore, it is essential for public health policy to encourage vaccination while also planning for contingencies, including diminished long-term protection.

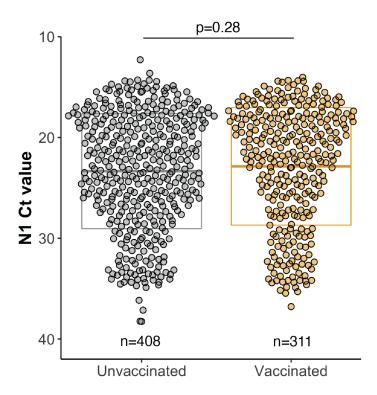


Figure 1. Distributions of SARS-CoV-2 PCR cycle threshold (Ct) values at the time of testing do not differ by vaccination status. N1 PCR Ct values for SARS-CoV-2-positive specimens grouped by vaccination status. Boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values between the groups by Welch two-sample t-test.

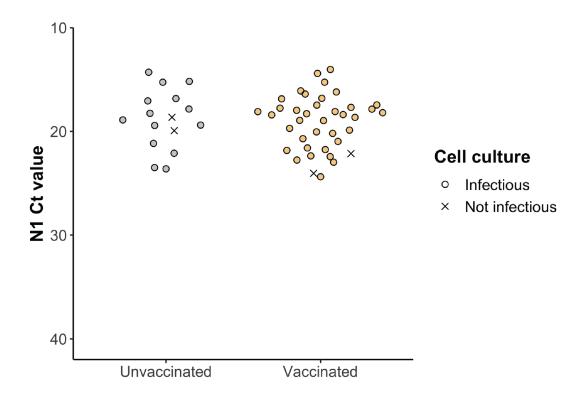


Figure 2. Infectious virus detected in nasal swab specimens from unvaccinated and fully vaccinated cases with Ct values < 25. Infectiousness was determined by the presence of cytopathic effects (CPE) after 5 days of replication in Vero E6 TMPRSS2 cells. Specimens with visually apparent CPE under a light microscope are represented by filled circles, and specimens without apparent CPE are represented by 'X'.

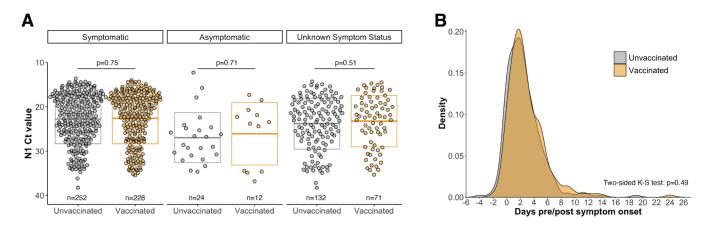


Figure 3. Symptom status does not affect distributions of SARS-CoV-2 PCR cycle threshold (Ct) values at the time of testing in vaccinated vs. unvaccinated persons. A) N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for symptomatic, asymptomatic, and unknown symptom status cases. Boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values between groups by Welch two-sample t-tests. B) Density distributions of unvaccinated and vaccinated specimen collection dates by day since symptom onset. Day 0 on the x-axis denotes self-reported day of symptom onset. Negative values for days indicate specimen collection prior to symptom onset. Symptom onset data were available for n=249 unvaccinated cases and n=222 vaccinated cases.

Acknowledgments

We would like to acknowledge the local health departments in Wisconsin who referred samples for SARS-CoV-2 testing. We gratefully acknowledge Shelby O'Connor and Hannah Segaloff for critical review of the manuscript and helpful discussion. We also acknowledge all Exact Sciences employees who contributed to sample testing. This work was supported by Centers for Disease Control and Prevention contracts 75D30120C09870 and 75D30121C11060 to D.H.O and T.C.F. The authors are also members of the Upper Midwest Regional Accelerator for Genomic Surveillance funded by the Rockefeller Foundation.

Conflict of interest

The authors declare no conflicting interests.

Ethics statement

Per the University of Wisconsin-Madison IRB, this project qualifies as public health surveillance activities as defined in the Common Rule, 45 CFR 46.102(I)(2). As such, the project is not deemed to be research regulated under the Common Rule and therefore, does not require University of Wisconsin-Madison IRB review and oversight.

Data availability

Data and processing workflows are available at https://go.wisc.edu/p22l16. To protect potentially personally identifiable information, the publicly available dataset contains only PCR Ct values, vaccine status, symptom status, and days from symptom onset to testing for each specimen.

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From: DAVID H O"CONNOR
To: Thomas Friedrich
Cc: Grande, Katarina

Subject: Re: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite Vaccination)

Date: Monday, October 25, 2021 10:23:52 AM

Attachments: <u>image.png</u>

Oops.

dave

Dave O'Connor | UW Medical Foundation Professor dhoconno@wisc.edu | +1

http://dho.pathology.wisc.edu

I choose to work flexibly & send emails outside normal office hours. No need to respond to my emails outside yours.

On Oct 25, 2021, 10:21 AM -0500, Thomas Friedrich <tfriedri@wisc.edu>, wrote:

Taking the JAMA editor off. :)

I fully agree on bringing it back to Google Docs.

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

DAVID H O'CONNOR wrote on 2021-10-25 09:55:

A point on process - I really think we should bring it back into gDocs. Doing this in Word was a huge PITA and required excessive formatting to get right at the end. Would be much better to edit collaboratively in gDocs and export to Word at the very end.

dave

Dave O'Connor | UW Medical Foundation Professor dhoconno@wisc.edu | +1 http://dho.pathology.wisc.edu

I choose to work flexibly & send emails outside normal office hours. No need to respond to my emails outside yours.

On Oct 25, 2021, 9:29 AM -0500, Grande, Katarina <<u>KGrande@publichealthmdc.com</u>>, wrote:

Thanks, Jody, we appreciate your response. Given this, we'd like to withdraw our submission from consideration.

Thanks again for your time, we hope you have a nice week!

-Katarina

From: Jody Zylke Jody Zylke@jamanetwork.org

Sent: Saturday, October 23, 2021 5:11 AM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Subject: RE: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite

Vaccination)

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Yes, all the JAMA Network journals have the same policies.

Jody

From: Grande, Katarina < KGrande@publichealthmdc.com>

Sent: Friday, October 22, 2021 11:45 AM

To: Jody Zylke < <u>Jody.Zylke@jamanetwork.org</u>>

Cc: 'DAVID H O'CONNOR' < dhoconno@wisc.edu; Thomas Friedrich

<tfriedri@wisc.edu>

Subject: RE: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite

Vaccination)

[Warning External Email]

Thanks for your response, Dr. Zylke. We're struggling with this since this endeavor was such a massive collaborative effort! Does JAMA Open Network have the same 7 author limit for a Research Letter submission?

Thanks again for your time!

-Katarina

KATARINA GRANDE, MPH (pronouns: she/her/hers)

Public Health Supervisor/COVID-19 Data Team Lead | Public Health Madison & Dane County

2300 South Park St, Rm 2010, Madison, WI 53713

Phone: (608) 243-0409 | Cell: | Fax: (608) 266-4858

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<image002.png>

From: Jody.Zylke@jamanetwork.org>

Sent: Thursday, October 21, 2021 5:02 PM

To: Grande, Katarina < <u>KGrande@publichealthmdc.com</u>>

Subject: JAMA21-11227 (Shedding of Infectious SARS-CoV-2 Despite

Vaccination)

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Dear Ms Grande:

Thanks for submitting a research letter to JAMA. The study is interesting and I would be willing to send it for peer review. However, research letters are limited to 7 authors, and we cannot make an exception.

Would you be willing to decrease the number of authors to 7? If not, we will not be able to consider your manuscript.

Sincerely,

Jody W Zylke, MD Deputy Editor, JAMA

Email: Jody.Zylke@jamanetwork.org

From: Dave O"Connor
To: Letter

Cc: Thomas Friedrich

Subject: Re: New England Journal of Medicine - 21-14060 **Date:** Tuesday, September 28, 2021 11:29:47 AM

Sure, can we get it to you by COB tomorrow? It will take a day or so to remake the figures and update the text.

dave

Letter wrote on 9/28/21 10:58 AM:

Hello Dr. O'Connor,

You can send the manuscript to me via email as a word doc. I can upload it to your submission. This way, you will not need to start a new submission. Let me know what you prefer.

Best,

Vivian Vu Editorial Assistant

New England Journal of Medicine

From: Dave O'Connor dhoconno@wisc.edu Sent: Tuesday, September 28, 2021 11:56 AM

To: Letter < letter@neim.org>

Cc: Thomas Friedrich

Subject: Re: New England Journal of Medicine - 21-14060

Hi Vivian,

In the month that we've been under review, we've collected additional data that strengthens the paper. We didn't anticipate this kind of lengthy delay in reviewing a short note. Is there any easy way that we can add this new data to the manuscript without having it compromise our position in the queue, especially if the editor has not yet read the version that is currently queued up?

If not, no worries, but we figure it wouldn't hurt to ask.

Thanks,

dave

Letter wrote on 9/28/21 9:43 AM:

Hello Dr. O'Connor,

We are still waiting for a decision from the editor. He is one of the editors chiefly handling Covid-19 submissions at the Journal and his response time is slower than usual due to the volume of submissions. I apologize for the delay. I have sent an additional reminder to the editor for a decision. You'll receive an email from us with a decision as soon as possible.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: Dave O'Connor <u><dhoconno@wisc.edu></u> Sent: Monday, September 27, 2021 3:59 PM

To: Letter < letter@neim.org >

Cc: Thomas Friedrich

Subject: Re: New England Journal of Medicine - 21-14060

Hi Vivian,

Thanks for checking in with the editor about two weeks ago. Given that our short letter has now been with the editor under internal review for more than a month (August 23), I'm hoping this bodes will for a favorable outcome.

Thanks again for any updates you can provide,

dave

Dave O'Connor wrote on 9/14/21 4:01 PM:

Thanks Vivian for sending the reminder. Please let us know if you need additional information from us.

Best,

dave

Letter wrote on 9/14/21 3:32 PM:

Hello Dr. O'Connor,

Thank you for your email. Unfortunately a decision has not be made regarding your letter. An additional reminder has been sent to the editor for a decision. An exact date for a decision cannot be provided given the increased volume in covid-related submissions but know that we strive to give authors as timely a decision as possible. We apologize for the delay, and thank you for your interest in the Journal.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: Dave O'Connor dhoconno@wisc.edu Sent: Tuesday, September 14, 2021 4:26 PM

To: Letter letter@nejm.org

Cc: Thomas Friedrich ctfriedri@wisc.edu Subject: Re: New England Journal of Medicine -

21-14060

HI Vivian,

I apologize for asking again, but it has now been another week and a half that the 400 word letter has been with the editor. Do you have an update on when we might receive a final editorial decision?

Thanks again,

dave

Letter wrote on 9/3/21 2:05 PM:

Hello Dr. O'Connor,

Thank you for your email. Your letter is currently with the editor and a decision regarding possible publication has not yet been made. You will be informed of the final editorial decision via e-mail.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: NEJM Editorial <a href

Sent: Friday, September 3, 2021

2:58 PM

To: Letter **Subject:** FW: New England Journal

of Medicine - 21-14060

From: Dave O'Connor <dhoconno@wisc.edu>

Sent: Friday, September 3, 2021

10:17 AM

To: NEJM Editorial editorial@nejm.org

Subject: Re: New England Journal

of Medicine - 21-14060

To whom it may concern,

I am writing on behalf of our coauthors to ask if there are any updates on the status of the 400 word correspondence we submitted to NEJM on August 23. We are keenly aware that this is timely data given the current landscape of SARS-CoV-2 infection despite vaccination.

One small note: some vocal scientists have criticized our work on social media. The primary claim they make is that virus culture in low Ct samples does not mean that there is similar amounts of replication-competent virus in these samples. Subsequent to our August 23 submission, we re-thawed these samples and showed that virus titers are similar in those who are unvaccinated and infected despite infection (see attached), generally tracking with PCR RNA levels. We would likely want to include a version of this plot in a revised NEJM correspondence to silence this inaccurate criticism.

Thanks in advance for your consideration,

dave

New England Journal of Medicine wrote on 8/23/21 1:39 PM:

Dear Ms. Grande and co-authors,

Thank you for submitting your manuscript, "Shedding of Infectious SARS-CoV-2 Despite Vaccination" to the New England Journal of Medicine.

Your manuscript has been

forwarded to members of our editorial staff, who will make an initial evaluation and decide whether it merits further consideration. You will be notified of the decision as soon as possible.

Your manuscript ID is 21-14060.

Please mention the above manuscript ID in all future correspondence or when calling the office for questions. If there are any changes in your street address or e-mail address, please log in to ScholarOne

er information as appropriate. You may also view the status of your manuscript at any time by checking For Authors section of the site.

We are undertaking evaluation of your manuscript with the understanding that neither the substance of the article nor the figures or tables have been published or will be submitted for publication elsewhere during the period of review.

Please provide the editors with copies of other manuscripts by you or your coauthors addressing

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Please call us at 617-734-9800 if you have any questions.

Sincerely,

New England Journal of Medicine 10 Shattuck Street Boston, MA 02115 (617) 734-9800 Fax: (617) 739-9864 http://www.nejm. org

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http://dho.pathology.wisc.edu @dho • 608-890-0845 From: Dave O"Connor
To: Letter

Cc: Thomas Friedrich

Subject: Re: New England Journal of Medicine - 21-14060 **Date:** Thursday, September 30, 2021 7:03:56 AM

Attachments: EOC Riemersma Viral loads in vaccinees NEJM revised 2021-09-29.docx

Hi Vivian,

Please find attached an updated version of our NEJM submission. The key change (denoted with track changes in case it is helpful) is that the virus culture data is now shown with quantitative titers.

Thanks again in advance for your consideration,

dave

Letter wrote on 9/28/21 2:35 PM:

That would be fine.

Best,

Vivian Vu

Editorial Assistant

New England Journal of Medicine

From: Dave O'Connor dhoconno@wisc.edu Sent: Tuesday, September 28, 2021 12:30 PM

To: Letter letter@neim.org

Cc: Thomas Friedrich <tfriedri@wisc.edu>

Subject: Re: New England Journal of Medicine - 21-14060

Sure, can we get it to you by COB tomorrow? It will take a day or so to remake the figures and update the text.

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To: Letter letter@neim.org

Cc: Thomas Friedrich <a href="mailto:<a hre

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Letter wrote on 9/28/21 9:43 AM:

Hello Dr. O'Connor,

We are still waiting for a decision from the editor. He is one of the editors chiefly handling Covid-19 submissions at the Journal and his response time is slower than usual due to the volume of submissions. I apologize for the delay. I have sent an additional reminder to the editor for a decision. You'll receive an email from us with a decision as soon as possible.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: Dave O'Connor <a href="mailto:sde-charge-decomposition-color: blue-charge-decomposition-color: blue-charge-decomposition-charge-decomposition-color: blue-charge-decomposition-charge-decomposit

To: Letter letter@nejm.org

Cc: Thomas Friedrich <a href="mailto:<a hre

Subject: Re: New England Journal of Medicine - 21-14060

Hi Vivian,

Thanks for checking in with the editor about two weeks ago. Given that our short letter has now been with the editor under internal review for more than a month (August 23), I'm hoping this bodes will for a favorable outcome.

Thanks again for any updates you can provide,

dave

Dave O'Connor wrote on 9/14/21 4:01 PM:

Thanks Vivian for sending the reminder. Please let us know if you need additional information from us.

Best,

dave

Letter wrote on 9/14/21 3:32 PM:

Hello Dr. O'Connor,

Thank you for your email.
Unfortunately a decision has not be made regarding your letter. An additional reminder has been sent

to the editor for a decision. An exact date for a decision cannot be provided given the increased volume in covid-related submissions but know that we strive to give authors as timely a decision as possible. We apologize for the delay, and thank you for your interest in the Journal.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: Dave O'Connor dhoconno@wisc.edu

Sent: Tuesday, September 14,

2021 4:26 PM

To: Letter <a href="mailto:

Cc: Thomas Friedrich

Subject: Re: New England Journal

of Medicine - 21-14060

HI Vivian,

I apologize for asking again, but it has now been another week and a half that the 400 word letter has been with the editor. Do you have an update on when we might receive a final editorial decision?

Thanks again,

dave

Letter wrote on 9/3/21 2:05 PM:

Hello Dr. O'Connor,

Thank you for your email. Your letter is currently with the editor and a decision regarding possible publication has not yet been made. You will be informed of the final editorial decision via e-mail.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: NEJM Editorial <e ditorial@nejm.org

 \geq

Sent: Friday, September 3, 2021

2:58 PM **To:** Letter

<letter@nejm.org>
Subject: FW: New
England Journal of
Medicine - 21-14060

From: Dave
O'Connor
<dhoconno@wisc.ed

<u>u</u>>

Sent: Friday, September 3, 2021

10:17 AM

To: NEJM Editorial editorial@nejm.org

>

Subject: Re: New England Journal of Medicine - 21-14060

To whom it may concern,

I am writing on behalf of our coauthors to ask if there are any updates on the status of the 400 word correspondence we submitted to NEJM on August 23. We are keenly aware that this is timely data given the current landscape of SARS-CoV-2 infection despite vaccination.

One small note: some vocal scientists have criticized our work on social media. The primary claim they make is that virus culture in low Ct samples does not mean that there is similar amounts of replicationcompetent virus in these samples. Subsequent to our August 23 submission, we rethawed these samples and showed that virus titers are similar in those who are unvaccinated and infected despite infection (see attached), generally tracking with PCR RNA levels. We would likely want to include a version of this plot in a revised NEJM correspondence to silence this inaccurate criticism.

Thanks in advance for your consideration,

dave

New England Journal of Medicine wrote on 8/23/21 1:39 PM:

Dear

Ms. Grande and coauthor Thank you for submit ting your manusc ript, "Shedd ing of Infect ious SARS-CoV-2 Despit Vaccin ation" to the New Englan Journa l of Medici ne.

Your manusc ript has been forwar ded to member s of our editor ial staff, who will make an initia l evalua tion and decide whethe r it merits furthe consid eratio n. You will be notifi ed of the decisi on as soon as possib le.

Your manusc ript ID is 21-14060.

Please mentio n the above manusc ript ID in all future corres ponden ce or when callin g the office for questi ons. Ιf

there are any change s in your street addres s or e-mail addres s, please log in to Schola rOne Manusc ripts at https: //mc05 .manus criptc entral .com/n ejm and edit your ūser inform ation as approp riate. You may also view the status of your manusc ript at any time by checki ng For Author s sectio n of the site. We are undert aking evalúa tion of your manusc ript with the unders tandin g that neithe r the

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tion with scient ific meetin gs or ŧο news report S based on presen tation s at such meetin gs.

The Journa l's policy is explai ned more fully at https: //www.nejm.org/about-nejm/editorial-policies.

Please call us at 617-734-9800 if you have any questions.

Sincer ely,

New Englan d Journa 1 of Medici ne 10 Shattu ck Street Boston , MA 02115 (617) 734-9800 Fax: (617) 739-9864 http:/ /www.n ejm.or

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Shedding of Infectious SARS-CoV-2 Despite Vaccination

Kasen K. Riemersma, DVM, PhD¹; Brittany E. Grogan, MPH²; Amanda Kita-Yarbro, MPH²; Peter J. Halfmann, PhD¹; Hannah E. Segaloff, PhD³; Anna Kocharian, MS⁴; Kelsey R. Florek, MPH, PhD⁵; Ryan Westergaard, MD, PhD⁶; Allen Bateman, PhD⁵; Gunnar E. Jeppson, BS⁷; Yoshihiro Kawaoka, DVM, PhD¹; David H. O'Connor, PhD⁸, Thomas C. Friedrich, PhD¹, Katarina M. Grande, MPH²

Katarina Grande KGrande@publichealthmdc.com

¹ Department of Pathobiological Sciences, University of Wisconsin-Madison, Madison, WI, USA

² Public Health Madison & Dane County, Madison, WI, USA

³ Epidemic Intelligence Service, CDC, Atlanta, GA, USA

³ Wisconsin Department of Health Services, Madison, WI, USA

⁵ Wisconsin State Laboratory of Hygiene, Madison, WI, USA

⁶ Department of Medicine, University of Wisconsin School of Medicine and Public Health, Madison, WI, USA

⁷ Exact Sciences, Madison, WI, USA

⁸ Department of Pathology and Laboratory Medicine, University of Wisconsin-Madison, Madison, WI, USA

[^]These authors contributed equally. Correspondence can be addressed to:

Main text (3959 words; limit 400)

The SARS-CoV-2 Delta variant might cause high viral loads, is highly transmissible, and contains mutations that confer partial immune escape ^{1,2}. Outbreak investigations suggest that vaccinated persons can spread Delta ^{3,4}. We compared RT-PCR cycle threshold (Ct) data from 699 swab specimens collected in Wisconsin 29 June through 31 July 2021 and tested with a qualitative assay by a single contract laboratory. Specimens came from residents of 36 counties, most in southern and southeastern Wisconsin, and 81% of cases were not associated with an outbreak. During this time, estimated prevalence of Delta variants in Wisconsin increased from 69% to over 95%. Vaccination status was determined via self-reporting and state immunization records (Supplemental Figure 1).

We observed low Ct values (<25) in 212 of 310 fully vaccinated (68%; Figure 1A) and 246 of 389 (63%) unvaccinated individuals. Testing a subset of <u>such</u> low-Ct samples revealed <u>infectious that</u> <u>infectious</u> SARS-CoV-2 <u>was present at similar levels in vaccinated and unvaccinated persons in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people (Figure 1B).</u>

Low Ct values were detected in vaccinated people regardless of symptoms at the time of testing (Figure 1C). Ct values <25 were detected in 7 of 24 unvaccinated (29%; CI: 13-51%) and 9 of 11 fully vaccinated asymptomatic individuals (82%; CI: 48-97%), and 158 of 232 unvaccinated (68%, CI: 62-74%) and 156 of 225 fully vaccinated (69%; CI: 63-75%) symptomatic individuals. Time from symptom onset to testing did not vary by vaccination status (p=0.40; Supplemental Figure 2). Infectious virus was detected in the sole specimen tested from an asymptomatic fully vaccinated individual. Although few asymptomatic individuals were sampled, these results indicate that even asymptomatic, fully vaccinated people might shed infectious virus.

Combined with other studies ^{2–5}, these data indicate that <u>both</u> vaccinated and unvaccinated individuals infected with the Delta variant might transmit infection. Importantly, we show that infectious SARS-CoV-2 is frequently found even in vaccinated persons when specimen Ct values are low. The inclusion of viruses from Pango lineages B.1.617.2, AY.2, and AY.3, and multiple counties without a linking

outbreak, indicate that Delta-lineage SARS-CoV-2 can achieve low Ct values consistent with transmissibility in fully vaccinated individuals across a range of settings. Vaccinated and unvaccinated persons should get tested when symptomatic or after close contact with someone with suspected or confirmed COVID-19. Continued adherence to non-pharmaceutical interventions during periods of high community transmission to mitigate spread of COVID-19 remain important for both vaccinated and unvaccinated individuals.

Figure

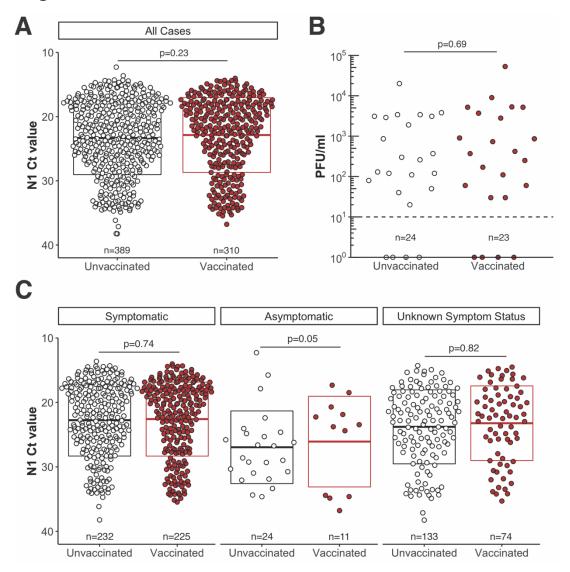
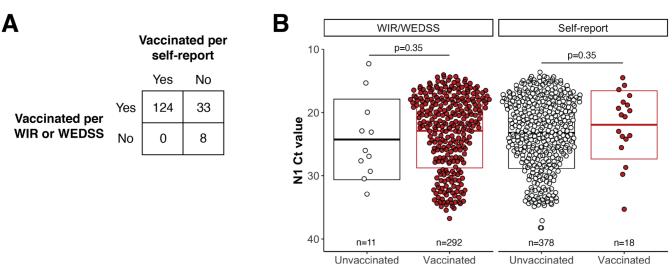


Figure 1. Individuals infected with SARS-CoV-2 despite full vaccination have low Ct values and shed infectious virus. A. Ct values for SARS-CoV-2-positive specimens grouped by vaccination status. RT-PCR was performed by Exact Sciences Corporation, responsible for over 10% of all PCR tests in Wisconsin during this period, using a qualitative diagnostic assay targeting the SARS-CoV-2 N gene (oligonucleotides identical to CDC's N1 primer and probe set) that has been authorized for emergency use by FDA (https://www.fda.gov/media/138328/download). B. Infectiousness was determined for We performed plaque assays on Vero E6 TMPRSS2 cells on a subset of N1 Ct-matched specimens with Ct <25_ by inoculation onto Vero E6 TMPRSS2 cells and determining presence of cytopathic effects (CPE) after 5 days in culture. Specimens -were selected by N1 Ct-matching between fully vaccinated and not fully unvaccinated persons, then specimens from persons with unknown vaccination status were excluded from the analysis. Circles indicate presence of CPE; 'X' indicates no CPE detected Infectious titers are expressed as plaque-forming units (pfu) per milliliter specimen. Specimens underwent a freeze-thaw cycle prior to virus titration. C. N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for individuals who were symptomatic or asymptomatic, or those whose symptom status was not determined, at the time of testing. In A and C,

boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values by independent two-group Mann-Whitney U tests.

Supplemental materials

Supplemental figure 1



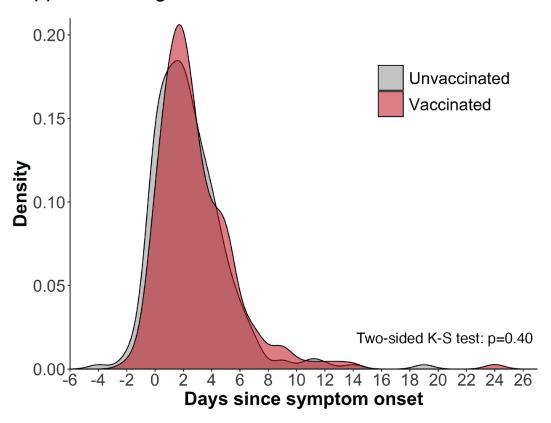
Supplemental figure 1. Concordance between self-reported vaccination status and the Wisconsin Immunization Registry (WIR) or Wisconsin Electronic Disease Surveillance System (WEDSS). For all individuals, vaccination status was determined using WIR/WEDSS electronic registries when data were available. Individuals were identified as unvaccinated at the time of testing if WIR/WEDSS data indicated receipt of a first SARS-CoV-2 vaccine dose after the test date.

Individuals were considered fully vaccinated based on WIR/WEDSS data if the registries indicated receipt of a final vaccine dose at least 14 days prior to testing. For individuals whose vaccination status could not be verified in WIR/WEDSS, self-reported data collected at the time of testing were used. Individuals were considered unvaccinated based on self-report only if there was an explicit declaration of unvaccinated status in the self-reported data. Individuals were considered fully vaccinated based on self-report if they fulfilled all of the following criteria: (1) indicated that they had received a COVID vaccine prior to testing; (2) indicated that they did not require another vaccine dose; and (3) reported a date of last vaccine dose that was at least 14 days prior to testing.

Specimens lacking data on vaccination status were excluded from the study. Specimens from partially vaccinated individuals (incomplete vaccine series, or <14 days post-final dose) were also excluded. Fully vaccinated status was determined by WIR/WEDSS for 292 specimens and by self-reported data for 18. Unvaccinated status was determined by WIR/WEDSS for 11 and by self-reported data by 378. **A.** Of the 699 specimens with vaccination status available from at least one source, 165 specimens had data available from both sources. For self-reporting, under-reporting of full vaccination status (33/157) was more common than over-reporting (0/124). **B.** N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for individuals whose vaccination status was determined by WIR/WEDDS or by self-reported data. Boxplots represent mean N1 Ct values +/- one standard

deviation. P-values were calculated by comparing mean Ct values by independent two-group Mann-Whitney U tests.

Supplemental figure 2



Supplemental figure 2. Density distributions of unvaccinated and vaccinated specimen collection dates by day since symptom onset. Day 0 on the x-axis denotes self-reported day of symptom onset. Negative values for days indicate specimen collection prior to symptom onset. Symptom onset data were available for n=263 unvaccinated cases and n=232 vaccinated cases.

Conflict of interest

The authors declare no conflicting interests.

Ethics statement

Per the University of Wisconsin-Madison IRB, this project qualifies as public health surveillance activities as defined in the Common Rule, 45 CFR 46.102(I)(2). As such, the project is not deemed to be research regulated under the Common Rule and therefore, does not require University of Wisconsin-Madison IRB review and oversight.

The opinions expressed by authors contributing to this journal do not necessarily reflect the opinions of the Centers for Disease Control and Prevention or the institutions with which the authors are affiliated.

Data availability

Data and processing workflows are available at https://go.wisc.edu/p22l16. To protect potentially personally identifiable information, the publicly available dataset contains only PCR Ct values, vaccine status, symptom status, and days from symptom onset to testing for each specimen.

References

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 Delta variant vaccine-breakthrough infections: a multi-center cohort study [Internet]. bioRxiv.

 2021;Available from: http://medrxiv.org/lookup/doi/10.1101/2021.07.28.21261295

From: DAVID H O"CONNOR

To: editorial@nejm.org

Subject: Re: New England Journal of Medicine - 21-14060

Date: Friday, September 3, 2021 9:17:26 AM

Attachments: <u>Culture titers.pdf</u>

To whom it may concern,

I am writing on behalf of our co-authors to ask if there are any updates on the status of the 400 word correspondence we submitted to NEJM on August 23. We are keenly aware that this is timely data given the current landscape of SARS-CoV-2 infection despite vaccination.

One small note: some vocal scientists have criticized our work on social media. The primary claim they make is that virus culture in low Ct samples does not mean that there is similar amounts of replication-competent virus in these samples. Subsequent to our August 23 submission, we re-thawed these samples and showed that virus titers are similar in those who are unvaccinated and infected despite infection (see attached), generally tracking with PCR RNA levels. We would likely want to include a version of this plot in a revised NEJM correspondence to silence this inaccurate criticism.

Thanks in advance for your consideration,

dave

New England Journal of Medicine wrote on 8/23/21 1:39 PM:

Dear Ms. Grande and co-authors,

Thank you for submitting your manuscript, "Shedding of Infectious SARS-CoV-2 Despite Vaccination" to the New England Journal of Medicine.

Your manuscript has been forwarded to members of our editorial staff, who will make an initial evaluation and decide whether it merits further consideration. You will be notified of the decision as soon as possible.

Your manuscript ID is 21-14060.

Please mention the above manuscript ID in all future correspondence or when calling the office for questions. If there are any changes in your street address or _____

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We are undertaking evaluation of your manuscript with the understanding that neither the substance of the article nor the figures or tables have been published or will be submitted for publication elsewhere during the period of review.

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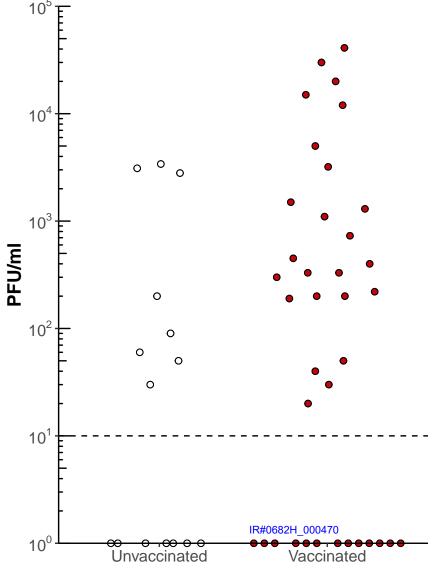
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Please call us at 617-734-9800 if you have any questions. Sincerely,

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From: DAVID H O"CONNOR

To: <u>Nidhi Subbaraman</u>; <u>Thomas Friedrich</u>

Cc: Katarina Grande

Subject: Re: News query from Nature - vaccines and Delta Date: Wednesday, August 11, 2021 1:35:40 PM

Also, Nidhi, we posted an update of our preprint this morning that strengthens the findings by including more people and showing that the majority of high viral load samples we tested have replication-competent

virus. https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v2 (the correct abstract is in the PDF - we're working to update the one in the medrxiv summary page).

Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021 | medRxiv

SARS-CoV-2 variant B.1.617.2 (delta) is associated with higher viral loads [1] and increased transmissibility relative to other variants, as well as partial escape from polyclonal and monoclonal antibodies [2]. The emergence of the delta variant has been associated with increasing case counts and test-positivity rates, indicative of rapid community spread. Since early July 2021, SARS-CoV-2 ...

www.medrxiv.org

dave

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From: Nidhi Subbaraman < nidhi.subbaraman@us.nature.com>

Sent: Wednesday, August 11, 2021 13:22

To: Thomas Friedrich <tfriedri@wisc.edu>; DAVID H O'CONNOR <dhoconno@wisc.edu>

Cc: Katarina Grande < kgrande@publichealthmdc.com> **Subject:** Re: News query from Nature - vaccines and Delta

Hi everyone, Thanks for the Zoom call the other day. Is one of you available for a 5 min fact check this afternoon? I got edits back on the story and have a few minor things to iron out.

Perhaps Dr Katarina Grande, if you're available – missed you the other day since you were out.

In any case, just let me know what number to call! Thanks, Nidhi

--

Nidhi Subbaraman (she/her)

Senior reporter, *Nature*

https://www.nature.com/news

O: +1 202 626 2523 | C: +

@nidhisubs

From: Thomas Friedrich <tfriedri@wisc.edu> **Date:** Wednesday, August 4, 2021 at 8:41 AM **To:** DAVID H O'CONNOR <dhoconno@wisc.edu>

Cc: Nidhi Subbaraman < nidhi.subbaraman@us.nature.com >, Katarina Grande

<kgrande@publichealthmdc.com>

Subject: Re: News query from Nature - vaccines and Delta

[External - Use Caution]

Great. Nidhi, if you could send a calendar invitation for a Zoom call at 13:30 CDT that would be great.

Thanks,

Τ

Sent from my iPhone

On Aug 4, 2021, at 07:10, DAVID H O'CONNOR <dhoconno@wisc.edu> wrote:

Yep, 1:30 PM is good for me.

dave

Nidhi Subbaraman wrote on 8/4/21 7:05 AM:

Thanks very much. How about the 13:30-1400 slot? I can send a zoom link or call, whatever's best for you. Thanks!

-

Nidhi Subbaraman (she) Senior reporter, Nature Cell: +
Sent from my phone

On Aug 4, 2021, at 8:00 AM, Thomas Friedrich stfriedri@wisc.edu wrote:

[External - Use Caution]

Hi Nidhi.

Looping in my colleagues Dave O'Connor and Kat Grande here. I think Kat is away today, but Dave and/or I should have time to talk.

How about:

11:30-noon CDT 13:30-14:00 CDT

Best,

Tom

Sent from my iPhone

On Aug 3, 2021, at 23:24, Nidhi Subbaraman <nidhi.subbaraman@us.nature.com> wrote:

Prof Friedrich, I report on biomedical research for the news team at Nature. I'm working on a story about vaccines and the Delta variant and had a few questions about your recent preprint on this topic:

https://www.medrxiv.org/content/10.1101/20 21.07.31.21261387v1

Would you be free for a phone conversation about this on Weds.? Let me know there are any windows that work, and thanks so much for considering this, Nidhi

--

Nidhi Subbaraman (she/her)

Senior reporter, *Nature*

https://www.nature.com/news

O: +1 202 626 2523 | C: +

@nidhisubs

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http://dho.pathology.wisc.edu @dho • 608-890-0845 From: <u>Dave O"Connor</u>
To: <u>Tyler Cardon</u>

Cc: <u>Grande, Katarina; Thomas Friedrich</u>

Subject: Re: Question re Shedding of Infectious SARS-CoV-2 Despite Vaccination

Date: Wednesday, September 22, 2021 2:55:59 PM

Attachments: <u>image.png</u>

image.png

No. Because presenting the data numerically like that implies that there is enough data to make a robust comparison - there isn't in this case.

dave

Tyler Cardon wrote on 9/22/21 1:58 PM:

Thanks, Dave! I hadn't seen the snapshots. What a great resource for Dane County, and very well presented, too.

After reading your response to my question in the first bullet below, I realized I could have phrased it more clearly. My question is not whether the low CT values at which infectious virus was detected on the vaccinated asymptomatic specimens described in your paper provides sufficient support to make any sort of broad assertion. Acknowledging limitations due to small sample size, my question is whether the following is a *fair interpretation* of the data regarding the asymptomatic specimens you described in the paper:

Given that low CT values are associated with higher viral loads and increased transmissibility, the fact that virus was detected at a lower average CT value on specimens from the asymptomatic vaccinated group (23.64) than the asymptomatic unvaccinated group (27.23) indicates that the asymptomatic vaccinated group, on average, carried ~8 to 16x higher viral loads than the asymptomatic unvaccinated group.

Again, the sample size is too small to draw any conclusions from these results alone, but do you consider the above a fair interpretation of the data on asymptomatic specimens presented in your paper? If not, what am I missing?

Thanks again for your time.

To: Tyler Cardon ctcardon@blazemedia.com>

Cc: Grande, Katarina < KGrande@publichealthmdc.com>, Thomas Friedrich

<tfriedri@wisc.edu>

Subject: Re: Question re Shedding of Infectious SARS-CoV-2 Despite Vaccination

Yep, typo. Should read, "...is important for transmission"

The benefit of vaccination of rate of infection in this same population comes from the PHMDC data snapshots maintained by Kat and her team (https://publichealthmdc.com/documents/2021-09-16_data_snapshot.pdf) The rate fluctuates from week to week, but infections among unvaccinated occur about 3x as often. Kat can provide more info.

Per questions to group:

- 1. No, you can't make the assertion in the first bullet point. Sample size of asymptomatics is far too small for this particular analysis.
- 2. Asymptomatic vs. symptomatic is hard to compare since self-reporting is subjective, and someone who is asymptomatic at time of testing could go on to develop symptoms later that aren't captured in the data. It is something we will continue to look at periodically, but with so many other competing demands on our time, it isn't a priority at the moment.

dave

Tyler Cardon wrote on 9/21/21 1:36 PM:

Thanks for the quick responses, Dave and Katarina! Very much appreciated. I've included a couple of quick follow up questions for you below:

Question for the group:

- One of the most surprising results from your study was the low CT values on your vaccinated asymptomatic group. Given that each cycle represents a doubling, and the average variance between asymptomatic vaccinated and asymptomatic unvaccinated appears to be 3-4 cycles, is it fair to say that the average viral load in the asymptomatic vaccinated group in your study was 8-16x higher than the asymptomatic unvaccinated group?
- Given the small sample size of asymptomatic vaccinated specimens (11), are you planning on doing a follow up study to confirm this surprising result?

Question for Katarina:

 Did you select for vaccination status when determining which specimens from the convenience sample to include in the study described in the paper? In other words, were the 699 specimens

- randomly selected from the convenience sample and the respective vaccination status for each determined later?
- For context, I was surprised (perhaps I shouldn't be) to see roughly as many specimens in the vaccinated group (310) as the unvaccinated group (389), which made me wonder whether you selected for vaccination status to compare roughly the same number of specimens for each group.

Questions for Dave:

- Did you mean to write, "What is happening in the nose **is** important for transmission ..."? You wrote "isn't", but that strikes me as inconsistent with the conclusion of your paper and my own understanding, limited though it is, so I wanted to double check.
- In citing the comparative data regarding the relative likelihood of infection, disease, hospitalization, etc., between unvaccinated and vaccinated persons, you're referring to the best/most recent information available, and not the results of the research you and your colleagues described in the paper, correct? Unless I missed it, I didn't see discussion on the relative likelihood of SARS-CoV-2 infection between the two groups in your paper.

From: Dave O'Connor dhoconno@wisc.edu>

Date: Tuesday, September 21, 2021 at 9:25 AM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Cc: Tyler Cardon <a href="mailto:ktma

Subject: Re: Question re Shedding of Infectious SARS-CoV-2 Despite Vaccination

Only that it is essential to remember that those who are unvaccinated are 3 x more likely to become infected and much, much more likely to develop severe disease and require hospitalization, even though the amount of virus we detect in the noses of both groups are similar. What is happening in the nose isn't important for transmission but doesn't tell the whole story. Much of the disease pathology happens in the lower respiratory tract which is not evaluated in our study.

dave

Grande, Katarina wrote on 9/21/21 7:53 AM:

Hi Tyler,

The specimens were a convenience sample, representing samples we were already sequencing as part of public health practice to identify clusters and conduct variant surveillance. Anything to add, Tom and Dave?

-Katarina

KATARINA GRANDE, MPH (pronouns: she/her/hers)

Public Health Supervisor/COVID-19 Data Team Lead | Public

Health Madison & Dane County

2300 South Park St, Rm 2010, Madison, WI 53713

Phone: (608) 243-0409 | Cell: | Fax: (608) 266-

4858

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From: Tyler Cardon ctcardon@blazemedia.com>

Sent: Monday, September 20, 2021 6:02 PM

To: Grande, Katarina KGrande@publichealthmdc.com Subject: Question re Shedding of Infectious SARS-CoV-2

Despite Vaccination

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Hi Katarina,

Kudos on the important paper. I hope it's progressing through the peer review process, as it contains important information that policy makers and public health officials should be taking into account as they consider how to best respond to Delta.

Quick question for you: How were the 699 swab specimens selected for the study? Did you and the other authors ask Exact Sciences for samples below a certain threshold and the distribution between vaccinated and unvaccinated was random? Or did you specifically request that Exact Sciences provide relatively equal numbers of specimens from vaccinated and unvaccinated groups?

Many thanks,

Tyler CardonCEO
Blaze Media

http://dho.pathology.wisc.edu @dho • 608-890-0845

http://dho.pathology.wisc.edu @dho • 608-890-0845

http://dho.pathology.wisc.edu @dho • 608-890-0845 From: Dave O"Connor

To: KGrande@publichealthmdc.com

Cc: "Sanjay Mishra"; Kasen Riemersma; Thomas Friedrich Subject: Re: Request to interview from National Geographic

Date: Thursday, August 12, 2021 2:37:58 PM

Attachments: image.png

image.png

I can chat after 4:30 CDT, or go ahead without me!

dave

KGrande@publichealthmdc.com wrote on 8/12/21 2:36 PM:

Hi Dr. Mishra,

Thanks for reaching out. I could jump on a call after 3:30pm. I'm cc'ing my co-authors, who are the true scientists on the paper—I'm the applied public health person of the bunch. So depending on your angle, it may be helpful to link with them, or see if we could jump on a call together.

-Katarina

KATARINA GRANDE, MPH (pronouns: she/her/hers)

Public Health Supervisor/COVID-19 Data Team Lead | Public Health Madison & Dane County

2300 South Park St, Rm 2010, Madison, WI 53713

Phone: (608) 243-0409 | Cell: | Fax: (608) 266-4858

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From: Sanjay Mishra mishra.sanjay@outlook.com>

Sent: Thursday, August 12, 2021 2:07 PM

To: Grande, Katarina < KGrande@publichealthmdc.com> **Subject:** Request to interview from National Geographic

Importance: High

Dear Katarina

I read your preprint posted earlier today with alarm: "Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021" Can I urgently talk to you since I am pitching this as story to my editor at National Geographic, as a follow up to my recent stories on Delta variant, value of masking and breakthrough infections:

In National Geographic:

- 1. Why is Delta more infectious and deadly? New research holds answers. (August 6, 2021)
- 2. <u>How dangerous is the new Delta Plus variant? Here's what we know</u>. (July 2, 2021)
- 3. The Delta variant is serious. Here's why it's on the rise. (June 16, 2021); updated:
 - a. The Delta variant is spreading fast, especially where vaccination rates are low (July 8, 2021)
- 4. This 'double mutant' variant is adding fuel to India's COVID-19 crisis (April 28, 2021)

In The Conversation:

- 1. What is a breakthrough infection? 6 questions answered about catching COVID-19 after vaccination (July 28, 2021)
- Can people vaccinated against COVID-19 still spread the coronavirus? (May 25, 2021)

I and the readers of National Geographic will highly appreciate it

Sanjay Mishra, MS, PhD

Nashville, TN 37221; USA

mishra.sanjay@outlook.com | @Ecquis | +1 (615) 829 6563

LinkedIn | Google Scholar | Contently | Skype

http://dho.pathology.wisc.edu @dho • 608-890-0845

IR#0682H_000481

From: Dave O"Connor

To: <u>Segaloff, Hannah E - DHS</u>

Cc: <u>Kasen Riemersma</u>; <u>Thomas Friedrich</u>; <u>Katarina Grande</u>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Date: Thursday, August 19, 2021 11:17:05 AM

No worries - we ported the comments into Google Drive and should be able to run a clean and tracked version from there by the end of the day.

dave

Segaloff, Hannah E - DHS wrote on 8/19/21 10:15 AM:

They do but it's in sharepoint that non-CDC authors can't access.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services

Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Dave O'Connor dhoconno@wisc.edu Sent: Thursday, August 19, 2021 10:05 AM

To: Segaloff, Hannah E - DHS segaloff@dhs.wisconsin.gov

Cc: Kasen Riemersma riemersma@wisc.edu; Thomas Friedrich tfriedri@wisc.edu;

Katarina Grande kgrande@publichealthmdc.com

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah,

We're trying to merge in the comments with the Google Drive version now. Can the CDC team that does review work out of Google Docs to have a single, live, synchronous version instead of Word?

dave

Segaloff, Hannah E - DHS wrote on 8/19/21 9:58 AM:

We will need to provide a tracked changes and clean version.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service

Epidemic Intelligence Service Officer
U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Segaloff, Hannah E - DHS

Sent: Thursday, August 19, 2021 9:41 AM

To: Kasen Riemersma riemersma@wisc.edu; DAVID H O'CONNOR dhoconno@wisc.edu; 'Thomas Friedrich' tfriedri@wisc.edu; Katarina Grande kgrande@publichealthmdc.com>

Subject: FW: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hi All.

Here are the first round of comments. We should get all responses within 24 to 48 hours of our submission. It looks like this needs to be approved by Lab TF, cross clearance and the response. Let me know if I can help with comments.

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: CDC IMS 2019 NCOV Response Lab TF Clearance

<eocevent216@cdc.gov>

Sent: Thursday, August 19, 2021 9:24 AM

To: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) <qdz0@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance

<eocevent216@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when

the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah,

Please address the mandatory comments and return for re-review.

Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < adz0@cdc.gov>

Sent: Wednesday, August 18, 2021 9:18 AM

To: CDC IMS 2019 NCOV Response Lab TF Clearance

<eocevent216@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when

the Delta Variant is Prevalent

Hello,

Thank you for the quick work getting this approved for DIM expedited clearance. I haven't had a manuscript in expedited clearance before. Does it have the same steps as standard? How much time should I anticipate for the clearance process?

Thank you! Hannah

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 11:51 AM

To: Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov >; CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent216@cdc.gov >; Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) < kya6@cdc.gov >

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD) < bbl7@cdc.gov>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < qdz0@cdc.gov>; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < iki5@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

NP! Glad we were able to turn this around so guickly.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Lab TF Communications Mailbox: eocevent503@cdc.gov
Cell:

From: Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov>

Sent: Tuesday, August 17, 2021 12:47 PM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) qqv9@cdc.gov; CDC IMS 2019 NCOV Response Lab TF Clearance qqv9@cdc.gov; Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) kya6@cdc.gov>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD) < bbl7@cdc.gov>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < qdz0@cdc.gov>; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < iki5@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thanks Shelbi!

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 12:43 PM

To: CDC IMS 2019 NCOV Response Lab TF Clearance

<eocevent216@cdc.gov>; Kools, John J. (CDC/DDID/NCEZID/OD)

<<u>czk7@cdc.gov</u>>; Dunworth, Soumya (CDC/DDPHSS/CSELS/OD)

< kya6@cdc.gov>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD) < bbl7@cdc.gov >; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov >; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < qdz0@cdc.gov >; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < iki5@cdc.gov >

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Afternoon,

This has been approved for expedited clearance.

Thanks, Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 12:40 PM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < qqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin,

Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when

the Delta Variant is Prevalent

Thank you. I approve expedited clearance.

Stephanie
Stephanie R. Bialek MD MPH
Deputy Incident Manager
COVID-19 Response

CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < qqv9@cdc.gov

Sent: Tuesday, August 17, 2021 12:16 PM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin,

Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when

the Delta Variant is Prevalent

Hey Stephanie,

Please see attached for the updated draft.

Thanks, Shelbi Davis

Communication Lead Health Communication Specialist Laboratory and Testing Task Force COVID-19 Emergency Response Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 11:05 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < <u>zqg7@cdc.gov</u>>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin,

Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when

the Delta Variant is Prevalent

Sure thing, working on the updated draft now.

Thanks, Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov >

Sent: Tuesday, August 17, 2021 10:56 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin,

Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when

the Delta Variant is Prevalent

Yes, please request an updated draft with Hannah's name on it and then I approve it going for expedited clearance.

Stephanie

Stephanie R. Bialek MD MPH

Deputy Incident Manager

COVID-19 Response

CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:56 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin,

Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when

the Delta Variant is Prevalent

Hey Stephanie,

From correspondence with ADS and STLT Hannah was inadvertently left off the manuscript but WI has confirmed that she is a co-author but her name is not on this draft. Should we request an updated draft with Hannah information on there as the co-author?

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:51 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin,

Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when

the Delta Variant is Prevalent

Hey,

I am working on getting clarification as we speak, update to follow.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) <zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:49 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < qqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin,

Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when

the Delta Variant is Prevalent

Hannah Segaloff EISO is listed on the clearance request form as an author but not on the manuscript. Can you clarify that she indeed and author? If so, then my approval for expedited clearance stands.

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) qqv9@cdc.gov

Sent: Tuesday, August 17, 2021 10:40 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin,

Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when

the Delta Variant is Prevalent

Thanks for the speedy response!

Thanks, Shelbi Davis

Communication Lead

Health Communication Specialist Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zgg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:39 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin,

Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when

the Delta Variant is Prevalent

I approve.

Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:38 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin,

Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when

the Delta Variant is Prevalent

Morning Stephanie,

Happy Tuesday! We would like to request DIM1 expedited approval for the attached manuscript. Please refer to the email thread below.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: CDC IMS 2019 NCOV Response Lab TF Clearance

<eocevent216@cdc.gov>

Sent: Tuesday, August 17, 2021 10:32 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < qqv9@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance

<eocevent216@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when

the Delta Variant is Prevalent

Hi Shelbi and Jarrett,

Should I begin clearance on this item or wait until you receive the DIM approval?

Thank you,

Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov>

Sent: Tuesday, August 17, 2021 9:59 AM

To: CDC IMS 2019 NCOV Response Lab TF Clearance

<<u>eocevent216@cdc.gov</u>>; Davis, Shelbi (CDC/DDID/NCIRD/DVD) <<u>qqv9@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Cc: Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) < kya6@cdc.gov; Limbago, Brandi (CDC/DDID/NCIRD/OD) < bbl7@cdc.gov; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < iki5@cdc.gov; Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI) < gif7@cdc.gov; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < qdz0@cdc.gov>

Subject: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Good Morning,

You may have heard but our task force was asked by STLT, and we agreed, to sponsor this manuscript through clearance. The authors are targeting NEJM and are requesting our task force to request IM approval for expedited clearance. Our main POC for this manuscript is our CDC EISO Hannah Segaloff (Cc'd). Let me know if you have any questions.

Hannah- our clearance team can help shepherd your paper through clearance. I would anticipate our laboratory SMEs to have some questions for your team.

Best regards,

John

John Kools

ADS, Laboratory & Testing Task Force
CDC COVID-19 Response
Phone:

From: Rose, Dale A. (CDC/DDID/NCEZID/DPEI) < ido8@cdc.gov>

Sent: Tuesday, August 17, 2021 4:51 AM

To: Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov>

Subject: FW: Follow up on your results

Morning John! Thanks for taking this on. We had intensive discussions with WI, IM, and MMWR last week about this. There's strong interest in supporting and moving this forward quickly in clearance, including securing approval for expedited clearance so it can quickly make it to NEJM for consideration. If you anticipate any issues with the content or timing, please do let me know as our TF is in routine conversation with the state epi and want to make sure we're aligned in our discussions.

Much appreciated, and I hope you are well!

Best, Dale

Dale Rose, Ph.D.

STLT Support Task Force

Cell:

From: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI) < gif7@cdc.gov>

Sent: Monday, August 16, 2021 3:35 PM

To: Segaloff, Hannah (CDC dhs.wisconsin.gov)

< hannah.segaloff@dhs.wisconsin.gov>; Rose, Dale A.

(CDC/DDID/NCEZID/DPEI) < ido8@cdc.gov>; Westergaard, Ryan (CDC dhs.wisconsin.gov) < ryan.westergaard@dhs.wisconsin.gov>; Bisgard, Kris (CDC/DDPHSS/CSELS/DSEPD) < kmb6@cdc.gov>

Cc: Ricaldi Camahuali, Jessica (CDC/DDID/NCEZID/DPEI) < mpi7@cdc.gov>; Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov>; Limbago, Brandi (CDC/DDID/NCIRD/OD) < bbl7@cdc.gov>; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < iki5@cdc.gov>; CDC IMS 2019 NCOV Response STLT ADS < eocevent410@cdc.gov>; CDC IMS 2019 NCOV Response Lab Task Force < eocevent177@cdc.gov>

Subject: Re: Follow up on your results

Dear Hannah,

Thank you for these additional documents. Due to this manuscript's

focus on laboratory data, our Laboratory and Testing Task Force colleagues have agreed to be the sponsoring task force for CDC COVID-19 Response clearance. John Kools is the Lab TF ADS and can assist with next steps.

Best Regards,

Anna

Anna Llewellyn, PhD
Associate Director for Science
State, Tribal, Local, and Territorial Support Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Office: 404-639-1538 | Cell:
cocevent410@cdc.gov

From: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov>

Sent: Monday, August 16, 2021 3:13 PM

To: Rose, Dale A. (CDC/DDID/NCEZID/DPEI) < ido8@cdc.gov;

Westergaard, Ryan (CDC dhs.wisconsin.gov)

<ryan.westergaard@dhs.wisconsin.gov>; Bisgard, Kris

(CDC/DDPHSS/CSELS/DSEPD) < kmb6@cdc.gov>

Cc: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI) <<u>gif7@cdc.gov</u>>; Ricaldi

Camahuali, Jessica (CDC/DDID/NCEZID/DPEI) < mpi7@cdc.gov >

Subject: RE: Follow up on your results

Thank you. I have attached the concept proposal that was approved from the original MMWR submission as well as a clearance request form.

Sincerely, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases
Wisconsin Department of Health Services
Currently Teleworking
Cell:

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov --

http://dho.pathology.wisc.edu @dho • 608-890-0845

--

http://dho.pathology.wisc.edu @dho • 608-890-0845 From: <u>Dave O"Connor</u>

To: <u>Segaloff, Hannah E - DHS</u>

Cc: Thomas Friedrich; Kasen Riemersma; Katarina Grande; Westergaard, Ryan P - DHS

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Date: Friday, August 20, 2021 4:14:32 PM

Looks fine to me Hannah. Thanks for taking care of the edits.

dave

Segaloff, Hannah E - DHS wrote on 8/20/21 4:12 PM:

Sorry for the repeat emails. I can just send this version back if you all agree since changes were so minor.

-Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: Thomas Friedrich tfriedri@wisc.edu Sent: Friday, August 20, 2021 3:44 PM

To: Segaloff, Hannah E - DHS segaloff@dhs.wisconsin.gov

Cc: Kasen Riemersma < riemersma@wisc.edu>; DAVID H O'CONNOR < dhoconno@wisc.edu>;

Katarina Grande kgrande@publichealthmdc.com; Westergaard, Ryan P - DHS

<ryan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah.

Do you have any updates on the CDC clearance process? Can you see if others have been able to look at the paper?

Thanks,

-T

Thomas Friedrich

Professor Dept. Pathobiological Sciences University of Wisconsin School of Veterinary Medicine @tcfriedrich On 19 Aug 2021, at 18:51, Thomas Friedrich < tfriedri@wisc.edu > wrote:

Okay, fingers crossed!

Sent from my iPhone

On Aug 19, 2021, at 18:02, Segaloff, Hannah E - DHS hannah.segaloff@dhs.wisconsin.gov wrote:

Though on second thought I can see that the STLT TF is reviewing now-so maybe this is moving faster than I thought.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Thursday, August 19, 2021 5:44 PM

To: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov > Cc: Kasen Riemersma < riemersma@wisc.edu >; DAVID H O'CONNOR

<<u>dhoconno@wisc.edu</u>>; Katarina Grande

<<u>kgrande@publichealthmdc.com</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Thanks Hannah.

I really hope they can return comments tomorrow so we can submit.

on Saturday and won't have WiFi for a week. Do you think that is at all possible?

Best,

Tom

Sent from my iPhone

< hannah.segaloff@dhs.wisconsin.gov > wrote:

Thanks Tom,

I will send these along and the note. I'm hoping we can switch over to a Google drive format for comments.

Best, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases
Wisconsin Department of Health Services
Currently Teleworking
Cell:

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Thursday, August 19, 2021 3:05 PM

To: Segaloff, Hannah E - DHS

hannah.segaloff@dhs.wisconsin.gov>

Cc: Kasen Riemersma <<u>riemersma@wisc.edu</u>>; DAVID H O'CONNOR <<u>dhoconno@wisc.edu</u>>; Katarina Grande <<u>kgrande@publichealthmdc.com</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite

Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not

click on links or open attachments unless you recognize the sender.

Hi Hannah.

Attached please find clean (well, clean-ish) and tracked versions of the revised manuscript. We addressed all the comments and made the changes requested. I hope this can be approved quickly.

Note: As you know, to edit collaboratively, we uploaded the Word doc with CDC comments to Google Drive. I re-downloaded the edited version as a Word doc — this is the "clean" version and preserves CDC comments and our responses. To make the "tracked" version I had to compare that downloaded document to the Word doc you forwarded from CDC. When I did that I noticed that it duplicated several comments from CDC folk. For the sake of readability I tried to delete duplicates, but there are still a lot of comments in a small space. It also appears that replies within comments were not recognized, so now they just appear

as comments on top of other comments. I hope that all makes sense.

If these copies do not come through, you can download them from the shared Google drive here:

Best,

-Tom

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 19 Aug 2021, at 09:41, Segaloff, Hannah E - DHS <<u>hannah.segaloff@dhs.wisconsin.gov</u>> wrote:

Hi All,

Here are the first round of comments. We should get all responses within 24 to 48 hours of our submission. It looks like this needs to be approved by Lab TF, cross clearance and the response.

Let me know if I can help with comments.

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking Cell:

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: CDC IMS 2019 NCOV Response Lab TF Clearance <<u>eocevent216@cdc.gov</u>>

Sent: Thursday, August 19, 2021 9:24 AM

To: Segaloff, Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<qdz0@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF

Clearance < eocevent 216@cdc.gov >

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah,

Please address the mandatory comments and return for re-review.

Shedding of Infectious SARS-CoV-2

Despite Vaccination when the Delta

Variant is Prevalent

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD)

<qdz0@cdc.gov>

Sent: Wednesday, August 18, 2021 9:18 AM **To:** CDC IMS 2019 NCOV Response Lab TF

Clearance < eocevent 216@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hello,

Thank you for the quick work getting this approved for DIM expedited clearance. I haven't had a manuscript in expedited clearance before. Does it have the same steps as standard? How much time should I anticipate for the clearance process?

Thank you! Hannah

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 11:51 AM **To:** Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov>; CDC IMS 2019 NCOV

Response Lab TF Clearance

<<u>eocevent216@cdc.gov</u>>; Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) <<u>kya6@cdc.gov</u>>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD)

<<u>bbl7@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<<u>xhg9@cdc.gov</u>>; Segaloff, Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<adz0@cdc.gov>; Moon, Jonathan L.

(CDC/DDID/NCEZID/DSR) < iki5@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

NP! Glad we were able to turn this around so quickly.

Thanks, Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications

Mailbox: eocevent503@cdc.gov

Cell:

From: Kools, John J. (CDC/DDID/NCEZID/OD)

<czk7@cdc.gov>

Sent: Tuesday, August 17, 2021 12:47 PM **To:** Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>; CDC IMS 2019 NCOV
Response Lab TF Clearance
<eocevent216@cdc.gov>; Dunworth, Soumya
(CDC/DDPHSS/CSELS/OD) <kya6@cdc.gov>
Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD)
<bbl/@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)
<xhg9@cdc.gov>; Segaloff, Hannah
(CDC/DDPHSS/CSELS/DSEPD)
<qdz0@cdc.gov>; Moon, Jonathan L.
(CDC/DDID/NCEZID/DSR) <iki5@cdc.gov>
Subject: RE: Shedding of Infectious SARS-CoV2 Despite Vaccination when the Delta Variant
is Prevalent

Thanks Shelbi!

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) <qqv9@cdc.gov>
Sent: Tuesday, August 17, 2021 12:43 PM
To: CDC IMS 2019 NCOV Response Lab TF
Clearance <eocevent216@cdc.gov>; Kools,

Clearance <<u>eocevent216@cdc.gov</u>>; Kools, John J. (CDC/DDID/NCEZID/OD) <<u>czk7@cdc.gov</u>>; Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) <<u>kya6@cdc.gov</u>>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD)
< bb/>
bb/7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)
< chgo@cdc.gov>; Sogaloff, Happah

<<u>xhg9@cdc.gov</u>>; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD)

<<u>qdz0@cdc.gov</u>>; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) <<u>iki5@cdc.gov</u>>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Afternoon,

This has been approved for expedited clearance.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov
Cell:

From: Bialek, Stephanie R.

(CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov> Sent: Tuesday, August 17, 2021 12:40 PM To: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov> Cc: Fisher, Angela H.

(CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) <xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thank you. I approve expedited clearance. Stephanie Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 12:16 PM

To: Bialek, Stephanie R.

(CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H.

(CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) <xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hey Stephanie,

Please see attached for the updated draft.

Thanks, Shelbi Davis Communication Lead Health Communication Specialist Laboratory and Testing Task Force COVID-19 Emergency Response Centers for Disease Control and Prevention Lab TF Communications

Mailbox: eocevent503@cdc.gov

Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 11:05 AM

To: Bialek, Stephanie R.

(CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H.

(CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Sure thing, working on the updated draft now.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov
Cell:

From: Bialek, Stephanie R.

(CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>
Sent: Tuesday, August 17, 2021 10:56 AM
To: Davis, Shelbi (CDC/DDID/NCIRD/DVD)
<qqv9@cdc.gov>

Cc: Fisher, Angela H.
(CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov>;
Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)
<xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Yes, please request an updated draft with Hannah's name on it and then I approve it going for expedited clearance.

Stephanie Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:56 AM

To: Bialek, Stephanie R.

(CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H.

(CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hey Stephanie,

From correspondence with ADS and STLT Hannah was inadvertently left off the manuscript but WI has confirmed that she is a co-author but her name is not on this draft. Should we request an updated draft with Hannah information on there as the co-author?

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

Sent: Tuesday, August 17, 2021 10:51 AM

To: Bialek, Stephanie R.

(CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H.

<qqv9@cdc.gov>

(CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Неу,

I am working on getting clarification as we speak, update to follow.

Thanks,
Shelbi Davis
Communication Lead

Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R.

(CDC/DDID/NCIRD/DVD) <zqg7@cdc.gov>
Sent: Tuesday, August 17, 2021 10:49 AM
To: Davis, Shelbi (CDC/DDID/NCIRD/DVD)
<qqv9@cdc.gov>

Cc: Fisher, Angela H.
(CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov >;
Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)
< xhg9@cdc.gov >

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hannah Segaloff EISO is listed on the clearance request form as an author but not on the manuscript. Can you clarify that she indeed and author? If so, then my approval for expedited clearance stands.

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) <auv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:40 AM

To: Bialek, Stephanie R.

(CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H.

(CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) <xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thanks for the speedy response!

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov
Cell:

From: Bialek, Stephanie R.

(CDC/DDID/NCIRD/DVD) <zqg7@cdc.gov>
Sent: Tuesday, August 17, 2021 10:39 AM
To: Davis, Shelbi (CDC/DDID/NCIRD/DVD)
<qqv9@cdc.gov>

Cc: Fisher, Angela H.

(CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov>;

Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

I approve.

Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) qqv9@cdc.gov

Sent: Tuesday, August 17, 2021 10:38 AM

To: Bialek, Stephanie R.

(CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H.

(CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Morning Stephanie,

Happy Tuesday! We would like to request DIM1 expedited approval for the attached manuscript. Please refer to the email thread below.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Lab TF Communications

Mailbox: eocevent503@cdc.gov

Cell:

From: CDC IMS 2019 NCOV Response Lab TF

Clearance < < eocevent 216@cdc.gov >

Sent: Tuesday, August 17, 2021 10:32 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<<u>qqv9@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<<u>xhg9@cdc.gov</u>>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent 216 @cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hi Shelbi and Jarrett.

Should I begin clearance on this item or wait until you receive the DIM approval?

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Kools, John J. (CDC/DDID/NCEZID/OD)

<czk7@cdc.gov>

Sent: Tuesday, August 17, 2021 9:59 AM

To: CDC IMS 2019 NCOV Response Lab TF

Clearance <eocevent216@cdc.gov>; Davis,
Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Cc: Dunworth, Soumya
(CDC/DDPHSS/CSELS/OD) < kya6@cdc.gov>;
Limbago, Brandi (CDC/DDID/NCIRD/OD)

bbl7@cdc.gov>; Moon, Jonathan L.
(CDC/DDID/NCEZID/DSR) < iki5@cdc.gov>;
Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI)

<gif7@cdc.gov>; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD)

<qdz0@cdc.gov>

Subject: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Good Morning,

You may have heard but our task force was asked by STLT, and we agreed, to sponsor this manuscript through clearance. The authors are targeting NEJM and are requesting our task force to request IM approval for expedited clearance. Our main POC for this manuscript is our CDC EISO Hannah Segaloff (Cc'd). Let me know if you have any questions.

Hannah- our clearance team can help shepherd your paper through clearance. I would anticipate our laboratory SMEs to have some questions for your team.

Best regards,

John

John Kools

ADS, Laboratory & Testing Task Force
CDC COVID-19 Response
Phone:

From: Rose, Dale A. (CDC/DDID/NCEZID/DPEI)

<ido8@cdc.gov>

Sent: Tuesday, August 17, 2021 4:51 AM **To:** Kools, John J. (CDC/DDID/NCEZID/OD)

<czk7@cdc.gov>

Subject: FW: Follow up on your results

Morning John! Thanks for taking this on. We had intensive discussions with WI, IM, and MMWR last week about this. There's strong interest in supporting and moving this forward quickly in clearance, including securing approval for expedited clearance so it can quickly make it to NEJM for consideration. If you anticipate any issues

with the content or timing, please do let me know as our TF is in routine conversation with the state epi and want to make sure we're aligned in our discussions.

Much appreciated, and I hope you are well!

Best,

Dale

Dale Rose, Ph.D.
STLT Support Task Force
Cell:

From: Llewellyn, Anna C.

(CDC/DDID/NCEZID/DPEI) <gif7@cdc.gov>
Sent: Monday, August 16, 2021 3:35 PM
To: Segaloff, Hannah (CDC dhs.wisconsin.gov)
<hannah.segaloff@dhs.wisconsin.gov>; Rose,
Dale A. (CDC/DDID/NCEZID/DPEI)
<ido8@cdc.gov>; Westergaard, Ryan
(CDC dhs.wisconsin.gov)
<ryan.westergaard@dhs.wisconsin.gov>;
Bisgard, Kris (CDC/DDPHSS/CSELS/DSEPD)
<kmb6@cdc.gov>

Cc: Ricaldi Camahuali, Jessica
(CDC/DDID/NCEZID/DPEI) < mpi7@cdc.gov>;
Kools, John J. (CDC/DDID/NCEZID/OD)
<czk7@cdc.gov>; Limbago, Brandi
(CDC/DDID/NCIRD/OD) < bbl7@cdc.gov>;
Moon, Jonathan L. (CDC/DDID/NCEZID/DSR)
<iki5@cdc.gov>; CDC IMS 2019 NCOV
Response STLT ADS < eocevent410@cdc.gov>;
CDC IMS 2019 NCOV Response Lab Task Force
<eocevent177@cdc.gov>

Subject: Re: Follow up on your results

Dear Hannah,

Thank you for these additional documents. Due to this manuscript's focus on laboratory data, our Laboratory and Testing Task Force colleagues have agreed to be the sponsoring task force for CDC COVID-19 Response clearance. John Kools

is the Lab TF ADS and can assist with next steps.

Best Regards,

Anna

Anna Llewellyn, PhD
Associate Director for Science
State, Tribal, Local, and Territorial Support Task
Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Office: 404-639-1538 | Cell:
eocevent410@cdc.gov

From: Segaloff, Hannah E - DHS
<hannah.segaloff@dhs.wisconsin.gov>
Sent: Monday, August 16, 2021 3:13 PM
To: Rose, Dale A. (CDC/DDID/NCEZID/DPEI)
<ido8@cdc.gov>; Westergaard, Ryan
(CDC dhs.wisconsin.gov)
<ryan.westergaard@dhs.wisconsin.gov>;
Bisgard, Kris (CDC/DDPHSS/CSELS/DSEPD)

Thank you. I have attached the concept proposal that was approved from the original MMWR submission as well as a clearance request form.

Sincerely, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking Cell:

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

<Reimersma_Viral loads in vaccinees_ NEJM_editedauthorlist_LABTFCOMMENTS.docx>

--

http://dho.pathology.wisc.edu @dho • 608-890-0845 From: <u>Dave O"Connor</u>

To: dg2810@cumc.columbia.edu
Cc: Thomas Friedrich; Peter Halfmann

Subject: Re: [EXTERNAL] Automatic reply: Preprint: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the

Delta Variant is Prevalent - Wisconsin, July 2021

Date: Sunday, August 15, 2021 12:56:22 PM

Yeah, Tom and I were on TWIV a few times several years back. At that time we were talking about predicting future pandemic threats and coping with Zika virus with real-time data sharing. In this era of preprints and what not, it seems both quaint and forever ago!

dave

dg2810@cumc.columbia.edu wrote on 8/15/21 12:45 PM:

Dave,

Appreciate the information. I am planning on discussing your preprint on our next TWIV so would look forward to the quantitative data! Not sure if you are a listener to any of our podcasts. https://www.microbe.tv

Daniel

On Aug 15, 2021, at 10:58 AM, DAVID H O'CONNOR < dhoconno@wisc.edu> wrote:

Hi Daniel,

Not yet. Hopefully Peter from Yoshi's lab will have quantitative data later this coming week or next week. Initial goal was to simply address the criticism that the high PCR levels didn't correspond to replication competent virus.

Cheers,

Dave

Get Outlook for iOS

From: dg2810@cumc.columbia.edu <dg2810@cumc.columbia.edu>

Sent: Sunday, August 15, 2021 7:22 AM

To: DAVID H O'CONNOR

Subject: Fwd: [EXTERNAL] Automatic reply: Preprint: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent - Wisconsin, July 2021

Dr O'Connor,

I forwarded my email you way as suggested by Dr Grande,

Look forward to your response

I hope this email finds you well. I was hoping to a ask a few questions about the preprint Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021.

You report "Infectious SARS-CoV-2 was isolated from 14 of 16 specimens (88%) from unvaccinated individuals and 37 of 39 specimens (95%) from vaccinated people."

In figure 2 According to figure 2 Infectiousness was determined by the presence of cytopathic effects (CPE) after 5 days of replication in Vero E6 TMPRSS2 cells with visually apparent CPE under a light microscope. Any real time monitoring or quantification?

Sincerely,

Daniel Griffin, MD PhD CTropMed CTH
Chief Division of Infectious Disease ProHEALT

Chief, Division of Infectious Disease - ProHEALTH, an OPTUM Company

Senior Fellow for Infectious Disease - UHG Research and Development

Clinical Instructor of Medicine - Columbia University College of Physicians and Surgeons

Department of Medicine-Division of Infectious Diseases President -Parasites Without Borders

1 Dakota Drive Suite 205

New Hyde Park, NY 11042 Office Tel: (516)-656-6500

Cell:

Email: danielgriffinmd@gmail.com www.parasiteswithoutborders.com www.microbe.tv

Twitter @DanielGriffinMD

Begin forwarded message:

From: "Grande, Katarina"

< KGrande@publichealthmdc.com>

Subject: [EXTERNAL] Automatic reply: Preprint:

Shedding of Infectious SARS-CoV-2 Despite

Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021

Date: August 14, 2021 at 10:43:41 PM EDT

To: "Griffin, Daniel" < dg2810@cumc.columbia.edu>

I will return to the office on Monday, August 16.

For public health COVID data questions, please reach out to Brittany Grogan, Manjari Ojha, or Crystal Gibson.

For questions related to the medRxiv pre-print, please contact Tom Friedrich [tfriedri@wisc.edu] or Dave O'Connor [dhoconno@wisc.edu]

If you need to reach someone at Public Health Madison & Dane County more urgently, please call 608-266-4821 to speak with a receptionist.

--

http://dho.pathology.wisc.edu @dho • 608-890-0845 From: **Thomas Friedrich** To: Katarina Grande **DAVID H O"CONNOR** Cc:

Subject: Re: medRxiv -- Manuscript Screened Date: Wednesday, August 11, 2021 3:50:38 PM

And, to be totally clear, I suspect they will not view those 2 things as sufficiently novelty-inducing.

So my expectation is that we'll submit elsewhere, perhaps to Nature Med or Nature Communications.

-T

Thomas Friedrich

Professor Dept. Pathobiological Sciences University of Wisconsin School of Veterinary Medicine @tcfriedrich @tcf-lab www.vetmed.wisc.edu/friedrichlab

> On 11 Aug 2021, at 15:47, Grande, Katarina < KGrande@publichealthmdc.com > wrote:

> Totally fair! Got it. > > -----Original Message-----

> From: Thomas Friedrich <tfriedri@wisc.edu> > Sent: Wednesday, August 11, 2021 3:45 PM

> To: Grande, Katarina < KGrande@publichealthmdc.com> > Cc: DAVID H O'CONNOR <dhoconno@wisc.edu>

> Subject: Re: medRxiv -- Manuscript Screened

> Importance: High

> >

> Caution: This email was sent from an external source. Avoid unknown links and attachments.

>

> The data are already up, it's just that the main page for the preprint was still showing the old abstract. So too late.

> Between us, I think MMWR is way behind the times on that. My gut feeling is that we should go ahead and submit elsewhere, unless they accept a few extra tidbits of new data that would make the manuscript novel. These could be:

>

- > 1. Expand cell culture data to include the 14 samples from partially vaxed people.
- > 2. Include description of Ct values in 53 serial samples.

> I would not do any new experiments now to satisfy MMWR requirements, because they have already burned us once. There is no guarantee that they will take it, or that they will move with any speed faster than glacial, even if they agree to consider it.

> > -T

```
> Thomas Friedrich
> Professor
> Dept. Pathobiological Sciences
> University of Wisconsin
> School of Veterinary Medicine
> @tcfriedrich
> @tcf-lab
> www.vetmed.wisc.edu/friedrichlab
>> On 11 Aug 2021, at 15:33, Grande, Katarina < KGrande@publichealthmdc.com > wrote:
>> Should we intervene/revoke given MMWR just said they don't allow data shared in a pre-print???
>>
>>
>> ----Original Message-----
>> From: medrxiv@cshlbp.org <medrxiv@cshlbp.org>
>> Sent: Wednesday, August 11, 2021 3:33 PM
>> To: dhoconno@wisc.edu; Grande, Katarina < KGrande@publichealthmdc.com>
>> Subject: medRxiv -- Manuscript Screened
>>
>>
>>
>> Caution: This email was sent from an external source. Avoid unknown links and attachments.
>>
>> MS ID#: MEDRXIV/2021/261387
>> MS TITLE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent -
Wisconsin, July 2021
>>
>> Dear Dr. Grande,
>> We are pleased to inform you that the above manuscript has passed screening and will be online shortly.
Processing typically completes same or next day (occasionally longer if over a weekend or a holiday).
>>
>> Once an article is published in a journal, medRxiv will automatically update the preprint with a link to the
published version. Depending on the journal, this process may take up to two weeks.
>> The medRxiv team
```

DAVID H O"CONNOR From: To: Grande, Katarina **Thomas Friedrich**

Re: medRxiv -- Manuscript Screened Subject: Date: Wednesday, August 11, 2021 3:43:30 PM

Nope, our previous experience with MMWR was not positive. CDC can take our data if they want it for MMWR. If they don't, that's OK too. Their preprint policy is backwards and nonsensical.

dave

Grande, Katarina wrote on 8/11/21 3:33 PM:

Should we intervene/revoke given MMWR just said they don't allow data shared in a pre-print???

----Original Message----

From: medrxiv@cshlbp.org <medrxiv@cshlbp.org>
Sent: Wednesday, August 11, 2021 3:33 PM To: dhoconno@wisc.edu; Grande, Katarina KGrande@publichealthmdc.com>

Subject: medRxiv -- Manuscript Screened

Caution: This email was sent from an external source. Avoid unknown links and attachments.

MS ID#: MEDRXIV/2021/261387 MS TITLE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021

Dear Dr. Grande,

We are pleased to inform you that the above manuscript has passed screening and will be online shortly. Processing typically completes same or next day (occasionally longer if over a weekend or a holiday).

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The medRxiv team

http://dho.pathology.wisc.edu @dho • 608-890-0845

From: Thomas Friedrich (Google Docs)

To: **DAVID H O"CONNOR**

Subject: Shedding of Infec... - An additional relatively recent one (...

Date: Wednesday, October 27, 2021 5:55:16 PM

Thomas Friedrich resolved a comment in the following document



Shedding of Infectious SARS-CoV-2 Despite Vaccination

Bergwerk et al. 2021



Katarina Grande

An additional relatively recent one (9/8) to cite may be: https://www.nejm.org/doi/full/10.1056/NEJMc2106757

"We provide empirical evidence suggesting that vaccination may reduce transmission by showing that vaccination of health care workers is associated with a decrease in documented cases of Covid-19 among members of their households."



Thomas Friedrich



Marked as resolved

Open

Google LLC, 1600 Amphitheatre Parkway, Mountain View, CA 94043, USA

You have received this email because you are subscribed to all discussions on Shedding of Infectious SARS-CoV-2 Despite Vaccination. Change what Google Docs sends you. You can reply to this email to reply to the discussion.



From: Thomas Friedrich (Google Docs)

DAVID H O"CONNOR To:

Subject: Shedding of Infec... - Instead of Eyre who found that vaccin...

Date: Wednesday, October 27, 2021 4:21:41 PM



Shedding of Infectious SARS-CoV-2 Despite Vaccination

Eyre et al. 2021



Katarina Grande

Instead of Eyre who found that vaccination lowered the odds of transmitting to contacts, how about citing Gage's new lab's paper that looked at genomic and epi data from P-

town: https://www.medrxiv.org/content/10.1101/2021.10.20.21265137v1.fulltext conclusion: "Together, genomic epidemiology provides a high-resolution picture of the Provincetown outbreak, revealing multiple cases of transmission of Delta from fully vaccinated individuals. However, despite its magnitude, the outbreak was restricted in its onward impact in MA and the US, likely due to high vaccination rates and a robust public health response."



Thomas Friedrich New



Marked as resolved

Open

Google LLC, 1600 Amphitheatre Parkway, Mountain View, CA 94043, USA

You have received this email because you are subscribed to all discussions on Shedding of Infectious SARS-CoV-2 Despite Vaccination. Change what Google Docs sends you. You can reply to this email to reply to the discussion.

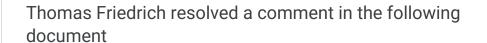


From: Thomas Friedrich (Google Docs)

To: <u>DAVID H O"CONNOR</u>

Subject: Shedding of Infec... - This study (updated 10/5 on medrix) c...

Date: Wednesday, October 27, 2021 5:35:32 PM



Shedding of Infectious SARS-CoV-2 Despite Vaccination

other studies



This study (updated 10/5 on medrix) cited

ours: https://www.medrxiv.org/content/10.1101/2021.09.28.21264262v2.full-text

and basically had the same findings and conclusions as our study.

Thomas Friedrich Ne

Marked as resolved

Open

Google LLC, 1600 Amphitheatre Parkway, Mountain View, CA 94043, USA

You have received this email because you are subscribed to all discussions on Shedding of Infectious SARS-CoV-2 Despite Vaccination. Change what Google Docs sends you. You can reply to this email to reply to the discussion.



From: <u>Katarina Grande (Google Docs)</u>

To: <u>DAVID H O"CONNOR</u>

Subject: Shedding of Infec... - This study (updated 10/5 on medrix) c...

Date: Tuesday, October 26, 2021 5:32:48 PM



Shedding of Infectious SARS-CoV-2 Despite Vaccination

other studies





This study (updated 10/5 on medrix) cited ours: https://www.medrxiv.org/content/10.1101/2021.09.28.21264262v2.full-text

and basically had the same findings and conclusions as our study.

Open

Google LLC, 1600 Amphitheatre Parkway, Mountain View, CA 94043, USA

You have received this email because you are subscribed to all discussions on Shedding of Infectious SARS-CoV-2 Despite Vaccination. Change what Google Docs sends you. You can reply to this email to reply to the discussion.

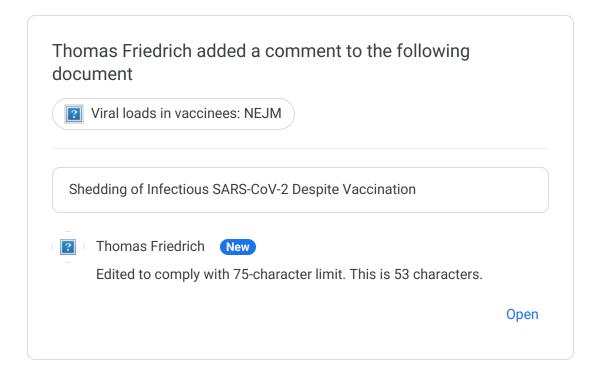


From: Thomas Friedrich (Google Docs)

To: DAVID H O"CONNOR

Subject: Viral loads in va... - Edited to comply with 75-character li...

Date: Tuesday, August 17, 2021 2:50:23 PM



Google LLC, 1600 Amphitheatre Parkway, Mountain View, CA 94043, USA

You have received this email because you are subscribed to all discussions on Viral loads in vaccinees: NEJM. Change what Google Docs sends you. You can reply to this email to reply to the discussion.



From: medrxiv@cshlbp.org

To: <u>DAVID H O"CONNOR</u>; <u>kgrande@publichealthmdc.com</u>

Subject: medRxiv -- Manuscript Screened

Date: Wednesday, August 25, 2021 1:41:54 AM

MS ID#: MEDRXIV/2021/261387

MS TITLE: Shedding of Infectious SARS-CoV-2 Despite Vaccination

Dear Dr. Grande,

We are pleased to inform you that the above manuscript has passed screening and will be online shortly. Processing typically completes same or next day (occasionally longer if over a weekend or a holiday).

Once an article is published in a journal, medRxiv will automatically update the preprint with a link to the published version. Depending on the journal, this process may take up to two weeks.

Cc: kgrande@publichealthmdc.com

Subject: medRxiv -- Please Approve Your Submission **Date:** Friday, November 5, 2021 5:17:12 PM

This is an automatic notification that the file(s) for manuscript MEDRXIV/2021/261387 ("Shedding of Infectious SARS-CoV-2 Despite Vaccination" by Katarina M Grande) have been successfully uploaded and converted to PDF format. This DOES NOT mean that the manuscript has been submitted.

To complete the submission process, please click on https://submit.medrxiv.org/submission/submit?
msid=MEDRXIV/2021/261387. (Alternatively, log into https://submit.medrxiv.org, enter your "Author Area," and click on "Ready for You to Proof.") Once you have approved your submission, you will receive an email message confirming it.

Please note that only an author on the paper can complete the submission. If you are not an author on the paper and the corresponding author does not yet have a medRxiv account, then they will need to create an account first, using the email address included in the submission. The paper then will appear in their Author Area at https://submit.medrxiv.org.

Thank you for your submission.

Cc: kgrande@publichealthmdc.com

Subject: medRxiv -- Please Approve Your Submission **Date:** Wednesday, August 11, 2021 11:03:16 AM

This is an automatic notification that the file(s) for manuscript MEDRXIV/2021/261387 ("Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021" by Katarina M Grande) have been successfully uploaded and converted to PDF format. This DOES NOT mean that the manuscript has been submitted.

To complete the submission process, please click on https://submit.medrxiv.org/submission/submit?
msid=MEDRXIV/2021/261387. (Alternatively, log into https://submit.medrxiv.org, enter your "Author Area," and click on "Ready for You to Proof.") Once you have approved your submission, you will receive an email message confirming it.

Please note that only an author on the paper can complete the submission. If you are not an author on the paper and the corresponding author does not yet have a medRxiv account, then they will need to create an account first, using the email address included in the submission. The paper then will appear in their Author Area at https://submit.medrxiv.org.

Thank you for your submission.

 Cc:
 kgrande@publichealthmdc.com

 Subject:
 medRxiv -- Revision Acknowledgment

 Date:
 Tuesday, August 10, 2021 5:47:03 PM

MS ID#: MEDRXIV/2021/261387

MS TITLE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent -

Wisconsin, July 2021

Dear Dr. Grande,

This is to acknowledge the receipt of your revised paper.

If you would like to make changes to your revision submission prior to it being approved for posting on medRxiv, please contact medRxiv at medrxiv@cshl.edu and we will return your submission. Do not create a new submission to update your manuscript as this will create a duplicate submission and will significantly delay the screening of your manuscript.

Be certain to visit https://submit.medrxiv.org and login to the "author area." Once logged in, you may check on the status of your manuscript.

Cc:kgrande@publichealthmdc.comSubject:medRxiv -- Revision AcknowledgmentDate:Monday, August 23, 2021 2:02:20 PM

MS ID#: MEDRXIV/2021/261387

MS TITLE: Shedding of Infectious SARS-CoV-2 Despite Vaccination

Dear Dr. Grande,

This is to acknowledge the receipt of your revised paper.

If you would like to make changes to your revision submission prior to it being approved for posting on medRxiv, please contact medRxiv at medrxiv@cshl.edu and we will return your submission. Do not create a new submission to update your manuscript as this will create a duplicate submission and will significantly delay the screening of your manuscript.

Be certain to visit https://submit.medrxiv.org and login to the "author area." Once logged in, you may check on the status of your manuscript.

From: Segaloff, Hannah E - DHS

To: Kasen Riemersma; Katarina Grande; DAVID H O"CONNOR; Thomas Friedrich

Subject: FW: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Date: Monday, August 23, 2021 11:52:52 AM

Attachments: COPY EOC Riemersma Viral loads in vaccinees NEJM revised 8 21 resubmissiontoJICclearance FOR

OS OS.docx

Hi all,

We are cleared! There are some extremely tiny comments to incorporate/consider. Once we submit they just want me to send a final copy for their records. Note that I made two additional small changes (

without sending it back to facilitate quick review- so you many want to upload this version.

Thanks for your patience with this painful process!

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

Hannah. Segal of f@dhs. wis consin. gov

Qdz0@cdc.gov

From: CDC IMS 2019 NCOV Response Lab TF Clearance <eocevent216@cdc.gov>

Sent: Monday, August 23, 2021 11:47 AM

To: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) <qdz0@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance <eocevent216@cdc.gov>

Subject: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah:

The attached document has been cleared by JIC with comments.

Once you have addressed the reviewer's feedback, please send us a clean and final document, so we can provide it to JIC for their records.

JIC OS Content Comment.

Very informative study. It is approved with minor comments, see attached

Thanks,

Audrey

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM) From: Segaloff, Hannah E - DHS

To: Kasen Riemersma; DAVID H O"CONNOR; Thomas Friedrich; Katarina Grande

Subject: FW: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Date: Thursday, August 19, 2021 9:41:38 AM

Attachments: Reimersma Viral loads in vaccinees NEJM editedauthorlist LABTFCOMMENTS.docx

Hi All,

Here are the first round of comments. We should get all responses within 24 to 48 hours of our submission. It looks like this needs to be approved by Lab TF, cross clearance and the response. Let me know if I can help with comments.

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: CDC IMS 2019 NCOV Response Lab TF Clearance <eocevent216@cdc.gov>

Sent: Thursday, August 19, 2021 9:24 AM

To: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) <qdz0@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance <eocevent216@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah,

Please address the mandatory comments and return for re-review.

Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thank you, Alexis CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < adz0@cdc.gov>

Sent: Wednesday, August 18, 2021 9:18 AM

To: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent 216@cdc.gov >

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Hello,

Thank you for the quick work getting this approved for DIM expedited clearance. I haven't had a manuscript in expedited clearance before. Does it have the same steps as standard? How much time should I anticipate for the clearance process?

Thank you! Hannah

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < gqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 11:51 AM

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

NP! Glad we were able to turn this around so quickly.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov>

Sent: Tuesday, August 17, 2021 12:47 PM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) <aavy@cdc.gov>; CDC IMS 2019 NCOV Response Lab TF Clearance <eocevent216@cdc.gov>; Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) kva6@cdc.gov>"kva6@cdc.gov">kva6@cdc.gov>"cc: Limbago, Brandi (CDC/DDID/NCIRD/OD) bbl7@cdc.gov; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) xhg9@cdc.gov; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) qdz0@cdc.gov; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) kis5@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thanks Shelbi!

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) qqv9@cdc.gov

Sent: Tuesday, August 17, 2021 12:43 PM

To: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent216@cdc.gov; Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov; Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) < kya6@cdc.gov)

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD) < blf@cdc.gov"> ; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov ; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < qdz0@cdc.gov ; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < kis6@cdc.gov >

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Afternoon,

This has been approved for expedited clearance.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov >

Sent: Tuesday, August 17, 2021 12:40 PM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < <u>xhg9@cdc.gov</u>>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thank you. I approve expedited clearance.

Stephanie
Stephanie R. Bialek MD MPH
Deputy Incident Manager
COVID-19 Response
CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 12:16 PM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Hey Stephanie,

Please see attached for the updated draft.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 11:05 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov >; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Sure thing, working on the updated draft now.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:56 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Yes, please request an updated draft with Hannah's name on it and then I approve it going for expedited clearance.

Stephanie
Stephanie R. Bialek MD MPH
Deputy Incident Manager
COVID-19 Response
CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:56 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < <u>zqg7@cdc.gov</u>>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov >; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hey Stephanie,

From correspondence with ADS and STLT Hannah was inadvertently left off the manuscript but WI has confirmed that she is a co-author but her name is not on this draft. Should we request an updated draft with Hannah information on there as the co-author?

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:51 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Неу,

I am working on getting clarification as we speak, update to follow.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:49 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < ggv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Hannah Segaloff EISO is listed on the clearance request form as an author but not on the manuscript. Can you clarify that she indeed and author? If so, then my approval for expedited clearance stands.

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:40 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Thanks for the speedy response!

Thanks,

Shelbi Davis

Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:39 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < qqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

I approve.

Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:38 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Morning Stephanie,

Happy Tuesday! We would like to request DIM1 expedited approval for the attached manuscript. Please refer to the email thread below.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent 216@cdc.gov >

Sent: Tuesday, August 17, 2021 10:32 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < qqv9@cdc.gov; Gartin, Jarrett (CDC/DDID/NCIRD/OD)

 $(CTR) < \frac{xhg9@cdc.gov}{}$

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent216@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Hi Shelbi and Jarrett,

Should I begin clearance on this item or wait until you receive the DIM approval?

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov>

Sent: Tuesday, August 17, 2021 9:59 AM

To: CDC IMS 2019 NCOV Response Lab TF Clearance <<u>eocevent216@cdc.gov</u>>; Davis, Shelbi (CDC/DDID/NCIRD/DVD) <<u>qqv9@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) <<u>xhg9@cdc.gov</u>>

Cc: Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) < kya6@cdc.gov; Limbago, Brandi (CDC/DDID/NCIRD/OD) < bbl7@cdc.gov; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < iki5@cdc.gov; Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI) < gif7@cdc.gov; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < qdz0@cdc.gov>

Subject: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Good Morning,

You may have heard but our task force was asked by STLT, and we agreed, to sponsor this manuscript through clearance. The authors are targeting NEJM and are requesting our task force to request IM approval for expedited clearance. Our main POC for this manuscript is our CDC EISO Hannah Segaloff (Cc'd). Let me know if you have any questions.

Hannah- our clearance team can help shepherd your paper through clearance. I would anticipate our

laboratory SMEs to have some questions for your team.
Best regards,
John
John Kools ADS, Laboratory & Testing Task Force CDC COVID-19 Response Phone: 404-217-7258
From: Rose, Dale A. (CDC/DDID/NCEZID/DPEI) < ido8@cdc.gov> Sent: Tuesday, August 17, 2021 4:51 AM To: Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov> Subject: FW: Follow up on your results
Morning John! Thanks for taking this on. We had intensive discussions with WI, IM, and MMWR last week about this. There's strong interest in supporting and moving this forward quickly in clearance, including securing approval for expedited clearance so it can quickly make it to NEJM for consideration. If you anticipate any issues with the content or timing, please do let me know as our TF is in routine conversation with the state epi and want to make sure we're aligned in our discussions.
Much appreciated, and I hope you are well!
Best, Dale
Dale Rose, Ph.D. STLT Support Task Force Cell:
From: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI) < gif7@cdc.gov > Sent: Monday, August 16, 2021 3:35 PM To: Segaloff, Hannah (CDC dhs.wisconsin.gov) < hannah.segaloff@dhs.wisconsin.gov >; Rose, Dale A. (CDC/DDID/NCEZID/DPEI) < ido8@cdc.gov >; Westergaard, Ryan (CDC dhs.wisconsin.gov) < ryan.westergaard@dhs.wisconsin.gov >; Bisgard, Kris (CDC/DDPHSS/CSELS/DSEPD) < kmb6@cdc.gov >

Cc: Ricaldi Camahuali, Jessica (CDC/DDID/NCEZID/DPEI) < mpi7@cdc.gov; Kools, John J.

 $(\texttt{CDC/DDID/NCEZID/OD}) < \underline{\mathsf{czk7@cdc.gov}}; \ \mathsf{Limbago}, \ \mathsf{Brandi} \ (\texttt{CDC/DDID/NCIRD/OD}) < \underline{\mathsf{bbl7@cdc.gov}}; \ \mathsf{Limbago}; \ \mathsf{Brandi} \ \mathsf{CDC/DDID/NCIRD/OD}) < \underline{\mathsf{bbl7@cdc.gov}}; \ \mathsf{Limbago}; \ \mathsf{CDC/DDID/NCIRD/OD}) < \underline{\mathsf{cdc.gov}}; \ \mathsf{Limbago}; \ \mathsf{CDC/DDID/NCIRD/OD}) < \underline{\mathsf{cdc.gov}}; \ \mathsf{CDC/DDID/NCIRD/OD}$

IR#0682H_000538

Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < iki5@cdc.gov >; CDC IMS 2019 NCOV Response STLT ADS < eocevent410@cdc.gov >; CDC IMS 2019 NCOV Response Lab Task Force < eocevent177@cdc.gov >

Subject: Re: Follow up on your results

Dear Hannah,

Thank you for these additional documents. Due to this manuscript's focus on laboratory data, our Laboratory and Testing Task Force colleagues have agreed to be the sponsoring task force for CDC COVID-19 Response clearance. John Kools is the Lab TF ADS and can assist with next steps.

Best Regards,

Anna

Anna Llewellyn, PhD
Associate Director for Science
State, Tribal, Local, and Territorial Support Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Office: 404-639-1538 | Cell:
eocevent410@cdc.gov

From: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov>

Sent: Monday, August 16, 2021 3:13 PM

To: Rose, Dale A. (CDC/DDID/NCEZID/DPEI) < ido8@cdc.gov >; Westergaard, Ryan (CDC dhs.wisconsin.gov) < ryan.westergaard@dhs.wisconsin.gov >; Bisgard, Kris (CDC/DDPHSS/CSELS/DSEPD) < kmb6@cdc.gov >

Cc: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI) < gif7@cdc.gov >; Ricaldi Camahuali, Jessica (CDC/DDID/NCEZID/DPEI) < mpi7@cdc.gov >

Subject: RE: Follow up on your results

Thank you. I have attached the concept proposal that was approved from the original MMWR submission as well as a clearance request form.

Sincerely, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking Cell:
Hannah.Segaloff@dhs.wisconsin.gov
Odz0@cdc.gov

From: medicine@us.nature.com
To: Kasen Riemersma

Subject: NMED-BC116676 Receipt of New Paper by Nature Medicine

Date: Tuesday, November 2, 2021 2:05:05 PM

Dear Dr. Riemersma,

Please note that you are listed as a co-author on the manuscript "Shedding of Infectious SARS-CoV-2 Despite Vaccination" (reference number: NMED-BC116676), which was recently submitted to Nature Medicine.

The corresponding author is solely responsible for communicating with the journal and managing communication between co-authors. Please contact the corresponding author directly with any queries you may have related to this manuscript.

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Should you wish to publish your ORCID with this manuscript, please use the link below to access your account listed as co-author and attach your ORCID following

">these

instructions. Please note that it must be linked prior to acceptance, it will not be possible to add/modify ORCIDs at proof, and you may not receive further notification before an accept decision is made. Please ensure the ORCID is linked to your account associated with this manuscript, and not to any other account you may have on our system.

Login = Access your account

If you have any issues attaching an ORCID to your Manuscript Tracking System account, please contact the <u>Platform Support Helpdesk</u>.

Many thanks,

Editorial Assistant Nature Medicine medicine@us.nature.com

Our flexible approach during the COVID-19 pandemic

If you need more time at any stage of the peer-review process, please do let us know. While our systems will continue to remind you of the original timelines, we aim to be as flexible as possible during the current pandemic.

This email has been sent through the Springer Nature Tracking System NY-610A-NPG&MTS

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From: onbehalfof@manuscriptcentral.com

To: Kasen Riemersma

Subject: New England Journal of Medicine Letter NOT about NEJM Article 21-14060: Account Created for you in

ScholarOne Manuscripts

Date: Monday, August 23, 2021 1:39:11 PM

Dear Dr. Riemersma:

A submission entitled Shedding of Infectious SARS-CoV-2 Despite Vaccination (21-14060) has been submitted by Ms. Katarina Grande to the New England Journal of Medicine.

You are listed as a co-author for this manuscript. The online peer-review system, ScholarOne Manuscripts, automatically created a user account for you. Your USER ID and PASSWORD for your account is as follows:

Site URL: <u>https://mc05.manuscriptcentral.com/nejm</u>

USER ID:

PASSWORD: For security reasons your password is not contained in this e-mail. To set your password click the link below.

You can use the above USER ID and PASSWORD (once set) to log in to the site and check the status of papers you have authored/co-authored. Please log in to information via the edit account tab at the top right.

If you believe you already have an account with us and this is a duplicate account, or if you do not wish to have an account with the New England Journal of Medicine, please contact us and we will be happy to assist you.

Thank you for your participation.

Sincerely,

Editorial Office

New England Journal of Medicine 10 Shattuck Street Boston, MA 02115 (617) 734-9800

Fax: (617) 739-9864 http://www.nejm.org

Log in to Remove This Account - https://mc05.manuscriptcentral.com/nejm?

URL_MASK=aff86baeeeec40c2a55580f54819aa5c

From: <u>em.ppathogens.0.77467c.eff3e03c@editorialmanager.com</u> on behalf of <u>PLOS Pathogens</u>

To: Kasen Riemersma

Subject: PLOS Pathogens: Please confirm your authorship - [EMID:7906952a92501deb]

Date: Thursday, November 11, 2021 4:58:55 PM

Dear Riemersma,

You are receiving this email because Ms. Katarina M Grande listed you as an author on the manuscript titled "Shedding of Infectious SARS-CoV-2 Despite Vaccination," recently submitted to PLOS Pathogens.

All co-authors MUST confirm their authorship before a manuscript can be accepted for publication.

Click this link to CONFIRM your authorship and/or add your ORCID to this submission now:

The Corresponding Author has entered your name into our online submission system as indicated below. Please ensure your name is entered correctly, as this impacts indexing. If your name is not entered correctly, please confirm your authorship and then email the journal office at plospathogens@plos.org.

First Name: Kasen Middle Name: K. Last Name: Riemersma

Alternatively, if you are not aware of this submission, or if you should not be listed as a co-author, then please contact the journal office at plospathogens@plos.org.

We appreciate your timely response. The abstract follows below, for your reference.

Kind regards,

PLOS Pathogens Staff plospathogens@plos.org

.____

Manuscript Title:

Shedding of Infectious SARS-CoV-2 Despite Vaccination

Article Type: Research Article

Authors:

Katarina Maria Grande; Kasen K. Riemersma; Brittany E. Grogan; Amanda Kita-Yarbro; Peter J. Halfmann; Hannah E. Segaloff; Anna Kocharian; Kelsey R. Florek; Ryan Westergaard; Allen Bateman; Gunnar E. Jeppson; Yoshihiro Kawaoka; David H. O'Connor; Thomas C. Friedrich

Abstract:

The SARS-CoV-2 Delta variant is highly transmissible and contains mutations that confer partial immune escape. We compared RT-PCR cycle threshold (Ct) data from 699 test-positive anterior nasal swab specimens from fully vaccinated (n = 310) or unvaccinated (n=389) individuals. We observed low Ct values (<25) in 212 of 310 fully vaccinated (68%) and 246 of 389 (63%) unvaccinated individuals. Testing a subset of these low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people. To determine whether infectious virus titers differed in vaccinated and unvaccinated persons, we performed plaque assays on an additional set of 48 samples with Ct <25, finding no difference in infectious virus titer between groups.

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: https://www.editorialmanager.com/ppathogens/login.asp?a=r). Please contact the publication office if you have any questions.

From: Grande, Katarina To: "Jon Poling"

DAVID H O"CONNOR; Kasen Riemersma; Thomas Friedrich Cc:

Subject: RE: A question regarding your paper Date: Wednesday, August 25, 2021 4:36:36 PM

Attachments: image001.png

image002.png

Hi Dr. Poling,

Thank you for your email. We do not have these data, but this is a good question. Did you see this recent pre-print out of the UK?

Dr. O'Connor noted, in regard to your question, that this study showed a *lower* Ct in people who were reinfected than in those who were vaccinated, in line with the idea that vaccines provide better immunity than natural infection.

-Katarina

KATARINA GRANDE, MPH (pronouns: she/her/hers)

Public Health Supervisor/COVID-19 Data Team Lead | Public Health Madison & Dane County

2300 South Park St, Rm 2010, Madison, WI 53713

Phone: (608) 243-0409 | Cell: | Fax: (608) 266-4858

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From: Jon Poling cjpoling@athensneuro.com> Sent: Wednesday, August 25, 2021 12:43 PM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Subject: A question regarding your paper

Importance: High

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Dear Dr. Grande,

I read with interest your manuscript entitled--Shedding of Infectious SARS-CoV-2 Despite

Vaccination. Do you have data on shedding of infectious SARS COV2 in patients who have recovered from prior ancestral COVID19? In other words, does natural mucosal immunity provide better protection against transmissible virus in this wave of Delta or other VOCs? Thank-you in advance for your attention to my question.

Regards,

Jon S. Poling MD/PhD
Department Chair of Neurology/Neurosurgery, Piedmont ARMC Hospital
Clinical Asst Professor AU/GRU School of Medicine
Athens Neurological Assoc. PC
Board Certified in Neurology, Neuromuscular Medicine, and Neuroimaging
www.athensneuro.com

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From: Grande, Katarina
To: DAVID H O"CONNOR

 Cc:
 Kasen Riemersma; Thomas Friedrich

 Subject:
 RE: A question regarding your paper

 Date:
 Wednesday, August 25, 2021 2:51:12 PM

Attachments: <u>image001.png</u>

Ok great, will respond and cc you all.

From: Dave O'Connor <dhoconno@wisc.edu>
Sent: Wednesday, August 25, 2021 2:17 PM

To: Grande, Katarina < KGrande@publichealthmdc.com>

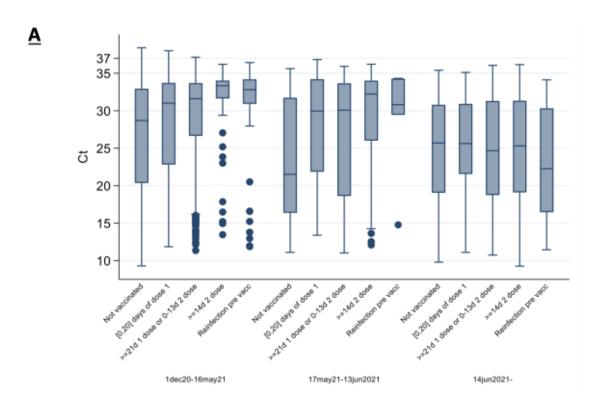
Cc: Kasen Riemersma <riemersma@wisc.edu>; Thomas Friedrich <tfriedri@wisc.edu>

Subject: Re: A question regarding your paper

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Hi Kat,

No, I don't think that data gets captured in the analysis. Though the UK study I shared earlier showed a *lower* Ct in people who were reinfected than in those who were vaccinated, in line with the idea that vaccines provide better immunity than natural infection.



Grande, Katarina wrote on 8/25/21 1:58 PM:

We don't have these data/didn't look at this—anything additional to add in a response to Jon, team?

From: Jon Poling spoling@athensneuro.com>
Sent: Wednesday, August 25, 2021 12:43 PM

To: Grande, Katarina < KGrande@publichealthmdc.com>

Subject: A question regarding your paper

Importance: High

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Dear Dr. Grande,

I read with interest your manuscript entitled--Shedding of Infectious SARS-CoV-2 Despite Vaccination. Do you have data on shedding of infectious SARS COV2 in patients who have recovered from prior ancestral COVID19? In other words, does natural mucosal immunity provide better protection against transmissible virus in this wave of Delta or other VOCs? Thank-you in advance for your attention to my question. Regards,

Jon S. Poling MD/PhD

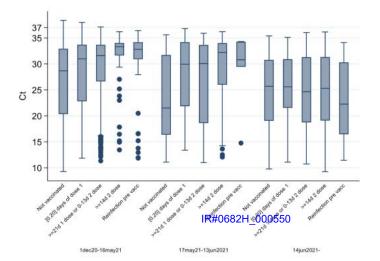
Department Chair of Neurology/Neurosurgery, Piedmont ARMC Hospital Clinical Asst Professor AU/GRU School of Medicine Athens Neurological Assoc. PC
Board Certified in Neurology, Neuromuscular Medicine, and Neuroimaging www.athensneuro.com

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__

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From: KGrande@publichealthmdc.com

To: <u>Thomas Friedrich</u>

Cc: Kasen Riemersma; DAVID H O"CONNOR; Grogan, Brittany

Subject: RE: Request to interview from National Geographic

Date: Thursday, August 12, 2021 4:01:45 PM

Heads up, I just chatted with Sanjay who had some public health policy questions. He plans to talk to y'all tomorrow! but if there's an emergent interview that needs a public health voice, Brittany is back and ready to be that voice!

Also Eric Topol tweeted the paper and the Nature coverage.

From: Sanjay Mishra <mishra.sanjay@outlook.com>

Sent: Thursday, August 12, 2021 3:26 PM **To:** Thomas Friedrich <tfriedri@wisc.edu>

Cc: Kasen Riemersma <riemersma@wisc.edu>; DAVID H O'CONNOR <dhoconno@wisc.edu>;

Grande, Katarina < KGrande@publichealthmdc.com>

Subject: RE: Request to interview from National Geographic

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Dear Tom, David and Kasen

I have been given go ahead to interview and write the story. Please suggest time(s) and what number(s) should I call? Anytime until 1 pm Central or after 4:30 Central would be fantastic.

Regards

Sanjay

Sanjay Mishra, MS, PhD

Nashville, TN 37221; USA

mishra.sanjay@outlook.com | @Ecquis | +1 (615) 829 6563

LinkedIn | Google Scholar | Contently | Skype

From: Thomas Friedrich

Sent: Thursday, August 12, 2021 3:20 PM

To: mishra.sanjay@outlook.com

Cc: <u>Kasen Riemersma</u>; <u>DAVID H O'CONNOR</u>; <u>Katarina Grande</u> **Subject:** Re: Request to interview from National Geographic

Hi Sanjay.

A follow up tomorrow sounds good. I am in meetings most of the rest of today anyway.

Best,

-Tom

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 12 Aug 2021, at 15:00, mishra.sanjay@outlook.com wrote:

Dear All

I really appreciate your reply. I will love to talk to you today, but I am still negotiating with my editors on how important and urgent your work is.

Can I reach out tomorrow, because I will hate to take your busy time in interviewing, but not being able to write about it.

I will love to talk to you today, if you prefer! Please advise.

Sanjay

Sanjay Mishra, MS, PhD
Nashville, TN 37221; USA
mishra.sanjay@outlook.com | @Ecquis | +1 (615) 829 6563
LinkedIn | Google Scholar | Contently | Skype

From: Kasen Riemersma

Sent: Thursday, August 12, 2021 2:56 PM

To: DAVID H O'CONNOR; KGrande@publichealthmdc.com

Cc: <u>'Sanjay Mishra'</u>; <u>Thomas Friedrich</u>

Subject: Re: Request to interview from National Geographic

I am unfortunately unavailable until tomorrow, but could chat anytime from 10-2 CDT then.

Kasen

From: DAVID H O'CONNOR < dhoconno@wisc.edu>

Date: Thursday, August 12, 2021 at 2:37 PM

To: KGrande@publichealthmdc.com

Cc: 'Sanjay Mishra' < mishra.sanjay@outlook.com >, Kasen Riemersma

<<u>riemersma@wisc.edu</u>>, Thomas Friedrich <<u>tfriedri@wisc.edu</u>>

Subject: Re: Request to interview from National Geographic

I can chat after 4:30 CDT, or go ahead without me!

dave

KGrande@publichealthmdc.com wrote on 8/12/21 2:36 PM:

Hi Dr. Mishra,

Thanks for reaching out. I could jump on a call after 3:30pm. I'm cc'ing my co-authors, who are the true scientists on the paper—I'm the applied public health person of the bunch. So depending on your angle, it may be helpful to link with them, or see if we could jump on a call together.

-Katarina

KATARINA GRANDE, MPH (pronouns: she/her/hers)

Public Health Supervisor/COVID-19 Data Team Lead | Public Health Madison &

Dane County

2300 South Park St, Rm 2010, Madison, WI 53713

Phone: (608) 243-0409 | Cell: | Fax: (608) 266-4858

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<image001.png>

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<image002.png>

From: Sanjay Mishra mishra.sanjay@outlook.com>

Sent: Thursday, August 12, 2021 2:07 PM

To: Grande, Katarina KGrande@publichealthmdc.com Subject: Request to interview from National Geographic

Importance: High

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Dear Katarina

I read your preprint posted earlier today with alarm: "Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021"

Can I urgently talk to you since I am pitching this as story to my editor at National Geographic, as a follow up to my recent stories on Delta variant, value of masking and breakthrough infections:

In National Geographic:

- 1. Why is Delta more infectious and deadly? New research holds answers. (August 6, 2021)
- 2. How dangerous is the new Delta Plus variant? Here's what we know. (July 2, 2021)
- 3. <u>The Delta variant is serious. Here's why it's on the rise.</u> (June 16, 2021); updated:
 - a. <u>The Delta variant is spreading fast, especially</u> where vaccination rates are low (July 8, 2021)
- 4. This 'double mutant' variant is adding fuel to India's COVID-19 crisis(April 28, 2021)

In The Conversation:

- 1. What is a breakthrough infection? 6 questions answered about catching COVID-19 after vaccination (July 28, 2021)
- 2. <u>Can people vaccinated against COVID-19 still spread the coronavirus?</u>(May 25, 2021)

I and the readers of National Geographic will highly appreciate it

Sanjay Mishra, MS, PhD
Nashville, TN 37221; USA
mishra.sanjay@outlook.com | @Ecquis | +1 (615) 829 6563
LinkedIn | Google Scholar | Contently | Skype

__

http://dho.pathology.wisc.edu @dho • 608-890-0845 From: <u>Grande, Katarina</u>

To: Segaloff, Hannah E - DHS; Kasen Riemersma; DAVID H O"CONNOR; Thomas Friedrich; bgrogan

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Date: Monday, August 23, 2021 12:07:01 PM

Thanks, Hannah!

Dave, you have everything you need to submit to the portal? I can lend a hand if you need anything.

-Kat

From: Segaloff, Hannah E - DHS <hannah.segaloff@dhs.wisconsin.gov>

Sent: Monday, August 23, 2021 11:53 AM

To: Kasen Riemersma <riemersma@wisc.edu>; Grande, Katarina <KGrande@publichealthmdc.com>;

DAVID H O'CONNOR <dhoconno@wisc.edu>; Thomas Friedrich <tfriedri@wisc.edu>

Subject: FW: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

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Hi all,

We are cleared! There are some extremely tiny comments to incorporate/consider. Once we submit they just want me to send a final copy for their records. Note that I made two additional small changes (added "qualitative in two places and deleted one word to keep it in the word count) without sending it back to facilitate quick review- so you many want to upload this version.

Thanks for your patience with this painful process!

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent 216@cdc.gov >

Sent: Monday, August 23, 2021 11:47 AM

To: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < adz0@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent216@cdc.gov>

Subject: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah:

The attached document has been cleared by JIC with comments.

Once you have addressed the reviewer's feedback, please send us a clean and final document, so we can provide it to JIC for their records.

JIC OS Content Comment.

• Very informative study. It is approved with minor comments, see attached Thanks,

Audrey

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM) From: Segaloff, Hannah E - DHS

To: Kasen Riemersma; DAVID H O"CONNOR; Thomas Friedrich

Cc: <u>Katarina Grande</u>; <u>Westergaard</u>, Ryan P - DHS

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Date: Saturday, August 21, 2021 4:33:45 PM

Attachments: Riemersma Viral loads in vaccinees NEJM revised 8 20 clean JICclearance-MDA MGG HScomments.docx

Sorry! I managed to not save my work before sending...

Use this one.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer

U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Segaloff, Hannah E - DHS

Sent: Saturday, August 21, 2021 4:32 PM

To: Kasen Riemersma <riemersma@wisc.edu>; DAVID H O'CONNOR <dhoconno@wisc.edu>; Thomas Friedrich

<tfriedri@wisc.edu>

Cc: Katarina Grande <kgrande@publichealthmdc.com>; Westergaard, Ryan P - DHS <ryan.westergaard@dhs.wisconsin.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thanks Kasen,

That was exactly what I needed.

I've addressed the comments I believe. I had to change some wording to fit in the words but changes are tracked if you don't like what I did.

Kasen, there's a few things I couldn't do or need you to check:



Unless they are feeling super prickly once we get this sent back we should get an approval, hopefully without comments but likely with a few.

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking Cell: **From:** Kasen Riemersma < <u>riemersma@wisc.edu</u>>

Sent: Saturday, August 21, 2021 3:30 PM

 $\textbf{To:} \ Segaloff, \ Hannah \ E-DHS < \underline{hannah.segaloff@dhs.wisconsin.gov}; \ DAVID\ H\ O'CONNOR < \underline{dhoconno@wisc.edu} >; \ Thomas$

Friedrich < tfriedri@wisc.edu>

Cc: Katarina Grande < kgrande@publichealthmdc.com >; Westergaard, Ryan P - DHS < ryan.westergaard@dhs.wisconsin.gov >

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hey Hannah,

The folder with the publicly shared dataset is currently restricted to UW addresses which is why it's denying you, but the files in the folder haven't been updated yet anyways. I've attached the updated dataset here. I tried to just include the data needed to address the questions so that it's easier to parse, but let me know if you need any other info. Also, I think the column names should be straightforward, but let me know if you have any questions.

Thanks for addressing the reviewer comments!

Kasen

From: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov >

Date: Saturday, August 21, 2021 at 2:26 PM

To: DAVID H O'CONNOR < dhoconno@wisc.edu >, Kasen Riemersma < riemersma@wisc.edu >, Thomas Friedrich < tfriedri@wisc.edu >

Cc: Katarina Grande < kgrande@publichealthmdc.com >, Westergaard, Ryan P - DHS

<ryan.westergaard@dhs.wisconsin.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

I don't seem to have access to the data that was used for this. Can someone grant me access? It may just be google acting up but my request to view the shared folder keeps was denied.

 $\label{thm:continuous} \mbox{Hannah Segaloff, PhD, MPH } \mbox{ \mid LT, U.S. Public Health Service} \\ \mbox{Epidemic Intelligence Service Officer}$

U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services

Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: DAVID H O'CONNOR < dhoconno@wisc.edu>

Sent: Saturday, August 21, 2021 12:47 PM

To: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov; Kasen Riemersma < riemersma@wisc.edu; Thomas Friedrich < hannah.segaloff@dhs.wisconsin.gov; Kasen Riemersma < riemersma@wisc.edu; Thomas Friedrich < hannah.segaloff@dhs.wisconsin.gov; Kasen Riemersma < riemersma@wisc.edu; Thomas Friedrich < hannah.segaloff@dhs.wisconsin.gov; Kasen Riemersma < riemersma@wisc.edu; Thomas Friedrich < hannah.segaloff@dhs.wisconsin.gov; Thomas Friedrich < hannah.segaloff@dhs.wisconsin.gov; Thomas Friedrich < hannah.segaloff@dhs.wisconsin.gov; Thomas Friedrich hannah.segaloff@dhs.wisconsin.gov; Thomas Friedrich hannah.segaloff@dhs.wisconsin.gov; Thomas Friedrich hannah.gov; Thomas Friedrich <a

Cc: Katarina Grande < kgrande@publichealthmdc.com >; Westergaard, Ryan P - DHS < ryan.westergaard@dhs.wisconsin.gov >

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah,

I'm still not sure I understand. Why are there new comments now after we responded to the ones that were issued

yesterday? If there are edits that can fit in the 400 word limit that's fine but I worry that the request for more information is at odds with the word count.

Do you want to take a crack at these edits since you know how to write these things on the way that the clearance process expects?

Cheers,

Dave

Get Outlook for iOS

From: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov >

Sent: Saturday, August 21, 2021 11:49:15 AM

To: Kasen Riemersma <<u>riemersma@wisc.edu</u>>; Thomas Friedrich <<u>tfriedri@wisc.edu</u>>

Cc: DAVID H O'CONNOR dhoconno@wisc.edu">dhoconno@wisc.edu; Katarina Grande kgrande@publichealthmdc.com; Westergaard, Ryan P -

DHS < ryan.westergaard@dhs.wisconsin.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hi All,

This was not cleared by the JIC- they want to see the new version before clearance. However, comments don't seem too extensive.

I can work on the comments about the statewide perspective.

Best,

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services

Currently Teleworking
Cell:

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Kasen Riemersma < riemersma@wisc.edu>

Sent: Friday, August 20, 2021 4:32 PM

To: Thomas Friedrich < tfriedri@wisc.edu>; Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov>

Cc: DAVID H O'CONNOR dhoconno@wisc.edu; Katarina Grande kgrande@publichealthmdc.com; Westergaard, Ryan P -

DHS < ryan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Thanks, Hannah!

Kasen

From: Thomas Friedrich < tfriedri@wisc.edu Date: Friday, August 20, 2021 at 4:25 PM

To: Segaloff, Hannah E - DHS < <u>Hannah.Segaloff@dhs.wisconsin.gov</u>>

Cc: DAVID H O'CONNOR < dhoconno@wisc.edu, Kasen Riemersma < riemersma@wisc.edu, Katarina Grande < kgrande@publichealthmdc.com, Westergaard, Ryan P - DHS < ryan.westergaard@dhs.wisconsin.gov

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Sweet, thanks Hannah!

-T

Thomas Friedrich

Professor Dept. Pathobiological Sciences University of Wisconsin School of Veterinary Medicine @tcfriedrich @tcf-lab www.vetmed.wisc.edu/friedrichlab

On 20 Aug 2021, at 16:24, Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov > wrote:

It's back in. Fingers crossed that we get this back quickly. It looks like the on call clearance coordinator has email check-ins over the weekend at 10am and 3pm so those are the times that you are likely to hear Saturday or Sunday.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu> Sent: Friday, August 20, 2021 4:18 PM

To: DAVID H O'CONNOR < dhoconno@wisc.edu>

Cc: Segaloff, Hannah E - DHS hannah.segaloff@dhs.wisconsin.gov; Kasen Riemersma riemersma@wisc.edu; Katarina Grande < kgrande@publichealthmdc.com >; Westergaard, Ryan P - DHS <ryan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Oops, just saw this. I think we should go with Hannah's version since she addresses the question about the CDC ethics statement.

-T

Thomas Friedrich

Professor Dept. Pathobiological Sciences University of Wisconsin School of Veterinary Medicine @tcfriedrich @tcf-lab www.vetmed.wisc.edu/friedrichlab On 20 Aug 2021, at 16:14, DAVID HO'CONNOR < dhoconno@wisc.edu > wrote:

Looks fine to me Hannah. Thanks for taking care of the edits.

Segaloff, Hannah E - DHS wrote on 8/20/21 4:12 PM:

Sorry for the repeat emails. I can just send this version back if you all agree since changes were so minor.

-Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services

Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Thomas Friedrich <a href="mailto:striedri@wis

Sent: Friday, August 20, 2021 3:44 PM

To: Segaloff, Hannah E - DHS segaloff@dhs.wisconsin.gov

Cc: Kasen Riemersma < riemersma@wisc.edu>; DAVID H

O'CONNOR chicken; Katarina

Grande kgrande@publichealthmdc.com; Westergaard, Ryan P -

DHS ryan.westergaard@dhs.wisconsin.gov

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah.

Do you have any updates on the CDC clearance process? Can you see if others have been able to look at the paper?

Thanks,

-T

Thomas Friedrich

Professor Dept. Pathobiological Sciences University of Wisconsin School of Veterinary Medicine @tcfriedrich @tcf-lab

www.vetmed.wisc.edu/friedrichlab

On 19 Aug 2021, at 18:51, Thomas Friedrich < tfriedri@wisc.edu> wrote:

Okay, fingers crossed!

Sent from my iPhone

On Aug 19, 2021, at 18:02, Segaloff, Hannah E - DHS hannah.segaloff@dhs.wisconsin.gov wrote:

Though on second thought I can see that the STLT TF is reviewing now- so maybe this is moving faster than I thought.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Thursday, August 19, 2021 5:44 PM

To: Segaloff, Hannah E - DHS

< hannah.segaloff@dhs.wisconsin.gov>

Cc: Kasen Riemersma <<u>riemersma@wisc.edu</u>>; DAVID H O'CONNOR <<u>dhoconno@wisc.edu</u>>; Katarina Grande <<u>kgrande@publichealthmdc.com</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Thanks Hannah.

I really hope they can return comments tomorrow so we can submit.

. Do you think that is at all

possible?

Best,

Tom

Sent from my iPhone

On Aug 19, 2021, at 15:20, Segaloff, Hannah E - DHS hannah.segaloff@dhs.wisconsin.gov wrote:

Thanks Tom,

I will send these along and the note. I'm hoping we can switch over to a Google drive format for comments.

Best, Hannah Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases
Wisconsin Department of Health Services
Currently Teleworking
Cell:
Hannah.Segaloff@dhs.wisconsin.gov

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Thursday, August 19, 2021 3:05 PM

To: Segaloff, Hannah E - DHS

< hannah.segaloff@dhs.wisconsin.gov>

Cc: Kasen Riemersma

Qdz0@cdc.gov

<<u>riemersma@wisc.edu</u>>; DAVID H O'CONNOR

; Katarina Grande

<kgrande@publichealthmdc.com>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah.

Attached please find clean (well, clean-ish) and tracked versions of the revised manuscript. We addressed all the comments and made the changes requested. I hope this can be approved quickly.

Note: As you know, to edit collaboratively, we uploaded the Word doc with CDC comments to Google Drive. I redownloaded the edited version as a Word doc - this is the "clean" version and preserves CDC comments and our responses. To make the "tracked" version I had to compare that downloaded document to the Word doc you forwarded from CDC. When I did that I noticed that it duplicated several comments from CDC folk. For the sake of readability I tried to delete duplicates, but there are still a lot of comments in a small space. It also appears that replies within comments were not recognized, so now they just appear as comments on top of other comments. I hope that all makes sense.

If these copies do not come through, you can download them from the shared Google drive here:

Best,

-Tom

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 19 Aug 2021, at 09:41, Segaloff, Hannah E - DHS <<u>hannah.segaloff@dhs.wisconsin.gov</u>> wrote:

Hi All,

Here are the first round of comments. We should get all responses within 24 to 48 hours of our submission. It looks like this needs to be approved by Lab TF, cross clearance and the response.

Let me know if I can help with comments.

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell: Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: CDC IMS 2019 NCOV Response Lab TF Clearance <<u>eocevent216@cdc.gov</u>>

Sent: Thursday, August 19, 2021

9:24 AM

To: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD)

<qdz0@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance <<u>eocevent216@cdc.gov</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite

Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah,

Please address the mandatory comments and return for rereview.

Shedding of Infectious
SARS-CoV-2 Despite
Vaccination when the Delta
Variant is Prevalent

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < adz0@cdc.gov>

Sent: Wednesday, August 18,

2021 9:18 AM

To: CDC IMS 2019 NCOV Response Lab TF Clearance <<u>eocevent216@cdc.gov</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hello,

Thank you for the quick work getting this approved for DIM expedited clearance. I haven't

had a manuscript in expedited clearance before. Does it have the same steps as standard? How much time should I anticipate for the clearance process?

Thank you! Hannah

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<<u>qqv9@cdc.gov</u>>

Sent: Tuesday, August 17, 2021

11:51 AM

To: Kools, John J. (CDC/DDID/NCEZID/OD)

<<u>czk7@cdc.gov</u>>; CDC IMS 2019

NCOV Response Lab TF

Clearance

<<u>eocevent216@cdc.gov</u>>;

Dunworth, Soumya

(CDC/DDPHSS/CSELS/OD)

<kya6@cdc.gov>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD)

<<u>bbl7@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<<u>xhg9@cdc.gov</u>>; Segaloff,

Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<qdz0@cdc.gov>; Moon,

Jonathan L.

(CDC/DDID/NCEZID/DSR)

<iki5@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

NP! Glad we were able to turn this around so quickly.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist Laboratory and Testing Task Force COVID-19 Emergency Response

Centers for Disease Control and

Prevention

Lab TF Communications

Mailbox: eocevent503@cdc.gov

Cell:

From: Kools, John J.

(CDC/DDID/NCEZID/OD)

<czk7@cdc.gov>

Sent: Tuesday, August 17, 2021

12:47 PM

To: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>; CDC IMS 2019

NCOV Response Lab TF

Clearance

<eocevent216@cdc.gov>;

Dunworth, Soumya

(CDC/DDPHSS/CSELS/OD)

<kya6@cdc.gov>

Cc: Limbago, Brandi

(CDC/DDID/NCIRD/OD)

<<u>bbl7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR)

<<u>xhg9@cdc.gov</u>>; Segaloff,

Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<adz0@cdc.gov>; Moon,

Jonathan L.

(CDC/DDID/NCEZID/DSR)

<iki5@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Thanks Shelbi!

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021

12:43 PM

To: CDC IMS 2019 NCOV

Response Lab TF Clearance

<<u>eocevent216@cdc.gov</u>>; Kools,

John J. (CDC/DDID/NCEZID/OD)

<<u>czk7@cdc.gov</u>>; Dunworth,

Soumya

(CDC/DDPHSS/CSELS/OD)

<kya6@cdc.gov>

Cc: Limbago, Brandi

(CDC/DDID/NCIRD/OD)

<<u>bbl7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR)

<<u>xhg9@cdc.gov</u>>; Segaloff,

Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<qdz0@cdc.gov>; Moon,

Jonathan L.

(CDC/DDID/NCEZID/DSR)

<iki5@cdc.gov>

Subject: Fw: Shedding of

Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Afternoon,

This has been approved for expedited clearance.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and
Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov
Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<<u>zqg7@cdc.gov</u>>

Sent: Tuesday, August 17, 2021

12:40 PM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Cc: Fisher, Angela H.
(CDC/DDPHSS/CSELS/OD)
<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thank you. I approve expedited clearance. Stephanie Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021

12:16 PM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H.

(CDC/DDPHSS/CSELS/OD)

<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hey Stephanie,

Please see attached for the updated draft.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and
Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov
Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<<u>qqv9@cdc.gov</u>>

Sent: Tuesday, August 17, 2021

11:05 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<<u>zqg7@cdc.gov</u>>

Cc: Fisher, Angela H.

(CDC/DDPHSS/CSELS/OD)

<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Sure thing, working on the updated draft now.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and
Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov
Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021

10:56 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Yes, please request an updated draft with Hannah's name on it and then I approve it going for expedited clearance. Stephanie Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<aav9@cdc.gov>

Sent: Tuesday, August 17, 2021

10:56 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hey Stephanie,

From correspondence with ADS and STLT Hannah was inadvertently left off the manuscript but WI has confirmed that she is a co-author but her name is not on this draft. Should we request an updated draft with Hannah information on there as the co-author?

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist Laboratory and Testing Task Force COVID-19 Emergency Response Centers for Disease Control and Prevention

Lab TF Communications

Mailbox: eocevent503@cdc.gov

Cell:

From: Davis, Shelbi
(CDC/DDID/NCIRD/DVD)

Sent: Tuesday, August 17, 2021

10:51 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

<<u>iwg7@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Неу,

I am working on getting clarification as we speak, update to follow.

Thanks, Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force COVID-19 Emergency Response Centers for Disease Control and

Prevention

Lab TF Communications
Mailbox: eocevent503@cdc.gov
Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<<u>zqg7@cdc.gov</u>>

Sent: Tuesday, August 17, 2021

10:49 AM

To: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Cc: Fisher, Angela H.
(CDC/DDPHSS/CSELS/OD)
<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hannah Segaloff EISO is listed on the clearance request form as an author but not on the manuscript. Can you clarify that she indeed and author? If so, then my approval for expedited clearance stands.

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) <aav9@cdc.gov>

Sent: Tuesday, August 17, 2021

10:40 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<<u>zqg7@cdc.gov</u>>

Cc: Fisher, Angela H.
(CDC/DDPHSS/CSELS/OD)
<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thanks for the speedy response!

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and
Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<<u>zqg7@cdc.gov</u>>

Sent: Tuesday, August 17, 2021

10:39 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

Cc: Fisher, Angela H.
(CDC/DDPHSS/CSELS/OD)

<qqv9@cdc.gov>

< iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

I approve.

Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021

10:38 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H.
(CDC/DDPHSS/CSELS/OD)
<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Morning Stephanie,

Happy Tuesday! We would like to request DIM1 expedited approval for the attached manuscript. Please refer to the email thread below.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and
Prevention
Lab TF Communications
Mailbox: cocevent503@cdc.gov

From: CDC IMS 2019 NCOV
Response Lab TF Clearance
<eocevent216@cdc.gov>

Sent: Tuesday, August 17, 2021

10:32 AM **To:** Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<<u>qqv9@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance <<u>eocevent216@cdc.gov</u>>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hi Shelbi and Jarrett,

Should I begin clearance on this item or wait until you receive the DIM approval?

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Kools, John J. (CDC/DDID/NCEZID/OD) <czk7@cdc.gov>

Sent: Tuesday, August 17, 2021

9:59 AM

To: CDC IMS 2019 NCOV
Response Lab TF Clearance
<eocevent216@cdc.gov>; Davis,
Shelbi (CDC/DDID/NCIRD/DVD)
<qqv9@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)
<xhg9@cdc.gov>

Cc: Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) <kya6@cdc.gov>; Limbago, Brandi (CDC/DDID/NCIRD/OD) <bbl7@cdc.gov>; Moon,
Jonathan L.
(CDC/DDID/NCEZID/DSR)
<<u>iki5@cdc.gov</u>>; Llewellyn, Anna
C. (CDC/DDID/NCEZID/DPEI)
<gif7@cdc.gov>; Segaloff,
Hannah
(CDC/DDPHSS/CSELS/DSEPD)
<qdz0@cdc.gov>

Subject: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Good Morning,

You may have heard but our task force was asked by STLT, and we agreed, to sponsor this manuscript through clearance. The authors are targeting NEJM and are requesting our task force to request IM approval for expedited clearance. Our main POC for this manuscript is our CDC EISO Hannah Segaloff (Cc'd). Let me know if you have any questions.

Hannah- our clearance team can help shepherd your paper through clearance. I would anticipate our laboratory SMEs to have some questions for your team.

Best regards,

John

John Kools ADS, Laboratory & Testing Task Force CDC COVID-19 Response Phone: 404-217-7258

From: Rose, Dale A.
(CDC/DDID/NCEZID/DPEI)
<ido8@cdc.gov>

Sent: Tuesday, August 17, 2021

4:51 AM

To: Kools, John J. (CDC/DDID/NCEZID/OD)

<<u>czk7@cdc.gov</u>>

Subject: FW: Follow up on your results

Morning John! Thanks for taking this on. We had intensive discussions with WI, IM, and MMWR last week about this. There's strong interest in supporting and moving this forward quickly in clearance, including securing approval for expedited clearance so it can quickly make it to NEJM for consideration. If you anticipate any issues with the content or timing, please do let me know as our TF is in routine conversation with the state epi and want to make sure we're aligned in our discussions.

Much appreciated, and I hope you are well!

Best, Dale

Dale Rose, Ph.D.
STLT Support Task Force
Cell:

From: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI)

<gif7@cdc.gov>

Sent: Monday, August 16, 2021

3:35 PM

To: Segaloff, Hannah (CDC <u>dhs.wisconsin.gov</u>)

< hannah.segaloff@dhs.wisconsin.gov>;

Rose, Dale A.

(CDC/DDID/NCEZID/DPEI)

<idos@cdc.gov>; Westergaard,

Ryan (CDC dhs.wisconsin.gov)

<ryan.westergaard@dhs.wisconsin.gov>;

Bisgard, Kris

(CDC/DDPHSS/CSELS/DSEPD)

< kmb6@cdc.gov>

Cc: Ricaldi Camahuali, Jessica (CDC/DDID/NCEZID/DPEI) < mpi7@cdc.gov; Kools, John J.

(CDC/DDID/NCEZID/OD)

<<u>czk7@cdc.gov</u>>; Limbago,

Brandi (CDC/DDID/NCIRD/OD)

bbl7@cdc.gov>; Moon,

Jonathan L.

(CDC/DDID/NCEZID/DSR)

<iki5@cdc.gov>; CDC IMS 2019

NCOV Response STLT ADS

<<u>eocevent410@cdc.gov</u>>; CDC

IMS 2019 NCOV Response Lab

Task Force

<eocevent177@cdc.gov>

Subject: Re: Follow up on your

results

Dear Hannah,

Thank you for these additional documents. Due to this manuscript's focus on laboratory data, our Laboratory and Testing Task Force colleagues have agreed to be the sponsoring task force for CDC COVID-19 Response clearance. John Kools is the Lab TF ADS and can assist with next steps.

Best Regards,

Anna

Anna Llewellyn, PhD Associate Director for Science State, Tribal, Local, and Territorial Support Task Force COVID-19 Emergency Response Centers for Disease Control and

Prevention

Office: 404-639-1538 | Cell:

eocevent410@cdc.gov

-

From: Segaloff, Hannah E - DHS

< hannah.segaloff@dhs.wisconsin.gov>

Sent: Monday, August 16, 2021

3:13 PM

To: Rose, Dale A.

(CDC/DDID/NCEZID/DPEI)

<<u>ido8@cdc.gov</u>>; Westergaard,

Ryan (CDC <u>dhs.wisconsin.gov</u>)

<ryan.westergaard@dhs.wisconsin.gov>;

Bisgard, Kris

(CDC/DDPHSS/CSELS/DSEPD)

<<u>kmb6@cdc.gov</u>>

Cc: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI) <gif7@cdc.gov>; Ricaldi Camahuali, Jessica (CDC/DDID/NCEZID/DPEI) <mpi7@cdc.gov>

Subject: RE: Follow up on your results

Thank you. I have attached the concept proposal that was approved from the original MMWR submission as well as a clearance request form.

Sincerely, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell: Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

<Reimersma Viral loads in vaccinees NEJM editedauthorlist LABTFCOMMENTS.docx>

http://dho.pathology.wisc.edu @dho • 608-890-0845

From: Segaloff, Hannah E - DHS

To: Kasen Riemersma; DAVID H O"CONNOR; Thomas Friedrich

Cc: Katarina Grande; Westergaard, Ryan P - DHS

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Date: Saturday, August 21, 2021 9:26:50 PM

Thanks Kasen,

I sent it back into clearance. Hopefully this is the last step!

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Kasen Riemersma < riemersma@wisc.edu>

Sent: Saturday, August 21, 2021 9:11 PM

To: DAVID H O'CONNOR <dhoconno@wisc.edu>; Thomas Friedrich <tfriedri@wisc.edu>; Segaloff, Hannah E - DHS

<hannah.segaloff@dhs.wisconsin.gov>

Cc: Katarina Grande < kgrande@publichealthmdc.com>; Westergaard, Ryan P - DHS < ryan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Kasen

From: DAVID H O'CONNOR < dhoconno@wisc.edu Date: Saturday, August 21, 2021 at 5:23 PM

To: Thomas Friedrich tfriedri@wisc.edu, Segaloff, Hannah E - DHS Hannah.Segaloff@dhs.wisconsin.gov

Cc: Kasen Riemersma < riemersma@wisc.edu >, Katarina Grande < kgrande@publichealthmdc.com >, Westergaard, Ryan P - DHS

<rvan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Yep, that's my plan. Once we have the NEJM submitted I figured I'd take everything and create a v3 of the Medrxiv paper.

Get Outlook for iOS

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Saturday, August 21, 2021 5:19:25 PM

To: Segaloff, Hannah E - DHS < Hannah.Segaloff@dhs.wisconsin.gov >

Cc: Kasen Riemersma < riemersma@wisc.edu; DAVID H O'CONNOR < dhoconno@wisc.edu; Katarina Grande kgrande@publichealthmdc.com; Westergaard, Ryan P - DHS ryan.westergaard@dhs.wisconsin.gov>
Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Okay, thanks Hannah. I agree these are fair points, but it is indeed challenging to address everything you might want to say in 400 words.

Kasen and Dave, once all these revisions are made we should update the preprint with the new dataset.

Τ

Sent from my iPhone

On Aug 21, 2021, at 16:39, Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov > wrote:

Hi Tom,

Most of the comments were about either what evidence we had that these specimens were representative of more than one event/outbreak and one reviewer who wanted the proportions of things for comparison groups to be included. I think that they were all fair comments and potentially things we would hear at the editor/peer review level, but extremely difficult to work into the word limit.

I think it is very likely this will be approved at the next pass through either with a few comments or no comments, though honestly who can predict CDC clearance? They are required to get back to use within 48 hours and they seem to be operating on a <24 hour turnaround, so I think it is pretty likely we'll hear tomorrow or Monday morning at the very latest. Fingers crossed that this process is over.

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu > Sent: Saturday, August 21, 2021 4:31 PM
To: Kasen Riemersma < riemersma@wisc.edu >

 $\textbf{Cc:} \ Segaloff, \ Hannah \ E-DHS < \underline{hannah.segaloff@dhs.wisconsin.gov}; \ DAVID\ H\ O'CONNOR < \underline{dhoconno@wisc.edu}>; \ Katarinah.segaloff@dhs.wisconsin.gov>; \ DAVID\ H\ O'CONNOR < \underline{dhoconno@wisc.edu}>; \ Connormal.segaloff@dhs.wisconsin.gov>; \ DAVID\ H\ O'CONNOR < \underline{dhoconno@wisc.edu}>; \ Connormal.segaloff@dhs.wisconsin.gov>; \ Connormal.segaloff@d$

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi all. Thanks to Hannah for addressing the comments.

I can't see the comments on my phone—can you briefly summarize what the concerns are?

Is there any chance we can submit tomorrow?

T

Thanks to Hannah

Sent from my iPhone

On Aug 21, 2021, at 15:30, Kasen Riemersma < riemersma@wisc.edu > wrote:

Hey Hannah,

The folder with the publicly shared dataset is currently restricted to UW addresses which is why it's denying you, but the files in the folder haven't been updated yet anyways. I've attached the updated dataset here. I tried to just include the data needed to address the questions so that it's easier to parse, but let me know if you need

any other info. Also, I think the column names should be straightforward, but let me know if you have any questions.

Thanks for addressing the reviewer comments!

Kasen

From: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov >

Date: Saturday, August 21, 2021 at 2:26 PM

To: DAVID H O'CONNOR < dhoconno@wisc.edu>, Kasen Riemersma < riemersma@wisc.edu>,

Thomas Friedrich < tfriedri@wisc.edu >

Cc: Katarina Grande < kgrande@publichealthmdc.com >, Westergaard, Ryan P - DHS

<ryan.westergaard@dhs.wisconsin.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

I don't seem to have access to the data that was used for this. Can someone grant me access? It may just be google acting up but my request to view the shared folder keeps was denied.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services

Currently Teleworking Cell:

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: DAVID H O'CONNOR < dhoconno@wisc.edu>

Sent: Saturday, August 21, 2021 12:47 PM

To: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov; Kasen Riemersma < riemersma@wisc.edu;

Thomas Friedrich < tfriedri@wisc.edu>

Cc: Katarina Grande < kgrande@publichealthmdc.com >; Westergaard, Ryan P - DHS

<ryan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

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Hi Hannah,

I'm still not sure I understand. Why are there new comments now after we responded to the ones that were issued yesterday? If there are edits that can fit in the 400 word limit that's fine but I worry that the request for more information is at odds with the word count.

Do you want to take a crack at these edits since you know how to write these things on the way that the clearance process expects?

Cheers,

Dave

Get Outlook for iOS

From: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov>

Sent: Saturday, August 21, 2021 11:49:15 AM

To: Kasen Riemersma < riemersma@wisc.edu >; Thomas Friedrich < tfriedri@wisc.edu >

Cc: DAVID H O'CONNOR < dhoconno@wisc.edu; Katarina Grande < kgrande@publichealthmdc.com;

Westergaard, Ryan P - DHS < ryan.westergaard@dhs.wisconsin.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hi All,

This was not cleared by the JIC- they want to see the new version before clearance. However, comments don't seem too extensive.

I can work on the comments about the statewide perspective.

Best, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Kasen Riemersma < riemersma@wisc.edu>

Sent: Friday, August 20, 2021 4:32 PM

To: Thomas Friedrich < tfriedri@wisc.edu; Segaloff, Hannah E - DHS hannah.segaloff@dhs.wisconsin.gov CC: DAVID H O'CONNOR dhoconno@wisc.edu; Katarina Grande kgrande@publichealthmdc.com;

Westergaard, Ryan P - DHS < ryan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Thanks, Hannah!

Kasen

From: Thomas Friedrich < tfriedri@wisc.edu Date: Friday, August 20, 2021 at 4:25 PM

To: Segaloff, Hannah E - DHS < <u>Hannah.Segaloff@dhs.wisconsin.gov</u>>

Cc: DAVID H O'CONNOR < dhoconno@wisc.edu >, Kasen Riemersma < riemersma@wisc.edu >, Katarina

Grande < kgrande@publichealthmdc.com >, Westergaard, Ryan P - DHS

<ryan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Sweet, thanks Hannah!

-T

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab

www.vetmed.wisc.edu/friedrichlab

On 20 Aug 2021, at 16:24, Segaloff, Hannah E - DHS < $\underline{ hannah.segaloff@dhs.wisconsin.gov} > wrote:$

It's back in. Fingers crossed that we get this back quickly. It looks like the on call clearance coordinator has email check-ins over the weekend at 10am and 3pm so those are the times that you are likely to hear Saturday or Sunday.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases

Wisconsin Department of Health Services
Currently Teleworking
Cell:
Hannah, Segaloff@dhs, wisconsin.gov

Odz0@cdc.gov

Quzotwcuc.gov

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Friday, August 20, 2021 4:18 PM

To: DAVID H O'CONNOR < dhoconno@wisc.edu>

Cc: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov>; Kasen Riemersma

<riemersma@wisc.edu>; Katarina Grande <<u>kgrande@publichealthmdc.com</u>>; Westergaard, Ryan P

- DHS < ryan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

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Oops, just saw this. I think we should go with Hannah's version since she addresses the question about the CDC ethics statement.

-T

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 20 Aug 2021, at 16:14, DAVID H O'CONNOR < dhoconno@wisc.edu>

Looks fine to me Hannah. Thanks for taking care of the edits.

dave

Segaloff, Hannah E - DHS wrote on 8/20/21 4:12 PM:

Sorry for the repeat emails. I can just send this version back if you all agree since changes were so minor.

-Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services

Currently Teleworking
Cell:

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: Thomas Friedrich <a href="mailto:striedri@wis

To: Segaloff, Hannah E - DHS segaloff@dhs.wisconsin.gov

Cc: Kasen Riemersma riemersma@wisc.edu; DAVID H

O'CONNOR dhoconno@wisc.edu; Katarina

 ${\sf Grande} \, \underline{<\! {\sf kgrande@publichealthmdc.com} \!\!>}; \, {\sf Westergaard, \, Ryan \, P \, -}$

DHS cryan.westergaard@dhs.wisconsin.gov

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination

when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah.

Do you have any updates on the CDC clearance process? Can you see if others have been able to look at the paper?

Thanks,

-T

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tefriedrich
@tef-lab
www.vetmed.wisc.edu/friedrichlab

On 19 Aug 2021, at 18:51, Thomas Friedrich <<u>tfriedri@wisc.edu</u>> wrote:

Okay, fingers crossed!

Sent from my iPhone

On Aug 19, 2021, at 18:02, Segaloff, Hannah E - DHS <hannah.segaloff@dhs.wisconsin.gov> wrote:

Though on second thought I can see that the STLT TF is reviewing now- so maybe this is moving faster than I thought.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking Cell:

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Thursday, August 19, 2021 5:44 PM

To: Segaloff, Hannah E - DHS

hannah.segaloff@dhs.wisconsin.gov>

Cc: Kasen Riemersma

<<u>riemersma@wisc.edu</u>>; DAVID H O'CONNOR <<u>dhoconno@wisc.edu</u>>; Katarina Grande <<u>kgrande@publichealthmdc.com</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Thanks Hannah.

I really hope they can return comments

tomorrow so we can submit. I will be heading up north on Saturday and won't have WiFi for a week. Do you think that is at all possible?

Best,

Tom

Sent from my iPhone

On Aug 19, 2021, at 15:20, Segaloff, Hannah E - DHS hannah.segaloff@dhs.wisconsin.gov wrote:

Thanks Tom,

I will send these along and the note. I'm hoping we can switch over to a Google drive format for comments.

Best, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases
Wisconsin Department of Health Services
Currently Teleworking
Cell:
Hannah.Segaloff@dhs.wisconsin.gov
Od20@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu >

Sent: Thursday, August 19, 2021

3:05 PM

To: Segaloff, Hannah E - DHS

hannah.segaloff@dhs.wisconsin.gov

Cc: Kasen Riemersma

<re><riemersma@wisc.edu>; DAVID

H O'CONNOR

<<u>dhoconno@wisc.edu</u>>;

Katarina Grande

< kgrande@publichealthmdc.com>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah.

Attached please find clean (well, clean-ish) and tracked versions of the revised manuscript. We addressed all the comments and made the changes requested. I hope this can be approved quickly.

Note: As you know, to edit collaboratively, we uploaded the Word doc with CDC comments to Google Drive. I re-downloaded the edited version as a Word doc - this is the "clean" version and preserves CDC comments and our responses. To make the "tracked" version I had to compare that downloaded document to the Word doc you forwarded from CDC. When I did that I noticed that it duplicated several comments from CDC folk. For the sake of readability I tried to delete duplicates, but there are still a lot of comments in a small space. It also appears that replies within comments were not recognized, so now they just appear as comments on top of other comments. I hope that all makes sense.

If these copies do not come through, you can download them from the shared Google drive here:

Best,

-Tom

Thomas Friedrich

Professor
Dept. Pathobiological
Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 19 Aug 2021, at 09:41, Segaloff, Hannah E - DHS <hannah.segaloff@dhs.wisconsin.gov> wrote:

Hi All,

Here are the first round of comments. We should get all responses within 24 to 48 hours of our submission. It looks like this needs to be approved by Lab TF, cross clearance and the response. Let me know if I can help with comments.

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking Cell:

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: CDC IMS 2019 NCOV Response Lab TF Clearance

<eocevent216@cdc.gov>

Sent: Thursday, August 19, 2021 9:24 AM To: Segaloff, Hannah

(CDC/DDPHSS/CSELS/DSEPD) <adz0@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance

<<u>eocevent216@cdc.gov</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution:
Message from
external
sender. Do not
click on links or
open
attachments
unless you
recognize the
sender.

Hi Hannah,

Please address the mandatory comments and return for rereview.

Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thank you, Alexis

CDC IMS 2019nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Segaloff, Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<adz0@cdc.gov>
Sent: Wednesday,

August 18, 2021

9:18 AM

To: CDC IMS 2019 NCOV Response Lab TF Clearance

<eocevent216@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hello,

Thank you for the quick work getting this approved for DIM expedited clearance. I
haven't had a
manuscript in
expedited
clearance before.
Does it have the
same steps as
standard? How
much time should
I anticipate for the
clearance

process?
Thank you!
Hannah

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<a href="mailto:<a href="m

To: Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov>;

CDC IMS 2019 NCOV Response Lab TF Clearance

<<u>eocevent216@cdc.gov</u>>;

Dunworth, Soumya (CDC/DDPHSS/CSELS/OD)

<<u>kya6@cdc.gov</u>> **Cc:** Limbago,

Brandi

(CDC/DDID/NCIRD/OD)

<<u>bbl7@cdc.gov</u>>;

Gartin, Jarrett

(CDC/DDID/NCIRD/OD)

(CTR)

<xhg9@cdc.gov>;

Segaloff, Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<<u>qdz0@cdc.gov</u>>;

Moon, Jonathan L.

(CDC/DDID/NCEZID/DSR)

<iki5@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

NP! Glad we were able to turn this around so quickly.

Thanks, Shelbi Davis Communication Lead Health

Communication Specialist Laboratory and Testing Task Force COVID-19 Emergency Response Centers for Disease Control and Prevention Lab TF Communications Mailbox: eocevent503@cdc.gov Cell: From: Kools, John J. (CDC/DDID/NCEZID/OD) <czk7@cdc.gov> Sent: Tuesday, August 17, 2021 12:47 PM To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) <qqv9@cdc.gov>; **CDC IMS 2019** NCOV Response

Lab TF Clearance <<u>eocevent216@cdc.gov</u>>;

Dunworth, Soumya

(CDC/DDPHSS/CSELS/OD)

<kya6@cdc.gov> Cc: Limbago,

Brandi

(CDC/DDID/NCIRD/OD)

<bbl/>bbl7@cdc.gov>;

Gartin, Jarrett

(CDC/DDID/NCIRD/OD)

(CTR)

<xhg9@cdc.gov>;

Segaloff, Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<qdz0@cdc.gov>;

Moon, Jonathan L.

(CDC/DDID/NCEZID/DSR)

<iki5@cdc.gov>

Subject: RE:

Shedding of

Infectious SARS-

CoV-2 Despite

Vaccination when

the Delta Variant is

Prevalent

Thanks Shelbi!

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov> Sent: Tuesday, August 17, 2021

12:43 PM

To: CDC IMS 2019 NCOV Response

(CDC/DDID/NCEZID/OD) <<u>czk7@cdc.gov</u>>; Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) <kya6@cdc.gov> Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD)

bbl7@cdc.gov>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) <xhg9@cdc.gov>; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) <qdz0@cdc.gov>; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) <iki5@cdc.gov> Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent Afternoon, This has been approved for expedited clearance. Thanks, Shelbi Davis Communication Lead Health Communication Specialist Laboratory and Testing Task Force COVID-19 Emergency Response Centers for Disease Control and Prevention Lab TF Communications Mailbox: eocevent503@cdc.gov Cell: From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) <zqg7@cdc.gov> Sent: Tuesday,

August 17, 2021
12:40 PM
To: Davis, Shelbi
(CDC/DDID/NCIRD/DVD)
<qqv9@cdc.gov>
Cc: Fisher, Angela

Н.

Lab TF Clearance < eocevent 216@cdc.gov >;

Kools, John J.

(CDC/DDPHSS/CSELS/OD)

<iwg7@cdc.gov>;

Gartin, Jarrett

(CDC/DDID/NCIRD/OD)

(CTR)

<xhg9@cdc.gov>

Subject: RE:

Shedding of

Infectious SARS-

CoV-2 Despite

Vaccination when

the Delta Variant is

Prevalent

Thank you. I

approve

expedited

clearance.

Stephanie

Stephanie R. Bialek

MD MPH

Deputy Incident

Manager

COVID-19

Response

CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<<u>qqv9@cdc.gov</u>>

Sent: Tuesday, August 17, 2021

12:16 PM

To: Bialek,

Stephanie R.

(CDC/DDID/NCIRD/DVD)

<<u>zqg7@cdc.gov</u>>

Cc: Fisher, Angela

Η.

(CDC/DDPHSS/CSELS/OD)

<<u>iwg7@cdc.gov</u>>;

Gartin, Jarrett

(CDC/DDID/NCIRD/OD)

(CTR)

<xhg9@cdc.gov>

Subject: Re:

Shedding of

Infectious SARS-

CoV-2 Despite

Vaccination when

the Delta Variant is

Prevalent

Hey Stephanie,

Please see attached for the updated draft.

Thanks, Shelbi Davis

Communication Lead Health Communication Specialist Laboratory and Testing Task Force COVID-19 Emergency Response Centers for Disease Control and Prevention Lab TF Communications Mailbox: eocevent503@cdc.gov Cell: From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) <qqv9@cdc.gov> Sent: Tuesday, August 17, 2021 11:05 AM To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) <zqg7@cdc.gov> Cc: Fisher, Angela (CDC/DDPHSS/CSELS/OD) <<u>iwg7@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) <xhg9@cdc.gov> Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent Sure thing, working on the updated draft now. Thanks, Shelbi Davis Communication Lead Health Communication Specialist Laboratory and Testing Task Force COVID-19 Emergency Response Centers for Disease Control and Prevention Lab TF Communications Mailbox: eocevent503@cdc.gov Cell: From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:56 AM To: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<<u>qqv9@cdc.gov</u>>

Cc: Fisher, Angela

Η.

(CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>;

Gartin, Jarrett

(CDC/DDID/NCIRD/OD)

(CTR)

<xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Yes, please

request an

updated draft

with Hannah's

name on it and

then I approve it

going for

expedited

clearance.

Stephanie

Stephanie R. Bialek

MD MPH

Deputy Incident

Manager

COVID-19

Response

CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<gqv9@cdc.gov> Sent: Tuesday, August 17, 2021 10:56 AM To: Bialek,

Stephanie R.

(CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela

Н.

(CDC/DDPHSS/CSELS/OD)

<<u>iwg7@cdc.gov</u>>;

Gartin, Jarrett

(CDC/DDID/NCIRD/OD)

(CTR)

<xhg9@cdc.gov>

Subject: Re:

Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hey Stephanie,

From correspondence with ADS and STLT Hannah was inadvertently left off the manuscript but WI has confirmed that she is a co-author but her name is not on this draft. Should we request an updated draft with Hannah information on there as the co-author?

Thanks,
Shelbi Davis
Communication Lead
Health
Communication Specialist
Laboratory and
Testing Task Force
COVID-19
Emergency Response
Centers for Disease
Control and
Prevention
Lab TF
Communications

Mailbox: eocevent503@cdc.gov

Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<aqv9@cdc.gov> Sent: Tuesday, August 17, 2021 10:51 AM To: Bialek,

Stephanie R.

(CDC/DDID/NCIRD/DVD) <zqg7@cdc.gov>

Cc: Fisher, Angela

Η.

(CDC/DDPHSS/CSELS/OD)

<<u>iwg7@cdc.gov</u>>;

Gartin, Jarrett

(CDC/DDID/NCIRD/OD)

(CTR)

<xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Неу,

I am working on getting clarification as we speak, update to follow.

Thanks, Shelbi Davis

Communication Lead

Health

Communication Specialist

Laboratory and Testing Task Force COVID-19 Emergency Response

Centers for Disease

Control and

Prevention Lab TF

Communications

Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R.

(CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:49 AM To: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

qqv9@cdc.gov">

Cc: Fisher, Angela

Η.

(CDC/DDPHSS/CSELS/OD)

<<u>iwg7@cdc.gov</u>>;

Gartin, Jarrett

(CDC/DDID/NCIRD/OD)

(CTR)

<xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-

CoV-2 Despite

Vaccination when

the Delta Variant is

Prevalent

Hannah Segaloff

EISO is listed on

the clearance

request form as

an author but not

on the

manuscript. Can

you clarify that

she indeed and

author? If so, then

my approval for

expedited

clearance stands.

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:40 AM To: Bialek, Stephanie R.

(CDC/DDID/NCIRD/DVD)

<<u>zqg7@cdc.gov</u>>

Cc: Fisher, Angela

Н

(CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>;

Gartin, Jarrett

(CDC/DDID/NCIRD/OD)

(CTR)

<xhg9@cdc.gov>

Subject: Re: Shedding of

Infectious SARS-

CoV-2 Despite

Vaccination when

the Delta Variant is

Prevalent

Thanks for the speedy

response!

Thanks,

Shelbi Davis

Communication Lead

Health

Communication Specialist

Laboratory and

Testing Task Force

COVID-19

Emergency Response

Centers for Disease Control and

Prevention

Lab TF

Communications

Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek,

Stephanie R.

(CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday,

August 17, 2021

10:39 AM

To: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Cc: Fisher, Angela

Н.

(CDC/DDPHSS/CSELS/OD)

<iwg7@cdc.gov>;

Gartin, Jarrett

(CDC/DDID/NCIRD/OD)

(CTR)

<xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

I approve.

Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<aqv9@cdc.gov> Sent: Tuesday, August 17, 2021 10:38 AM

To: Bialek, Stephanie R.

(CDC/DDID/NCIRD/DVD)

<<u>zqg7@cdc.gov</u>> **Cc:** Fisher, Angela

Н.

(CDC/DDPHSS/CSELS/OD)

<<u>iwg7@cdc.gov</u>>;

Gartin, Jarrett

(CDC/DDID/NCIRD/OD)

(CTR)

<xhg9@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Morning Stephanie,

Happy Tuesday! We would like to request DIM1 expedited approval for the attached manuscript. Please refer to the email thread below.

Thanks, Shelbi Davis Communication Lead Health Communication Specialist Laboratory and Testing Task Force
COVID-19
Emergency Response
Centers for Disease
Control and
Prevention
Lab TF
Communications

Mailbox: eocevent503@cdc.gov

Cell:

From: CDC IMS 2019 NCOV Response Lab TF

Clearance

<eocevent216@cdc.gov>

Sent: Tuesday, August 17, 2021 10:32 AM To: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<<u>qqv9@cdc.gov</u>>;

Gartin, Jarrett

(CDC/DDID/NCIRD/OD)

(CTR)

<xhg9@cdc.gov>

Cc: CDC IMS 2019

NCOV Response
Lab TF Clearance
<eocevent216@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hi Shelbi and Jarrett,

Should I begin clearance on this item or wait until you receive the DIM approval?

Thank you, Alexis

CDC IMS 2019nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM) From: Kools, John

(CDC/DDID/NCEZID/OD)

<czk7@cdc.gov>

Sent: Tuesday, August 17, 2021

9:59 AM

To: CDC IMS 2019 NCOV Response

Lab TF Clearance

<<u>eocevent216@cdc.gov</u>>;

Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>;

Gartin, Jarrett

(CDC/DDID/NCIRD/OD)

(CTR)

<xhg9@cdc.gov>

Cc: Dunworth,

Soumya

(CDC/DDPHSS/CSELS/OD)

<kya6@cdc.gov>;

Limbago, Brandi

(CDC/DDID/NCIRD/OD)

<<u>bbl7@cdc.gov</u>>;

Moon, Jonathan L.

(CDC/DDID/NCEZID/DSR)

<iki5@cdc.gov>;

Llewellyn, Anna C.

(CDC/DDID/NCEZID/DPEI)

<gif7@cdc.gov>;

Segaloff, Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<<u>qdz0@cdc.gov</u>>

Subject: Shedding

of Infectious SARS-

CoV-2 Despite

Vaccination when

the Delta Variant is

Prevalent

Good Morning,

You may have

heard but our task

force was asked by

STLT, and we

agreed, to sponsor

this manuscript

through clearance.

The authors are

targeting NEJM and

are requesting our

task force to

request IM

approval for

expedited

clearance. Our main POC for this

manuscript is our

CDC EISO Hannah Segaloff (Cc'd). Let me know if you have any questions.

Hannah- our clearance team can help shepherd your paper through clearance. I would anticipate our laboratory SMEs to have some questions for your team.

Best regards,

John

John Kools ADS, Laboratory & Testing Task Force CDC COVID-19 Response Phone: 404-217-7258

From: Rose, Dale A. (CDC/DDID/NCEZID/DPEI)

<ido8@cdc.gov>
Sent: Tuesday,
August 17, 2021

4:51 AM

To: Kools, John J. (CDC/DDID/NCEZID/OD)

<<u>czk7@cdc.gov</u>> **Subject:** FW:
Follow up on your results

Morning John!
Thanks for taking

this on. We had intensive discussions with WI, IM, and MMWR last week about this. There's strong interest in supporting and moving this forward quickly in clearance, including securing approval for expedited

clearance so it can quickly make it to NEJM for consideration. If you anticipate any issues with the content or timing, please do let me know as our TF is in routine conversation with the state epi and want to make sure we're aligned in our discussions.

Much appreciated, and I hope you are well!

Best, Dale

Dale Rose, Ph.D. STLT Support Task Force

Cell:

From: Llewellyn,

Anna C.

(CDC/DDID/NCEZID/DPEI)

<gif7@cdc.gov>
Sent: Monday,
August 16, 2021
3:35 PM

To: Segaloff, Hannah

(CDC dhs.wisconsin.gov)

< hannah.segaloff@dhs.wisconsin.gov>;

Rose, Dale A.

(CDC/DDID/NCEZID/DPEI)

<ido8@cdc.gov>;

Westergaard, Ryan

(CDC dhs.wisconsin.gov)

Bisgard, Kris

(CDC/DDPHSS/CSELS/DSEPD)

<kmb6@cdc.gov>

Cc: Ricaldi

Camahuali, Jessica

(CDC/DDID/NCEZID/DPEI)

<mpi7@cdc.gov>;

Kools, John J.

(CDC/DDID/NCEZID/OD)

<<u>czk7@cdc.gov</u>>;

Limbago, Brandi

(CDC/DDID/NCIRD/OD)

<bbl/>
dcdc.gov>; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) <iki5@cdc.gov>; CDC IMS 2019 NCOV Response STLT ADS <<u>eocevent410@cdc.gov</u>>;

CDC IMS 2019

NCOV Response Lab Task Force

<eocevent177@cdc.gov>

Subject: Re: Follow up on your results

Dear Hannah,

Thank you for these additional documents. Due to this manuscript's focus on laboratory data, our Laboratory and Testing Task Force colleagues have agreed to be the sponsoring task force for CDC COVID-19 Response clearance. John Kools is the Lab TF ADS and can assist with next steps.

Best Regards,

Anna

Anna Llewellyn, PhD Associate Director for Science State, Tribal, Local, and Territorial Support Task Force COVID-19 Emergency Response Centers for Disease Control and Prevention Office: 404-639-1538 | Cell:

eocevent410@cdc.gov

From: Segaloff, Hannah E - DHS

< hannah.segaloff@dhs.wisconsin.gov>

Sent: Monday,

August 16, 2021

3:13 PM

To: Rose, Dale A.

(CDC/DDID/NCEZID/DPEI)

<ido8@cdc.gov>;

Westergaard, Ryan

(CDC dhs.wisconsin.gov)

<ryan.westergaard@dhs.wisconsin.gov>;

Bisgard, Kris

(CDC/DDPHSS/CSELS/DSEPD)

< kmb6@cdc.gov>

Cc: Llewellyn, Anna

 Γ

(CDC/DDID/NCEZID/DPEI)

<gif7@cdc.gov>;

Ricaldi Camahuali,

Jessica

(CDC/DDID/NCEZID/DPEI)

<mpi7@cdc.gov>

Subject: RE: Follow up on your results

Thank you. I have

attached the

concept proposal

that was approved

from the original

MMWR submission

as well as a

clearance request

form.

Sincerely,

Hannah

Hannah Segaloff, PhD,

MPH | LT, U.S. Public

Health Service
Epidemic Intelligence

Service Officer

U.S. Centers for Disease

Control and Prevention

Bureau of Communicable

Diseases

Wisconsin Department of

Health Services

Currently Teleworking
Cell:

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

<Reimersma_Viral

loads in

vaccinees

NEJM_editedauthorlist_LABTFCOMMENTS.docx>

http://dho.pathology.wisc.edu @dho • 608-890-0845

<N1_Ct_updated_Hannah.csv>

From: Segaloff, Hannah E - DHS

To: <u>DAVID H O"CONNOR</u>; <u>Kasen Riemersma</u>; <u>Thomas Friedrich</u>

Cc: <u>Katarina Grande</u>; <u>Westergaard</u>, Ryan P - DHS

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Date: Saturday, August 21, 2021 1:26:12 PM

Hi Dave,

There are 3 clearance steps: main task force (for use was lab), cross clearance from other task forces (STLT for us) and then response level. This is the final level, yesterday was cross clearance. I think they suggested addressing things in the supplement due to the word limit. I'm happy to take a stab at the comments.

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: DAVID H O'CONNOR <dhoconno@wisc.edu>

Sent: Saturday, August 21, 2021 12:47 PM

 $\textbf{To:} \ Segal off, Hannah \ E-DHS < hannah.segal off @dhs.wisconsin.gov>; \ Kasen \ Riemersma < riemersma @wisc.edu>; \ Thomas < riemersma & riemer$

Friedrich <tfriedri@wisc.edu>

Cc: Katarina Grande <kgrande@publichealthmdc.com>; Westergaard, Ryan P - DHS <ryan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah,

I'm still not sure I understand. Why are there new comments now after we responded to the ones that were issued yesterday? If there are edits that can fit in the 400 word limit that's fine but I worry that the request for more information is at odds with the word count.

Do you want to take a crack at these edits since you know how to write these things on the way that the clearance process expects?

Cheers,

Dave

Get Outlook for iOS

From: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov>

Sent: Saturday, August 21, 2021 11:49:15 AM

To: Kasen Riemersma < riemersma@wisc.edu >; Thomas Friedrich < tfriedri@wisc.edu >

Cc: DAVID H O'CONNOR < dhoconno@wisc.edu; Katarina Grande < kgrande@publichealthmdc.com; Westergaard, Ryan P -

DHS < ryan.westergaard@dhs.wisconsin.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hi All,

This was not cleared by the JIC- they want to see the new version before clearance. However, comments don't seem too extensive.

I can work on the comments about the statewide perspective.

Best,

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Kasen Riemersma < riemersma@wisc.edu>

Sent: Friday, August 20, 2021 4:32 PM

To: Thomas Friedrich < tfriedri@wisc.edu; Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov>

Cc: DAVID H O'CONNOR dhoconno@wisc.edu">dhoconno@wisc.edu; Katarina Grande kgrande@publichealthmdc.com; Westergaard, Ryan P -

DHS < ryan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Thanks, Hannah!

Kasen

From: Thomas Friedrich < tfriedri@wisc.edu Date: Friday, August 20, 2021 at 4:25 PM

To: Segaloff, Hannah E - DHS < <u>Hannah.Segaloff@dhs.wisconsin.gov</u>>

Cc: DAVID H O'CONNOR < dhoconno@wisc.edu, Kasen Riemersma < riemersma@wisc.edu, Katarina Grande < kgrande@publichealthmdc.com, Westergaard, Ryan P - DHS < ryan.westergaard@dhs.wisconsin.gov>
Subread-althmdc.com, Westergaard, Ryan P - DHS < ryan.westergaard@dhs.wisconsin.gov>
Subread-althmdc.com, Westergaard, Ryan P - DHS < ryan.westergaard@dhs.wisconsin.gov>
Subread-althmdc.com, Westergaard, Ryan P - DHS < ryan.westergaard@dhs.wisconsin.gov>
subread-althmdc.com), Westergaard, Ryan P - DHS < ryan.westergaard@dhs.wisconsin.gov>
subread-althmdc.com), Westergaard, Ryan P - DHS < ryan.westergaard@dhs.wisconsin.gov>
subread-althmdc.com), Westergaard, Ryan P - DHS < ryan.westergaard@dhs.wisconsin.gov)

Sweet, thanks Hannah!

-T

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 20 Aug 2021, at 16:24, Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov > wrote:

It's back in. Fingers crossed that we get this back quickly. It looks like the on call clearance coordinator has email check-ins over the weekend at 10am and 3pm so those are the times that you are likely to hear Saturday or Sunday.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking Cell: Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu> **Sent:** Friday, August 20, 2021 4:18 PM

To: DAVID H O'CONNOR < dhoconno@wisc.edu>

Cc: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov>; Kasen Riemersma < riemersma@wisc.edu>;

Katarina Grande < kgrande@publichealthmdc.com >; Westergaard, Ryan P - DHS

<ryan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Oops, just saw this. I think we should go with Hannah's version since she addresses the question about the CDC ethics statement.

-T

Thomas Friedrich

Professor Dept. Pathobiological Sciences University of Wisconsin School of Veterinary Medicine @tcfriedrich @tcf-lab www.vetmed.wisc.edu/friedrichlab

On 20 Aug 2021, at 16:14, DAVID H O'CONNOR < dhoconno@wisc.edu > wrote:

Looks fine to me Hannah. Thanks for taking care of the edits.

dave

Segaloff, Hannah E - DHS wrote on 8/20/21 4:12 PM:

Sorry for the repeat emails. I can just send this version back if you all agree since changes were so minor.

-Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Thomas Friedrich <tfriedri@wisc.edu>

Sent: Friday, August 20, 2021 3:44 PM

To: Segaloff, Hannah E - DHS segaloff@dhs.wisconsin.gov

Cc: Kasen Riemersma riemersma@wisc.edu; DAVID H

O'CONNOR chicken; Katarina

Grande kgrande@publichealthmdc.com; Westergaard, Ryan P -

DHS <ryan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah.

Do you have any updates on the CDC clearance process? Can you see if others have been able to look at the paper?

Thanks,

-T

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 19 Aug 2021, at 18:51, Thomas Friedrich < tfriedri@wisc.edu wrote:

Okay, fingers crossed!

Sent from my iPhone

On Aug 19, 2021, at 18:02, Segaloff, Hannah E - DHS hannah.segaloff@dhs.wisconsin.gov wrote:

Though on second thought I can see that the STLT TF is reviewing now- so maybe this is moving faster than I thought.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

<u>Qazu@cac.gov</u>

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Thursday, August 19, 2021 5:44 PM

To: Segaloff, Hannah E - DHS

< hannah.segaloff@dhs.wisconsin.gov>

Cc: Kasen Riemersma riemersma@wisc.edu; DAVID H
O'CONNOR dhoconno@wisc.edu; Katarina Grande
kgrande@publichealthmdc.com>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Thanks Hannah.

I really hope they can return comments tomorrow so we can submit. I will be heading up north on Saturday and won't have WiFi for a week. Do you think that is at all possible?

Best,

Tom

Sent from my iPhone

On Aug 19, 2021, at 15:20, Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov > wrote:

Thanks Tom,

I will send these along and the note. I'm hoping we can switch over to a Google drive format for comments.

Best, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell: Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Thursday, August 19, 2021 3:05 PM

To: Segaloff, Hannah E - DHS

 $<\!\!\underline{hannah.segaloff@dhs.wisconsin.gov}\!\!>$

Cc: Kasen Riemersma

<<u>riemersma@wisc.edu</u>>; DAVID H O'CONNOR <<u>dhoconno@wisc.edu</u>>; Katarina Grande <<u>kgrande@publichealthmdc.com</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah.

Attached please find clean (well, clean-ish) and tracked versions of the revised manuscript. We addressed all the comments and made the changes requested. I hope this can be approved quickly.

Note: As you know, to edit collaboratively, we uploaded the Word doc with CDC comments to Google Drive. I redownloaded the edited version as a Word doc — this is the "clean" version and preserves CDC comments and our responses. To make the "tracked" version I had to compare that downloaded document to the Word doc you forwarded from CDC. When I did that I noticed that it duplicated several comments from CDC folk. For the sake of readability I tried to delete duplicates, but there are still a lot of comments in a small space. It also appears that replies within comments were not recognized, so now they just appear as comments on top of other comments. I hope that all makes sense.

If these copies do not come through, you can download them from the shared Google drive here:

Best,

-Tom

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 19 Aug 2021, at 09:41, Segaloff, Hannah E - DHS <hannah.segaloff@dhs.wisconsin.gov> wrote:

Hi All,

Here are the first round of comments. We should get all responses within 24 to 48 hours of our submission. It looks like this needs to be approved by Lab TF, cross clearance and the response.

Let me know if I can help with comments.

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases
Wisconsin Department of Health Services
Currently Teleworking
Cell:

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: CDC IMS 2019 NCOV Response Lab TF Clearance <eocevent216@cdc.gov>

Sent: Thursday, August 19, 2021

9:24 AM

To: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD)

<qdz0@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance <eocevent216@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah,

Please address the mandatory comments and return for re-

review.

Shedding of Infectious

SARS-CoV-2 Despite

Vaccination when the Delta

Variant is Prevalent

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD)

<qdz0@cdc.gov>

Sent: Wednesday, August 18,

2021 9:18 AM

To: CDC IMS 2019 NCOV Response Lab TF Clearance <<u>eocevent216@cdc.gov</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hello,

Thank you for the quick work getting this approved for DIM expedited clearance. I haven't had a manuscript in expedited clearance before. Does it have the same steps as standard? How much time should I anticipate for the clearance process?

Thank you! Hannah

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) <qqv9@cdc.gov> Sent: Tuesday, August 17, 2021

11:51 AM

To: Kools, John J.

(CDC/DDID/NCEZID/OD)

<czk7@cdc.gov>; CDC IMS 2019

NCOV Response Lab TF

Clearance

<eocevent216@cdc.gov>;

Dunworth, Soumya

(CDC/DDPHSS/CSELS/OD)

<kya6@cdc.gov>

Cc: Limbago, Brandi

(CDC/DDID/NCIRD/OD)

dc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR)

<<u>xhg9@cdc.gov</u>>; Segaloff,

Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<qdz0@cdc.gov>; Moon,

Jonathan L.

(CDC/DDID/NCEZID/DSR)

<iki5@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite

Vaccination when the Delta

Variant is Prevalent

NP! Glad we were able to turn this around so quickly.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force COVID-19 Emergency Response

Centers for Disease Control and

Prevention

Lab TF Communications

Mailbox: eocevent503@cdc.gov

Cell:

From: Kools, John J. (CDC/DDID/NCEZID/OD)

<<u>czk7@cdc.gov</u>>

Sent: Tuesday, August 17, 2021

12:47 PM

To: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>; CDC IMS 2019

NCOV Response Lab TF

Clearance

<eocevent216@cdc.gov>;

Dunworth, Soumya

(CDC/DDPHSS/CSELS/OD)

<<u>kya6@cdc.gov</u>>

Cc: Limbago, Brandi

(CDC/DDID/NCIRD/OD)

<<u>bbl7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>; Segaloff,

Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<qdz0@cdc.gov>; Moon,

Jonathan L.

(CDC/DDID/NCEZID/DSR)

<iki5@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Thanks Shelbi!

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021

12:43 PM

To: CDC IMS 2019 NCOV
Response Lab TF Clearance
<eocevent216@cdc.gov>; Kools,
John J. (CDC/DDID/NCEZID/OD)
<czk7@cdc.gov>; Dunworth,

Soumya

(CDC/DDPHSS/CSELS/OD)

<kya6@cdc.gov>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD)

<<u>bbl7@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<<u>xhg9@cdc.gov</u>>; Segaloff,

Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<adz0@cdc.gov>; Moon,

Jonathan L.

(CDC/DDID/NCEZID/DSR)

<iki5@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Afternoon,

This has been approved for expedited clearance.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and

Prevention

Lab TF Communications
Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021

12:40 PM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thank you. I approve expedited clearance. Stephanie Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<<u>qqv9@cdc.gov</u>>

Sent: Tuesday, August 17, 2021

12:16 PM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H.
(CDC/DDPHSS/CSELS/OD)
<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

(CDC/DDID/NCIRD/OD) (CI

<<u>xhg9@cdc.gov</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hey Stephanie,

Please see attached for the updated draft.

Thanks, Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response Centers for Disease Control and

Centers for Disease Control and

Prevention

Lab TF Communications

Mailbox: eocevent503@cdc.gov

Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) <aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021

11:05 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

<<u>iwg7@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Sure thing, working on the updated draft now.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response Centers for Disease Control and

Prevention

Lab TF Communications

Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<<u>zqg7@cdc.gov</u>>

Sent: Tuesday, August 17, 2021

10:56 AM

To: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Cc: Fisher, Angela H.

(CDC/DDPHSS/CSELS/OD)

<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: RE: Shedding of

Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Yes, please request an updated draft with Hannah's name on it and then I approve it going for expedited clearance.
Stephanie
Stephanie R. Bialek MD MPH Deputy Incident Manager
COVID-19 Response
CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021

10:56 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H.
(CDC/DDPHSS/CSELS/OD)
<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hey Stephanie,

From correspondence with ADS and STLT Hannah was inadvertently left off the manuscript but WI has confirmed that she is a co-author but her name is not on this draft. Should we request an updated draft with Hannah information on there as the co-author?

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and
Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov
Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021

10:51 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H.

(CDC/DDPHSS/CSELS/OD)

<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Неу,

I am working on getting clarification as we speak, update to follow.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and
Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov
Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<<u>zqg7@cdc.gov</u>>

Sent: Tuesday, August 17, 2021

10:49 AM

To: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hannah Segaloff EISO is listed on the clearance request form as an author but not on the manuscript. Can you clarify that she indeed and author? If so, then my approval for expedited clearance stands.

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021

10:40 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H.

(CDC/DDPHSS/CSELS/OD)

<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thanks for the speedy response!

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and
Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov
Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021

10:39 AM

To: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Cc: Fisher, Angela H.
(CDC/DDPHSS/CSELS/OD)
<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

I approve.

Stephanie R. Bialek MD MPH

Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021

10:38 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H.
(CDC/DDPHSS/CSELS/OD)
<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)
<xhg9@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Morning Stephanie,

Happy Tuesday! We would like to request DIM1 expedited approval for the attached manuscript. Please refer to the email thread below.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and
Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov
Cell:

From: CDC IMS 2019 NCOV Response Lab TF Clearance <eocevent216@cdc.gov>

Sent: Tuesday, August 17, 2021

10:32 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<<u>qqv9@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance <eocevent216@cdc.gov> **Subject:** Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hi Shelbi and Jarrett,

Should I begin clearance on this item or wait until you receive the DIM approval?

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Kools, John J. (CDC/DDID/NCEZID/OD)

<<u>czk7@cdc.gov</u>>

Sent: Tuesday, August 17, 2021

9:59 AM

To: CDC IMS 2019 NCOV
Response Lab TF Clearance
<eocevent216@cdc.gov>; Davis,
Shelbi (CDC/DDID/NCIRD/DVD)
<qqv9@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)
<xhg9@cdc.gov>

Cc: Dunworth, Soumya
(CDC/DDPHSS/CSELS/OD)
<kya6@cdc.gov>; Limbago,
Brandi (CDC/DDID/NCIRD/OD)
<bbf7@cdc.gov>; Moon,
Jonathan L.
(CDC/DDID/NCEZID/DSR)
<iki5@cdc.gov>; Llewellyn, Anna
C. (CDC/DDID/NCEZID/DPEI)
<gif7@cdc.gov>; Segaloff,
Hannah
(CDC/DDPHSS/CSELS/DSEPD)

<adz0@cdc.gov>

Subject: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Good Morning,

You may have heard but our task force was asked by STLT, and we agreed, to sponsor this manuscript through clearance. The authors are targeting NEJM and are requesting our task force to request IM approval for expedited clearance. Our main POC for this manuscript is our CDC EISO Hannah Segaloff (Cc'd). Let me know if you have any questions.

Hannah- our clearance team can help shepherd your paper through clearance. I would anticipate our laboratory SMEs to have some questions for your team.

Best regards,

John

John Kools ADS, Laboratory & Testing Task Force CDC COVID-19 Response Phone: 404-217-7258

From: Rose, Dale A. (CDC/DDID/NCEZID/DPEI) <ido8@cdc.gov>

Sent: Tuesday, August 17, 2021

4:51 AM

To: Kools, John J. (CDC/DDID/NCEZID/OD) <czk7@cdc.gov>

Subject: FW: Follow up on your

results

Morning John! Thanks for taking this on. We had intensive discussions with WI, IM, and MMWR last week about this. There's strong interest in supporting and moving this forward quickly in clearance, including securing approval for expedited clearance so it can quickly make it to NEJM for consideration. If you

anticipate any issues with the content or timing, please do let me know as our TF is in routine conversation with the state epi and want to make sure we're aligned in our discussions.

Much appreciated, and I hope you are well!

Best, Dale

Dale Rose, Ph.D. STLT Support Task Force

Cell:

From: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI)

<gif7@cdc.gov>

Sent: Monday, August 16, 2021

3:35 PM

To: Segaloff, Hannah (CDC dhs.wisconsin.gov)

hannah.segaloff@dhs.wisconsin.gov;

Rose, Dale A.

(CDC/DDID/NCEZID/DPEI)

<idos@cdc.gov>; Westergaard,

Ryan (CDC dhs.wisconsin.gov)

<ryan.westergaard@dhs.wisconsin.gov>;

Bisgard, Kris

(CDC/DDPHSS/CSELS/DSEPD)

<<u>kmb6@cdc.gov</u>>

Cc: Ricaldi Camahuali, Jessica (CDC/DDID/NCEZID/DPEI)

<<u>mpi7@cdc.gov</u>>; Kools, John J.

(CDC/DDID/NCEZID/OD)

<<u>czk7@cdc.gov</u>>; Limbago,

Brandi (CDC/DDID/NCIRD/OD)

bbl7@cdc.gov>; Moon,

Jonathan L.

(CDC/DDID/NCEZID/DSR)

<iki5@cdc.gov>; CDC IMS 2019

NCOV Response STLT ADS

<eocevent410@cdc.gov>; CDC

IMS 2019 NCOV Response Lab

Task Force

<<u>eocevent177@cdc.gov</u>>

Subject: Re: Follow up on your

results

Dear Hannah,

Thank you for these additional documents. Due to this manuscript's focus on laboratory data, our Laboratory and Testing Task Force colleagues have agreed to be the sponsoring task force for CDC COVID-19 Response clearance. John Kools is the Lab TF ADS and can assist with next steps.

Best Regards,

Anna

Anna Llewellyn, PhD Associate Director for Science State, Tribal, Local, and Territorial Support Task Force COVID-19 Emergency Response Centers for Disease Control and Prevention Office: 404-639-1538 | Cell:

eocevent410@cdc.gov

From: Segaloff, Hannah E - DHS <hannah.segaloff@dhs.wisconsin.gov>

Sent: Monday, August 16, 2021

3:13 PM

To: Rose, Dale A.

(CDC/DDID/NCEZID/DPEI)

<ido8@cdc.gov>; Westergaard,

Ryan (CDC dhs.wisconsin.gov)

<ryan.westergaard@dhs.wisconsin.gov>;

Bisgard, Kris

(CDC/DDPHSS/CSELS/DSEPD)

< kmb6@cdc.gov>

Cc: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI)

<gif7@cdc.gov>; Ricaldi

Camahuali, Jessica

(CDC/DDID/NCEZID/DPEI)

<mpi7@cdc.gov>

Subject: RE: Follow up on your

results

Thank you. I have attached the concept proposal that was approved from the original MMWR submission as well as a clearance request form.

Sincerely, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases
Wisconsin Department of Health Services
Currently Teleworking
Cell:
Hannah.Segaloff@dhs.wisconsin.gov
Qdz0@cdc.gov

<Reimersma_Viral loads in vaccinees_
NEJM_editedauthorlist_LABTFCOMMENTS.docx>

--

http://dho.pathology.wisc.edu @dho • 608-890-0845 From: Segaloff, Hannah E - DHS **Thomas Friedrich** To:

Kasen Riemersma; DAVID H O"CONNOR; Katarina Grande; Westergaard, Ryan P - DHS Cc:

RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent Subject:

Friday, August 20, 2021 4:12:15 PM Date:

Attachments: Riemersma Viral loads in vaccinees NEJM revised 8 20 tracked.docx

Sorry for the repeat emails. I can just send this version back if you all agree since changes were so minor.

-Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: Thomas Friedrich <tfriedri@wisc.edu> Sent: Friday, August 20, 2021 3:44 PM

To: Segaloff, Hannah E - DHS <hannah.segaloff@dhs.wisconsin.gov>

Cc: Kasen Riemersma <riemersma@wisc.edu>; DAVID H O'CONNOR <dhoconno@wisc.edu>; Katarina Grande <kgrande@publichealthmdc.com>; Westergaard, Ryan P - DHS

<ryan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah.

Do you have any updates on the CDC clearance process? Can you see if others have been able to look at the paper?

Thanks,

-T

Thomas Friedrich

Professor Dept. Pathobiological Sciences University of Wisconsin School of Veterinary Medicine @tcfriedrich @tcf-lab www.vetmed.wisc.edu/friedrichlab On 19 Aug 2021, at 18:51, Thomas Friedrich < tfriedri@wisc.edu > wrote:

Okay, fingers crossed!

Sent from my iPhone

On Aug 19, 2021, at 18:02, Segaloff, Hannah E - DHS hannah.segaloff@dhs.wisconsin.gov wrote:

Though on second thought I can see that the STLT TF is reviewing now- so maybe this is moving faster than I thought.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Thursday, August 19, 2021 5:44 PM

To: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov > Cc: Kasen Riemersma < riemersma@wisc.edu >; DAVID H O'CONNOR < dhoconno@wisc.edu >; Katarina Grande < kgrande@publichealthmdc.com > Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Thanks Hannah.

I really hope they can return comments tomorrow so we can submit. I will be heading up north on Saturday and won't have WiFi for a week. Do you think that is at all possible?

Best,

Tom

Sent from my iPhone

On Aug 19, 2021, at 15:20, Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov> wrote:

Thanks Tom,

I will send these along and the note. I'm hoping we can switch over to a Google drive format for comments.

Best, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Thursday, August 19, 2021 3:05 PM

To: Segaloff, Hannah E - DHS

< hannah.segaloff@dhs.wisconsin.gov>

Cc: Kasen Riemersma <<u>riemersma@wisc.edu</u>>; DAVID H O'CONNOR <<u>dhoconno@wisc.edu</u>>; Katarina Grande

< kgrande@publichealthmdc.com>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah.

Attached please find clean (well, clean-ish) and tracked versions of the revised manuscript. We addressed all the comments and made the changes requested. I hope this can be approved quickly.

Note: As you know, to edit collaboratively, we uploaded the Word doc with CDC comments to Google Drive. I redownloaded the edited version as a Word doc — this is the "clean" version and preserves CDC comments and our responses. To make the "tracked" version I had to compare that downloaded document to the Word doc you forwarded from CDC. When I did that I noticed that it duplicated several comments from CDC folk. For the sake of readability I tried to delete duplicates, but there are still a lot of comments in a small space. It also appears that replies within comments were not recognized, so now they just appear as comments on top of other comments. I hope that all makes sense.

If these copies do not come through, you can download them from the shared Google drive here:

Best,

-Tom

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 19 Aug 2021, at 09:41, Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov > wrote:

Hi All,

Here are the first round of comments. We should get all responses within 24 to 48 hours of our submission. It looks like this needs to be approved by Lab TF, cross clearance and the response. Let me know if I can help with comments.

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: CDC IMS 2019 NCOV Response Lab TF

Clearance <<u>eocevent216@cdc.gov</u>> **Sent:** Thursday, August 19, 2021 9:24 AM

To: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < adz0@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance eocevent216@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah,

Please address the mandatory comments and return for re-review.

Shedding of Infectious SARS-CoV-2 Despite
Vaccination when the Delta Variant is Prevalent

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Segaloff, Hannah

(CDC/DDPHSS/CSELS/DSEPD) < adz0@cdc.gov> **Sent:** Wednesday, August 18, 2021 9:18 AM

To: CDC IMS 2019 NCOV Response Lab TF Clearance

<<u>eocevent216@cdc.gov</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Hello,

Thank you for the quick work getting this approved for DIM expedited clearance. I haven't had a manuscript in expedited clearance before. Does it have the same steps as standard? How much time should I anticipate for the clearance process?

Thank you! Hannah

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 11:51 AM **To:** Kools, John J. (CDC/DDID/NCEZID/OD)

<<u>czk7@cdc.gov</u>>; CDC IMS 2019 NCOV Response Lab TF Clearance <<u>eocevent216@cdc.gov</u>>; Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) <<u>kya6@cdc.gov</u>>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD)

dc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>;

Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD)

<<u>qdz0@cdc.gov</u>>; Moon, Jonathan L.

(CDC/DDID/NCEZID/DSR) < iki5@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

NP! Glad we were able to turn this around so quickly.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Kools, John J. (CDC/DDID/NCEZID/OD)

From: Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov>

Sent: Tuesday, August 17, 2021 12:47 PM **To:** Davis, Shelbi (CDC/DDID/NCIRD/DVD)

qqv9@cdc.gov">; CDC IMS 2019 NCOV Response Lab TF Clearance < qecevent216@cdc.gov>;

Dunworth, Soumya (CDC/DDPHSS/CSELS/OD)

<kya6@cdc.gov>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD)

dcdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>;

Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD)

<<u>qdz0@cdc.gov</u>>; Moon, Jonathan L.

(CDC/DDID/NCEZID/DSR) < iki5@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Thanks Shelbi!

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 12:43 PM

To: CDC IMS 2019 NCOV Response Lab TF Clearance

<<u>eocevent216@cdc.gov</u>>; Kools, John J.

(CDC/DDID/NCEZID/OD) < czk7@cdc.gov>;

Dunworth, Soumya (CDC/DDPHSS/CSELS/OD)

<kya6@cdc.gov>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD)

bbl7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>;

Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD)

<qdz0@cdc.gov>; Moon, Jonathan L.

(CDC/DDID/NCEZID/DSR) < iki5@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Afternoon,

This has been approved for expedited clearance.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 12:40 PM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Thank you. I approve expedited clearance. Stephanie

Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 12:16 PM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<<u>zqg7@cdc.gov</u>>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) xhg9@cdc.gov

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Hey Stephanie,

Please see attached for the updated draft.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 11:05 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov> **Subject:** Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Sure thing, working on the updated draft now.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Lab TF Communications Mailbox: eocevent503@cdc.gov
Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:56 AM **To:** Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) <xhg9@cdc.gov> **Subject:** RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Yes, please request an updated draft with Hannah's name on it and then I approve it going for expedited clearance.

Stephanie Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<aav9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:56 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov >; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Hey Stephanie,

From correspondence with ADS and STLT Hannah was inadvertently left off the manuscript but WI has confirmed that she is a co-author but her name is not on this draft. Should we request an updated draft with Hannah information on there as the co-author?

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:51 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov >; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Неу,

I am working on getting clarification as we speak, update to follow.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:49 AM **To:** Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<aqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov >; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) <xhg9@cdc.gov> **Subject:** RE: Shedding of Infectious SARS-CoV-2
Despite Vaccination when the Delta Variant is
Prevalent

Hannah Segaloff EISO is listed on the clearance request form as an author but not on the manuscript. Can you clarify that she indeed and author? If so, then my approval for expedited

clearance stands.

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:40 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov > **Subject:** Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Thanks for the speedy response!

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:39 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov >; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

I approve.

Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:38 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<<u>zqg7@cdc.gov</u>>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Morning Stephanie,

Happy Tuesday! We would like to request DIM1 expedited approval for the attached manuscript. Please refer to the email thread below.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: CDC IMS 2019 NCOV Response Lab TF

Clearance < eocevent 216@cdc.gov >

Sent: Tuesday, August 17, 2021 10:32 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<agy9@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance

<eocevent216@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Hi Shelbi and Jarrett.

Should I begin clearance on this item or wait until you receive the DIM approval?

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Kools, John J. (CDC/DDID/NCEZID/OD)

<czk7@cdc.gov>

Sent: Tuesday, August 17, 2021 9:59 AM

To: CDC IMS 2019 NCOV Response Lab TF Clearance

<eocevent216@cdc.gov>; Davis, Shelbi

(CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov >; Gartin,

Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Cc: Dunworth, Soumya (CDC/DDPHSS/CSELS/OD)

<<u>kya6@cdc.gov</u>>; Limbago, Brandi

(CDC/DDID/NCIRD/OD)
bbl7@cdc.gov>; Moon,

Jonathan L. (CDC/DDID/NCEZID/DSR)

<iki5@cdc.gov>; Llewellyn, Anna C.

(CDC/DDID/NCEZID/DPEI) < gif7@cdc.gov >; Segaloff,

Hannah (CDC/DDPHSS/CSELS/DSEPD)

<adz0@cdc.gov>

Subject: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Good Morning,

You may have heard but our task force was asked by STLT, and we agreed, to sponsor this manuscript through clearance. The authors are targeting NEJM and are requesting our task force to request IM approval for expedited clearance. Our main POC for this manuscript is our CDC EISO Hannah Segaloff (Cc'd). Let me know if you have any questions.

Hannah- our clearance team can help shepherd your paper through clearance. I would anticipate our laboratory SMEs to have some questions for your team.

Best regards,

John

John Kools ADS, Laboratory & Testing Task Force CDC COVID-19 Response Phone: 404-217-7258

From: Rose, Dale A. (CDC/DDID/NCEZID/DPEI)

<ido8@cdc.gov>

Sent: Tuesday, August 17, 2021 4:51 AM **To:** Kools, John J. (CDC/DDID/NCEZID/OD)

<czk7@cdc.gov>

Subject: FW: Follow up on your results

Morning John! Thanks for taking this on. We had intensive discussions with WI, IM, and MMWR last week about this. There's strong interest in supporting and moving this forward quickly in clearance, including securing approval for expedited clearance so it can quickly make it to NEJM for consideration. If you anticipate any issues with the content or timing, please do let me know as our TF is in routine conversation with the state epi and want to make sure we're aligned in our discussions.

Much appreciated, and I hope you are well!

Best, Dale

Dale Rose, Ph.D. STLT Support Task Force

Cell:

From: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI) <gif7@cdc.gov>

Sent: Monday, August 16, 2021 3:35 PM To: Segaloff, Hannah (CDC dhs.wisconsin.gov) < hannah.segaloff@dhs.wisconsin.gov >; Rose, Dale A. (CDC/DDID/NCEZID/DPEI) < ido8@cdc.gov>; Westergaard, Ryan (CDC dhs.wisconsin.gov) <rvan.westergaard@dhs.wisconsin.gov>; Bisgard, Kris (CDC/DDPHSS/CSELS/DSEPD) < kmb6@cdc.gov> Cc: Ricaldi Camahuali, Jessica (CDC/DDID/NCEZID/DPEI) < mpi7@cdc.gov >; Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov >; Limbago, Brandi (CDC/DDID/NCIRD/OD)

bbl7@cdc.gov>; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < iki5@cdc.gov >; CDC IMS 2019 NCOV Response STLT ADS <eocevent410@cdc.gov>; CDC IMS 2019 NCOV Response Lab Task Force < eocevent 177@cdc.gov> Subject: Re: Follow up on your results

Dear Hannah,

Thank you for these additional documents. Due to this manuscript's focus on laboratory data, our Laboratory and Testing Task Force colleagues have agreed to be the sponsoring task force for CDC COVID-19 Response clearance. John Kools is the Lab TF ADS and can assist with next steps.

Best Regards,

Anna

Anna Llewellyn, PhD Associate Director for Science State, Tribal, Local, and Territorial Support Task Force COVID-19 Emergency Response Centers for Disease Control and Prevention Office: 404-639-1538 | Cell: eocevent410@cdc.gov

From: Segaloff, Hannah E - DHS

hannah.segaloff@dhs.wisconsin.gov">hannah.segaloff@dhs.wisconsin.gov

Sent: Monday, August 16, 2021 3:13 PM **To:** Rose, Dale A. (CDC/DDID/NCEZID/DPEI)
<ido8@cdc.gov>; Westergaard, Ryan

(CDC dhs.wisconsin.gov)

<ryan.westergaard@dhs.wisconsin.gov>; Bisgard,
Kris (CDC/DDPHSS/CSELS/DSEPD) < kmb6@cdc.gov>
Cc: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI)
<gif7@cdc.gov>; Ricaldi Camahuali, Jessica
(CDC/DDID/NCEZID/DPEI) < mpi7@cdc.gov>

Subject: RE: Follow up on your results

Thank you. I have attached the concept proposal that was approved from the original MMWR submission as well as a clearance request form.

Sincerely, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

<u>Hannah.Segaloff@dhs.wisconsin.gov</u> <u>Qdz0@cdc.gov</u>

<Reimersma_Viral loads in vaccinees_
NEJM editedauthorlist LABTFCOMMENTS.docx>

Shedding of Infectious SARS-CoV-2 Despite Vaccination

Kasen K. Riemersma, DVM, PhD¹; Brittany E. Grogan, MPH²; Amanda Kita-Yarbro, MPH²; Peter J. Halfmann, PhD¹; Hannah E. Segaloff, PhD³; Anna Kocharian, MS⁴; Kelsey R. Florek, MPH, PhD⁵; Ryan Westergaard, MD, PhD⁶; Allen Bateman, PhD⁵; Gunnar E. Jeppson, BS⁻; Yoshihiro Kawaoka, DVM, PhD¹; David H. O'Connor, PhD⁶ '; Thomas C. Friedrich, PhD¹ ', Katarina M. Grande, MPH² '

Katarina Grande KGrande@publichealthmdc.com

¹ Department of Pathobiological Sciences, University of Wisconsin-Madison, Madison, WI, USA

² Public Health Madison & Dane County, Madison, WI, USA

³ Epidemic Intelligence Service, CDC, Atlanta, GA, USA

³ Wisconsin Department of Health Services, Madison, WI, USA

⁵ Wisconsin State Laboratory of Hygiene, Madison, WI, USA

⁶ Department of Medicine, University of Wisconsin School of Medicine and Public Health, Madison, WI, USA

⁷ Exact Sciences, Madison, WI, USA

⁸ Department of Pathology and Laboratory Medicine, University of Wisconsin-Madison, Madison, WI, USA

[^]These authors contributed equally. Correspondence can be addressed to:

Main text (400 words; limit 400)

The SARS-CoV-2 Delta variant ean might cause high viral loads, is highly transmissible, and contains mutations that confer partial immune escape ^{1,2}. Outbreak investigations suggest that vaccinated persons can spread Delta ^{3,4}. We compared RT-qPCR cycle threshold (Ct) data from 699 swab specimens collected in Wisconsin 29 June through 31 July 2021 and tested by a single contract laboratory. During this time, estimated prevalence of Delta variants in Wisconsin increased from 69% to over 95%. Vaccination status was determined via self-reporting and state immunization records (Supplemental Figure 1).

We observed low Ct values (Ct <25) in 212 of 310 individuals infected despite full vaccination (68%; Figure 1A). Testing a subset of low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people (Figure 1B).

Ct values were similar in vaccinated and unvaccinated people whether or not they reported symptoms at the time of testing (Figure 1C). Among asymptomatic individuals, Ct values <25 were detected in 7 of 24 unvaccinated (29%; CI: 13-51%) and 9 of 11 fully vaccinated individuals (82%; CI: 52-95%). There was no significant difference in time from symptom onset to testing for vaccinated vs. unvaccinated individuals (two-sample K-S test, p=0.40; Supplemental Figure 2). Infectious virus was detected in the sole specimen tested from an asymptomatic fully vaccinated individual. Although the number of asymptomatic individuals sampled is small, these results indicate that people infected despite vaccination may have low Ct values and shed infectious virus even while asymptomatic.

Combined with other studies ^{2–5}, these data indicate that vaccinated individuals infected with the Delta variant may transmit infection to others. Importantly, we show that infectious SARS-CoV-2 is frequently found even in vaccinated persons when specimen Ct values are low. The co-circulation of viruses from Pango lineages B.1.617.2, AY.2, and AY.3, and the wide geographic area sampled, indicate that the infections analyzed here are not associated with any single large outbreak, and that Delta-lineage SARS-CoV-2 can achieve low Ct values consistent with transmissibility in fully vaccinated individuals

Commented [D(1]: Lab TF ADS: L2, suggest "may" because this is based on Ct values.

Commented [D(2]: Lab TF ADS: L1 mandatory, RT-PCR here and throughout. RT-qPCR suggests that this assay was quantitative.

across a range of exposure settings. Vaccinated persons should be encouraged to get tested when symptomatic or after close contact with someone with suspected or confirmed COVID-19. Continued adherence to non-pharmaceutical interventions during periods of high community transmission will remain important for both vaccinated and unvaccinated individuals to help contain the spread of COVID-19.

Figure Α В All Cases Infectious virus recovered: o Yes o XNo 10 p=0.23 10 20 **N1 Ct value** N1 Ct value 30 00 40 40 n=389 n=310 Unvaccinated Vaccinated Unvaccinated . Vaccinated C Unknown Symptom Status Symptomatic Asymptomatic 10 p=0.05 p=0.74 p=0.82N1 Ct value 00 40 n=133

n=24

n=232

. Unvaccinated

Figure 1. Individuals infected with SARS-CoV-2 despite full vaccination have low Ct values and shed infectious virus. A. Ct values for SARS-CoV-2-positive specimens grouped by vaccination status. RT-qPCR was performed by Exact Sciences Corporation using a diagnostic assay targeting the SARS-CoV-2 N gene (oligonucleotides identical to CDC's N1 primer and probe set) that has been authorized for emergency use by FDA (https://www.fda.gov/media/138328/download). B. Infectiousness was determined for a subset of specimens with Ct <25 by inoculation onto Vero E6 TMPRSS2 cells and determining presence of cytopathic effects (CPE) after 5 days in culture. Circles indicate presence of CPE; 'X' indicates no CPE detected. C. N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for individuals who were symptomatic or asymptomatic, or those whose symptom status was not determined, at the time of testing. In A and C, boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values by independent two-group Mann-Whitney U tests.

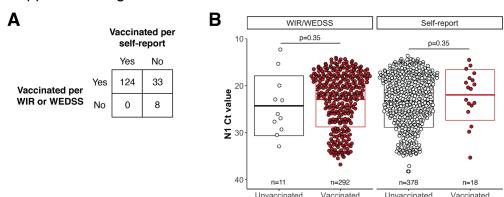
n=11

Vaccinated

Unvaccinated

Supplemental materials

Supplemental figure 1



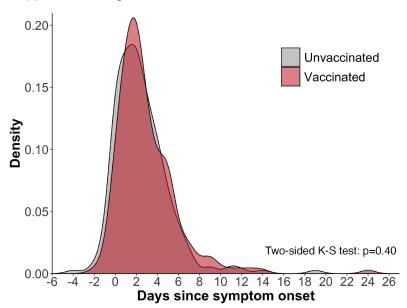
Supplemental figure 1. Concordance between self-reported vaccination status and the Wisconsin Immunization Registry (WIR) or Wisconsin Electronic Disease Surveillance System (WEDSS). For all individuals, vaccination status was determined using WIR/WEDSS electronic registries when data was available. Individuals were identified as unvaccinated at the time of testing if WIR/WEDSS data indicated receipt of a first SARS-CoV-2 vaccine dose after the test date.

Individuals were considered fully vaccinated based on WIR/WEDSS data if the registries indicated receipt of a final vaccine dose at least 14 days prior to testing. For individuals whose vaccination status could not be verified in WIR/WEDSS, self-reported data collected at the time of testing was used. Individuals were considered unvaccinated based on self-report only if there was an explicit declaration of unvaccinated status in the self-reported data. Individuals were considered fully vaccinated based on self-report if they fulfilled all of the following criteria: (1) indicated that they had received a COVID vaccine prior to testing; (2) indicated that they did not require another vaccine dose; and (3) reported a date of last vaccine dose that was at least 14 days prior to testing.

Specimens lacking data on vaccination status were excluded from the study. Specimens from partially vaccinated individuals (incomplete vaccine series, or <14 days post-final dose) were also excluded. Fully vaccinated status was determined by WIR/WEDSS for 292 specimens and by self-reported data for 18. Unvaccinated status was determined by WIR/WEDSS for 11 and by self-reported data by 378.

A. Of the 699 specimens with vaccination status available from at least one source, 165 specimens had data available from both sources. For self-reporting, under-reporting of full vaccination status (33/157) was more common than over-reporting (0/124). B. N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for individuals whose vaccination status was determined by WIR/WEDDS or by self-reported data. Boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values by independent two-group Mann-Whitney U tests.

Supplemental figure 2



Supplemental figure 2. Density distributions of unvaccinated and vaccinated specimen collection dates by day since symptom onset. Day 0 on the x-axis denotes self-reported day of symptom onset. Negative values for days indicate specimen collection prior to symptom onset. Symptom onset data were available for n=263 unvaccinated cases and n=232 vaccinated cases.

Conflict of interest

The authors declare no conflicting interests.

Ethics statement

Per the University of Wisconsin-Madison IRB, this project qualifies as public health surveillance activities as defined in the Common Rule, 45 CFR 46.102(I)(2). As such, the project is not deemed to be research regulated under the Common Rule and therefore, does not require University of Wisconsin-Madison IRB review and oversight. The opinions expressed by authors contributing to this journal do not necessarily reflect the opinions of the Centers for Disease Control and Prevention or the institutions with which the authors are affiliated.

Data availability

Data and processing workflows are available at https://go.wisc.edu/p22l16. To protect potentially personally identifiable information, the publicly available dataset contains only PCR Ct values, vaccine status, symptom status, and days from symptom onset to testing for each specimen.

Commented [L(3]: STLT ADS - Defer to rADS, but doesn't this also need the CDC ethics statement?

"This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy. §

§See e.g., 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq.

Commented [SHE-D4R3]: Happy to change this but this specific activity was not reviewed by CDC (I have a broad covid outbreak concept proposal that this falls under).

References

- Planas D, Veyer D, Baidaliuk A, et al. Reduced sensitivity of SARS-CoV-2 variant Delta to antibody neutralization. Nature [Internet] 2021 [cited 2021 Jul 28];1–7. Available from: https://www.nature.com/articles/s41586-021-03777-9
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- Chia PY, Xiang Ong SW, Chiew CJ, et al. Virological and serological kinetics of SARS-CoV-2
 Delta variant vaccine-breakthrough infections: a multi-center cohort study [Internet]. bioRxiv.

 2021;Available from: http://medrxiv.org/lookup/doi/10.1101/2021.07.28.21261295

From: Segaloff, Hannah E - DHS
To: Thomas Friedrich

Cc: Kasen Riemersma; DAVID H O"CONNOR; Katarina Grande; Westergaard, Ryan P - DHS

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Date: Friday, August 20, 2021 4:06:49 PM

Attachments: Riemersma Viral loads in vaccinees NEJM revised CLEAN 2021-08-19.docx

Perfect timing- just got it back- very minimal comments. This is cleared with comments so it goes to the final level of clearance once we are done. If you can just send me the word doc with comments and then change in google docs it will probably be fastest. I'm not sure if will make it before your vacation but we may get this back tomorrow.

Best,

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases
Wisconsin Department of Health Services
Currently Teleworking
Cell

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: Thomas Friedrich <tfriedri@wisc.edu>

Sent: Friday, August 20, 2021 3:44 PM

To: Segaloff, Hannah E - DHS <hannah.segaloff@dhs.wisconsin.gov>

Cc: Kasen Riemersma <riemersma@wisc.edu>; DAVID H O'CONNOR <dhoconno@wisc.edu>; Katarina Grande <kgrande@publichealthmdc.com>; Westergaard, Ryan P - DHS

<ryan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah.

Do you have any updates on the CDC clearance process? Can you see if others have been able to look at the paper?

Thanks,

-T

Thomas Friedrich

Professor Dept. Pathobiological Sciences University of Wisconsin School of Veterinary Medicine @tcfriedrich On 19 Aug 2021, at 18:51, Thomas Friedrich < tfriedri@wisc.edu > wrote:

Okay, fingers crossed!

Sent from my iPhone

On Aug 19, 2021, at 18:02, Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov> wrote:

Though on second thought I can see that the STLT TF is reviewing now- so maybe this is moving faster than I thought.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Thursday, August 19, 2021 5:44 PM

To: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov> **Cc:** Kasen Riemersma < riemersma@wisc.edu>; DAVID H O'CONNOR

dhoconno@wisc.edu; Katarina Grande kgrande@publichealthmdc.com>
Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the

Delta Variant is Prevalent

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Thanks Hannah.

I really hope they can return comments tomorrow so we can submit. I will be heading up north on Saturday and won't have WiFi for a week. Do you think that is at all possible?

Best,

Tom

Sent from my iPhone

On Aug 19, 2021, at 15:20, Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov > wrote:

Thanks Tom,

I will send these along and the note. I'm hoping we can switch over to a Google drive format for comments.

Best, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases
Wisconsin Department of Health Services
Currently Teleworking
Cell:

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Thursday, August 19, 2021 3:05 PM

To: Segaloff, Hannah E - DHS

<a href="mailto:hannah.segaloff@dhs.wisconsin.gov>

Cc: Kasen Riemersma < riemersma@wisc.edu>; DAVID H O'CONNOR < dhoconno@wisc.edu>; Katarina Grande < kgrande@publichealthmdc.com>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah.

Attached please find clean (well, clean-ish) and tracked versions of the revised manuscript. We addressed all the comments and made the changes requested. I hope this can be approved quickly.

Note: As you know, to edit collaboratively, we uploaded the Word doc with CDC comments to Google Drive. I redownloaded the edited version as a Word doc — this is the "clean" version and preserves CDC comments and our responses. To make the "tracked" version I had to compare that downloaded document to the Word doc you forwarded from CDC. When I did that I noticed that it duplicated several comments from CDC folk. For the sake of readability I tried

to delete duplicates, but there are still a lot of comments in a small space. It also appears that replies within comments were not recognized, so now they just appear as comments on top of other comments. I hope that all makes sense.

If these copies do not come through, you can download them from the shared Google drive here:

Best,

-Tom

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 19 Aug 2021, at 09:41, Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov > wrote:

Hi All,

Here are the first round of comments. We should get all responses within 24 to 48 hours of our submission. It looks like this needs to be approved by Lab TF, cross clearance and the response. Let me know if I can help with comments.

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases
Wisconsin Department of Health Services
Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov From: CDC IMS 2019 NCOV Response Lab TF

Clearance < eocevent 216@cdc.gov >

Sent: Thursday, August 19, 2021 9:24 AM

To: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD)

<adz0@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance

<eocevent216@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah,

Please address the mandatory comments and return for re-review.

Shedding of Infectious SARS-CoV-2 Despite
Vaccination when the Delta Variant is Prevalent

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Segaloff, Hannah

(CDC/DDPHSS/CSELS/DSEPD) < qdz0@cdc.gov> **Sent:** Wednesday, August 18, 2021 9:18 AM

To: CDC IMS 2019 NCOV Response Lab TF Clearance

<eocevent216@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Hello,

Thank you for the quick work getting this approved for DIM expedited clearance. I haven't had a manuscript in expedited clearance before. Does it have the same steps as standard? How much time should I anticipate for the clearance process?

Thank you! Hannah

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 11:51 AM **To:** Kools, John J. (CDC/DDID/NCEZID/OD)

<<u>czk7@cdc.gov</u>>; CDC IMS 2019 NCOV Response Lab TF Clearance <<u>eocevent216@cdc.gov</u>>; Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) <<u>kya6@cdc.gov</u>>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD)

<bbl/>bbl7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>;

Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD)

<<u>qdz0@cdc.gov</u>>; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) <<u>iki5@cdc.gov</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

NP! Glad we were able to turn this around so quickly.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Kools, John J. (CDC/DDID/NCEZID/OD)

<czk7@cdc.gov>

Sent: Tuesday, August 17, 2021 12:47 PM **To:** Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<a href="mailto:<a href="mailto:<a href="mailto: CDC IMS 2019 NCOV Response Lab TF Clearance <a href="mailto: Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto: <a href="mailto:<

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD)

bb17@cdc.gov; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) xhg9@cdc.gov; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD)

qdz0@cdc.gov; Moon, Jonathan L.

(CDC/DDID/NCEZID/DSR) kis5@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thanks Shelbi!

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 12:43 PM

To: CDC IMS 2019 NCOV Response Lab TF Clearance

<<u>eocevent216@cdc.gov</u>>; Kools, John J. (CDC/DDID/NCEZID/OD) <<u>czk7@cdc.gov</u>>; Dunworth, Soumya (CDC/DDPHSS/CSELS/OD)

<kya6@cdc.gov>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD)

<bbl/>bbl/@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>;

Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD)

<adz0@cdc.gov>; Moon, Jonathan L.

(CDC/DDID/NCEZID/DSR) < iki5@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Afternoon,

This has been approved for expedited clearance.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Lab TF Communications Mailbox: eocevent503@cdc.gov
Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 12:40 PM **To:** Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<gqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov >; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Thank you. I approve expedited clearance.

Stephanie

Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response

CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 12:16 PM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov >; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Hey Stephanie,

Please see attached for the updated draft.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 11:05 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov> **Subject:** Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Sure thing, working on the updated draft now.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Lab TF Communications Mailbox: eocevent503@cdc.gov
Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:56 AM **To:** Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov> **Subject:** RE: Shedding of Infectious SARS-CoV-2
Despite Vaccination when the Delta Variant is

Prevalent

Yes, please request an updated draft with Hannah's name on it and then I approve it going for expedited clearance.

Stephanie Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:56 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) <xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Hey Stephanie,

From correspondence with ADS and STLT Hannah was inadvertently left off the manuscript but WI has confirmed that she is a co-author but her name is not on this draft. Should we request an updated draft with Hannah information on there as the co-author?

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:51 AM

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<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Неу,

I am working on getting clarification as we speak, update to follow.

Thanks, Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force COVID-19 Emergency Response Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:49 AM **To:** Davis, Shelbi (CDC/DDID/NCIRD/DVD)

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hannah Segaloff EISO is listed on the clearance request form as an author but not on the manuscript. Can you clarify that she indeed and author? If so, then my approval for expedited clearance stands.

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:40 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov > **Subject:** Re: Shedding of Infectious SARS-CoV-2

Despite Vaccination when the Delta Variant is

Prevalent

Thanks for the speedy response!

Thanks, Shelbi Davis Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:39 AM **To:** Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<gqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov >; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

I approve.

Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:38 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Morning Stephanie,

Happy Tuesday! We would like to request DIM1 expedited approval for the attached manuscript. Please refer to the email thread below.

Thanks, Shelbi Davis Communication Lead **Health Communication Specialist** Laboratory and Testing Task Force COVID-19 Emergency Response Centers for Disease Control and Prevention Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: CDC IMS 2019 NCOV Response Lab TF

Clearance < eocevent 216@cdc.gov >

Sent: Tuesday, August 17, 2021 10:32 AM **To:** Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<a href="mailto:qqv9@cdc.gov; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance

<eocevent216@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hi Shelbi and Jarrett,

Should I begin clearance on this item or wait until you receive the DIM approval?

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Kools, John J. (CDC/DDID/NCEZID/OD)

<czk7@cdc.gov>

Sent: Tuesday, August 17, 2021 9:59 AM

To: CDC IMS 2019 NCOV Response Lab TF Clearance

<eocevent216@cdc.gov>; Davis, Shelbi

(CDC/DDID/NCIRD/DVD) < gqv9@cdc.gov>; Gartin,

Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Cc: Dunworth, Soumya (CDC/DDPHSS/CSELS/OD)

<kya6@cdc.gov>; Limbago, Brandi

(CDC/DDID/NCIRD/OD) < bb/>bb/7@cdc.gov>; Moon,

Jonathan L. (CDC/DDID/NCEZID/DSR)

<iki5@cdc.gov>; Llewellyn, Anna C.

(CDC/DDID/NCEZID/DPEI) < gif7@cdc.gov >; Segaloff,

Hannah (CDC/DDPHSS/CSELS/DSEPD)

<qdz0@cdc.gov>

Subject: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Good Morning,

You may have heard but our task force was asked by STLT, and we agreed, to sponsor this manuscript through clearance. The authors are targeting NEJM and are requesting our task force to request IM approval for expedited clearance. Our main POC for this manuscript is our CDC EISO Hannah Segaloff (Cc'd). Let me know if you have any questions.

Hannah- our clearance team can help shepherd your paper through clearance. I would anticipate our laboratory SMEs to have some questions for your team.

Best regards,

John

John Kools ADS, Laboratory & Testing Task Force CDC COVID-19 Response Phone: 404-217-7258

From: Rose, Dale A. (CDC/DDID/NCEZID/DPEI)

<ido8@cdc.gov>

Sent: Tuesday, August 17, 2021 4:51 AM **To:** Kools, John J. (CDC/DDID/NCEZID/OD)

<czk7@cdc.gov>

Subject: FW: Follow up on your results

Morning John! Thanks for taking this on. We had intensive discussions with WI, IM, and MMWR last week about this. There's strong interest in supporting and moving this forward quickly in clearance, including securing approval for expedited clearance so it can quickly make it to NEJM for consideration. If you anticipate any issues with the content or timing, please do let me know as our TF is in routine conversation with the state epi and want to make sure we're

aligned in our discussions.

Much appreciated, and I hope you are well!

Best, Dale

Dale Rose, Ph.D. STLT Support Task Force

Cell:

From: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI) < gif7@cdc.gov>

Sent: Monday, August 16, 2021 3:35 PM **To:** Segaloff, Hannah (CDC <u>dhs.wisconsin.gov</u>) < hannah.segaloff@dhs.wisconsin.gov >; Rose, Dale A. (CDC/DDID/NCEZID/DPEI) < ido8@cdc.gov>; Westergaard, Ryan (CDC dhs.wisconsin.gov) <ryan.westergaard@dhs.wisconsin.gov>; Bisgard, Kris (CDC/DDPHSS/CSELS/DSEPD) < kmb6@cdc.gov> Cc: Ricaldi Camahuali, Jessica (CDC/DDID/NCEZID/DPEI) < mpi7@cdc.gov >; Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov>; Limbago, Brandi (CDC/DDID/NCIRD/OD)
<bbl/>bbl/@cdc.gov>; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < iki5@cdc.gov>; CDC IMS 2019 NCOV Response STLT ADS <eocevent410@cdc.gov>; CDC IMS 2019 NCOV Response Lab Task Force < eocevent 177@cdc.gov> **Subject:** Re: Follow up on your results

Dear Hannah,

Thank you for these additional documents. Due to this manuscript's focus on laboratory data, our Laboratory and Testing Task Force colleagues have agreed to be the sponsoring task force for CDC COVID-19 Response clearance. John Kools is the Lab TF ADS and can assist with next steps.

Best Regards,

Anna

Anna Llewellyn, PhD

Associate Director for Science State, Tribal, Local, and Territorial Support Task Force COVID-19 Emergency Response Centers for Disease Control and Prevention Office: 404-639-1538 | Cell:

eocevent410@cdc.gov

From: Segaloff, Hannah E - DHS

hannah.segaloff@dhs.wisconsin.gov **Sent:** Monday, August 16, 2021 3:13 PM **To:** Rose, Dale A. (CDC/DDID/NCEZID/DPEI)

knowedge:channah.segaloff@dhs.wisconsin.gov **Sent:** Monday, August 16, 2021 3:13 PM **To:** Rose, Dale A. (CDC/DDID/NCEZID/DPEI)

knowedge:channah.segaloff@dhs.wisconsin.gov

* white the sequence of the sequence

(CDC dhs.wisconsin.gov)

<ryan.westergaard@dhs.wisconsin.gov>; Bisgard,
Kris (CDC/DDPHSS/CSELS/DSEPD) <kmb6@cdc.gov>
Cc: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI)
<gif7@cdc.gov>; Ricaldi Camahuali, Jessica
(CDC/DDID/NCEZID/DPEI) <mpi7@cdc.gov>
Subject: RE: Follow up on your results

Thank you. I have attached the concept proposal that was approved from the original MMWR submission as well as a clearance request form.

Sincerely, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

<Reimersma_Viral loads in vaccinees_
NEJM editedauthorlist LABTFCOMMENTS.docx>

From: Segaloff, Hannah E - DHS

To: <u>Thomas Friedrich</u>

Cc: Kasen Riemersma; DAVID H O"CONNOR; Katarina Grande

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Date: Thursday, August 19, 2021 3:20:19 PM

Thanks Tom,

I will send these along and the note. I'm hoping we can switch over to a Google drive format for comments.

Best,

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: Thomas Friedrich <tfriedri@wisc.edu> Sent: Thursday, August 19, 2021 3:05 PM

To: Segaloff, Hannah E - DHS <hannah.segaloff@dhs.wisconsin.gov>

Cc: Kasen Riemersma <riemersma@wisc.edu>; DAVID H O'CONNOR <dhoconno@wisc.edu>;

Katarina Grande <kgrande@publichealthmdc.com>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is

Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah.

Attached please find clean (well, clean-ish) and tracked versions of the revised manuscript. We addressed all the comments and made the changes requested. I hope this can be approved quickly.

Note: As you know, to edit collaboratively, we uploaded the Word doc with CDC comments to Google Drive. I re-downloaded the edited version as a Word doc — this is the "clean" version and preserves CDC comments and our responses. To make the "tracked" version I had to compare that downloaded document to the Word doc you forwarded from CDC. When I did that I noticed that it duplicated several comments from CDC folk. For the sake of readability I tried to delete duplicates, but there are still a lot of comments in a small space. It also appears that replies within comments were not recognized, so now they just appear as comments on top of other comments. I hope that all makes sense.

If these copies do not come through, you can download them from the shared Google drive here:

Best,

-Tom

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 19 Aug 2021, at 09:41, Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov > wrote:

Hi All,

Here are the first round of comments. We should get all responses within 24 to 48 hours of our submission. It looks like this needs to be approved by Lab TF, cross clearance and the response.

Let me know if I can help with comments.

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent 216@cdc.gov>

Sent: Thursday, August 19, 2021 9:24 AM

To: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < qdz0@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent216@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah,

Please address the mandatory comments and return for re-review.

Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < adz0@cdc.gov>

Sent: Wednesday, August 18, 2021 9:18 AM

To: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent216@cdc.gov **Subject:** Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Hello,

Thank you for the quick work getting this approved for DIM expedited clearance. I haven't had a manuscript in expedited clearance before. Does it have the same steps as standard? How much time should I anticipate for the clearance process?

Thank you! Hannah

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 11:51 AM

To: Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov>; CDC IMS 2019 NCOV

Response Lab TF Clearance < eocevent216@cdc.gov">eocevent216@cdc.gov>; Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) < kya6@cdc.gov>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD) < bbl7@cdc.gov; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < qdz0@cdc.gov; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < kis5@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

NP! Glad we were able to turn this around so quickly.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Lab TF Communications Mailbox: eocevent503@cdc.gov

From: Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov>

Sent: Tuesday, August 17, 2021 12:47 PM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < qqv9@cdc.gov">qqv9@cdc.gov>; CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent216@cdc.gov>; Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) < kya6@cdc.gov>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD) < bbl7@cdc.gov; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < qdz0@cdc.gov; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < iki5@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thanks Shelbi!

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < gqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 12:43 PM

To: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent216@cdc.gov; Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov; Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) < kya6@cdc.gov>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD) < bb/r@cdc.gov>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) < qdz0@cdc.gov>; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < iki5@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Afternoon,

This has been approved for expedited clearance.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 12:40 PM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < ggv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Thank you. I approve expedited clearance.

Stephanie

Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response

CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) ggv9@cdc.gov>

Sent: Tuesday, August 17, 2021 12:16 PM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Hey Stephanie,

Please see attached for the updated draft.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) <qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 11:05 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Sure thing, working on the updated draft now.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:56 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

 $\textbf{Cc:} \ \ \text{Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)} < \underline{\text{iwg7@cdc.gov}} >; \ \text{Gartin, Jarrett}$

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Yes, please request an updated draft with Hannah's name on it and then I approve it going for expedited clearance.

Stephanie

Stephanie R. Bialek MD MPH

Deputy Incident Manager

COVID-19 Response

CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:56 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < <u>xhg9@cdc.gov</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hey Stephanie,

From correspondence with ADS and STLT Hannah was inadvertently left off the manuscript but WI has confirmed that she is a co-author but her name is not on this draft. Should we request an updated draft with Hannah information on there as the co-author?

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention

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Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:51 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zgg7@cdc.gov >

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) < <u>xhg9@cdc.gov</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hey,

I am working on getting clarification as we speak, update to follow.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021 10:49 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < aqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Hannah Segaloff EISO is listed on the clearance request form as an author but not on the manuscript. Can you clarify that she indeed and author? If so, then my approval for expedited clearance stands.

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021 10:40 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Thanks for the speedy response!

Thanks,
Shelbi Davis
Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < <u>zqg7@cdc.gov</u>>

Sent: Tuesday, August 17, 2021 10:39 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < gav9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov >; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

I approve.

Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response From: Davis, Shelbi (CDC/DDID/NCIRD/DVD) ggv9@cdc.gov

Sent: Tuesday, August 17, 2021 10:38 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD) < zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < <u>iwg7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Morning Stephanie,

Happy Tuesday! We would like to request DIM1 expedited approval for the attached manuscript. Please refer to the email thread below.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist

Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent 216@cdc.gov>

Sent: Tuesday, August 17, 2021 10:32 AM

To: Davis, Shelbi (CDC/DDID/NCIRD/DVD) < qqv9@cdc.gov; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR) < xhg9@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance <eocevent216@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Hi Shelbi and Jarrett,

Should I begin clearance on this item or wait until you receive the DIM approval?

Thank you,

Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov>

Sent: Tuesday, August 17, 2021 9:59 AM

To: CDC IMS 2019 NCOV Response Lab TF Clearance <<u>eocevent216@cdc.gov</u>>; Davis, Shelbi (CDC/DDID/NCIRD/DVD) <<u>qqv9@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR) <<u>xhg9@cdc.gov</u>>

Cc: Dunworth, Soumya (CDC/DDPHSS/CSELS/OD) <<u>kya6@cdc.gov</u>>; Limbago, Brandi (CDC/DDID/NCIRD/OD) <<u>bbl7@cdc.gov</u>>; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) <<u>iki5@cdc.gov</u>>; Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI) <<u>gif7@cdc.gov</u>>; Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) <<u>qdz0@cdc.gov</u>>

Subject: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Good Morning,

You may have heard but our task force was asked by STLT, and we agreed, to sponsor this manuscript through clearance. The authors are targeting NEJM and are requesting our task force to request IM approval for expedited clearance. Our main POC for this manuscript is our CDC EISO Hannah Segaloff (Cc'd). Let me know if you have any questions.

Hannah- our clearance team can help shepherd your paper through clearance. I would anticipate our laboratory SMEs to have some questions for your team.

Best regards,

John

John Kools
ADS, Laboratory & Testing Task Force
CDC COVID-19 Response
Phone: 404-217-7258

From: Rose, Dale A. (CDC/DDID/NCEZID/DPEI) < ido8@cdc.gov>

Sent: Tuesday, August 17, 2021 4:51 AM

To: Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov>

Subject: FW: Follow up on your results

Morning John! Thanks for taking this on. We had intensive discussions with WI, IM, and MMWR last week about this. There's strong interest in supporting and moving this forward quickly in clearance, including securing approval for expedited clearance so it can quickly make it to NEJM for consideration. If you anticipate any issues with the content or timing, please do let me know as our TF is in routine conversation with the state epi and want to make sure we're aligned in our discussions.

Much appreciated, and I hope you are well!

Best, Dale

Dale Rose, Ph.D.

STLT Support Task Force

Cell:

From: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI) < gif7@cdc.gov>

Sent: Monday, August 16, 2021 3:35 PM

To: Segaloff, Hannah (CDC <u>dhs.wisconsin.gov</u>) < <u>hannah.segaloff@dhs.wisconsin.gov</u>>; Rose, Dale A. (CDC/DDID/NCEZID/DPEI) < <u>ido8@cdc.gov</u>>; Westergaard, Ryan (CDC <u>dhs.wisconsin.gov</u>) < <u>ryan.westergaard@dhs.wisconsin.gov</u>>; Bisgard, Kris (CDC/DDPHSS/CSELS/DSEPD) < <u>kmb6@cdc.gov</u>>

Cc: Ricaldi Camahuali, Jessica (CDC/DDID/NCEZID/DPEI) < mpi7@cdc.gov; Kools, John J. (CDC/DDID/NCEZID/OD) < czk7@cdc.gov; Limbago, Brandi (CDC/DDID/NCIRD/OD) < bb17@cdc.gov; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) < kis5@cdc.gov; CDC IMS 2019 NCOV Response STLT ADS < eocevent410@cdc.gov>; CDC IMS 2019 NCOV Response Lab Task Force < eocevent177@cdc.gov>

Subject: Re: Follow up on your results

Dear Hannah.

Thank you for these additional documents. Due to this manuscript's focus on laboratory data, our Laboratory and Testing Task Force colleagues have agreed to be the sponsoring task force for CDC COVID-19 Response clearance. John Kools is the Lab TF ADS and can assist with next steps.

Best Regards,

Anna

Anna Llewellyn, PhD Associate Director for Science State, Tribal, Local, and Territorial Support Task Force

COVID-19 Emergency Response

Centers for Disease Control and Prevention

Office: 404-639-1538 | Cell: eocevent410@cdc.gov

From: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov>

Sent: Monday, August 16, 2021 3:13 PM

To: Rose, Dale A. (CDC/DDID/NCEZID/DPEI) < ido8@cdc.gov>; Westergaard, Ryan (CDC dhs.wisconsin.gov) < ryan.westergaard@dhs.wisconsin.gov>; Bisgard, Kris (CDC/DDPHSS/CSELS/DSEPD) < kmb6@cdc.gov>

Cc: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI) < gif7@cdc.gov>; Ricaldi Camahuali,

Jessica (CDC/DDID/NCEZID/DPEI) < mpi7@cdc.gov>

Subject: RE: Follow up on your results

Thank you. I have attached the concept proposal that was approved from the original MMWR submission as well as a clearance request form.

Sincerely, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

Cell:

<Reimersma_Viral loads in vaccinees_
NEJM editedauthorlist LABTFCOMMENTS.docx>

From: KGrande@publichealthmdc.com

To: Thomas Friedrich; mishra.sanjay@outlook.com
Cc: DAVID H O"CONNOR; Kasen Riemersma

Subject: RE: [Nat Geo] Evidence mounts that people with breakthrough infections can spread Delta easily

Date: Friday, August 20, 2021 1:23:04 PM

Thanks for sharing, Sanjay!

-Katarina

From: Thomas Friedrich <tfriedri@wisc.edu> Sent: Friday, August 20, 2021 12:34 PM

To: mishra.sanjay@outlook.com

Cc: Grande, Katarina < KGrande@publichealthmdc.com>; DAVID H O'CONNOR

<dhoconno@wisc.edu>; Kasen Riemersma <riemersma@wisc.edu>

Subject: Re: [Nat Geo] Evidence mounts that people with breakthrough infections can spread Delta

easily

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Thanks Sanjay — the story looks great! I am glad to see Kasen and Kat featured.

Best,

-Tom

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 20 Aug 2021, at 12:12, mishra.sanjay@outlook.com wrote:

Dear Katrina, Kasen, Tom

My article is online

now: https://www.nationalgeographic.com/science/article/evidence-mounts-that-people-with-breakthrough-infections-can-spread-delta-easily

Dear Tom.

I apologize none of your wonderful quotes made it to the final story. Editors are tough

critics.

I really appreciate your time and help in getting this story out. I can only hope that these articles make even a tiny difference in convincing some fence sitters and help others to stay cautious.

Sanjay

From: Grande, Katarina

Sent: Thursday, August 12, 2021 2:36 PM

To: 'Sanjay Mishra'

Cc: <u>DAVID H O'CONNOR</u>; <u>'Kasen Riemersma'</u>; <u>Thomas Friedrich</u> **Subject:** RE: Request to interview from National Geographic

Hi Dr. Mishra,

Thanks for reaching out. I could jump on a call after 3:30pm. I'm cc'ing my co-authors, who are the true scientists on the paper—I'm the applied public health person of the bunch. So depending on your angle, it may be helpful to link with them, or see if we could jump on a call together.

-Katarina

KATARINA GRANDE, MPH (pronouns: she/her/hers)

Public Health Supervisor/COVID-19 Data Team Lead | Public Health Madison & Dane County 2300 South Park St, Rm 2010, Madison, WI 53713

Phone: (608) 243-0409 | Cell: | Fax: (608) 266-4858

Healthy People. Healthy Places.

<image001.png>

This email, including any attachments, may contain confidential or protected health information which is only for the intended recipient. If you received this email in error, please delete and notify the sender immediately. Emails sent or received by our agency are subject to open records requests and could be released to the public, unless there is an exception allowed by law.

<image002.png>

From: Sanjay Mishra < mishra.sanjay@outlook.com >

Sent: Thursday, August 12, 2021 2:07 PM

To: Grande, Katarina < <u>KGrande@publichealthmdc.com</u>> **Subject:** Request to interview from National Geographic

Importance: High

Caution: This email was sent from an external source. Avoid unknown links and attachments.

Dear Katarina

I read your preprint posted earlier today with alarm: "Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021" Can I urgently talk to you since I am pitching this as story to my editor at National Geographic, as a follow up to my recent stories on Delta variant, value of masking and breakthrough infections:

In National Geographic:

- 1. Why is Delta more infectious and deadly? New research holds answers. (August 6, 2021)
- 2. <u>How dangerous is the new Delta Plus variant? Here's what we know.</u> (July 2, 2021)
- 3. The Delta variant is serious. Here's why it's on the rise. (June 16, 2021); updated:
 - a. The Delta variant is spreading fast, especially where vaccination rates are low (July 8, 2021)
- 4. This 'double mutant' variant is adding fuel to India's COVID-19 crisis (April 28, 2021)

In The Conversation:

- 1. What is a breakthrough infection? 6 questions answered about catching COVID-19 after vaccination (July 28, 2021)
- Can people vaccinated against COVID-19 still spread the coronavirus? (May 25, 2021)

I and the readers of National Geographic will highly appreciate it

Sanjay Mishra, MS, PhD
Nashville, TN 37221; USA
mishra.sanjay@outlook.com | @Ecquis | +1 (615) 829 6563
LinkedIn | Google Scholar | Contently | Skype

From: <u>DAVID H O"CONNOR</u>

To: <u>Segaloff, Hannah E - DHS</u>

Cc: Kasen Riemersma; Katarina Grande; Thomas Friedrich

Subject: Re: FW: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Date: Monday, August 23, 2021 1:25:37 PM

Hi Hannah,

Thanks much - I'll upload as soon as I get the login credentials from Kat (or Tom, if he happens to be eavesdropping from up north).

dave

Segaloff, Hannah E - DHS wrote on 8/23/21 11:52 AM:

Hi all,

We are cleared! There are some extremely tiny comments to incorporate/consider. Once we submit they just want me to send a final copy for their records. Note that I made two additional small changes (added "qualitative in two places and deleted one word to keep it in the word count) without sending it back to facilitate quick review- so you many want to upload this version.

Thanks for your patience with this painful process!

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases
Wisconsin Department of Health Services
Currently Teleworking
Cell:

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: CDC IMS 2019 NCOV Response Lab TF Clearance <eocevent216@cdc.gov>

Sent: Monday, August 23, 2021 11:47 AM

To: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD) <qdz0@cdc.gov>

Cc: CDC IMS 2019 NCOV Response Lab TF Clearance <eocevent216@cdc.gov>

Subject: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant

is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah:

The attached document has been cleared by JIC with comments.

Once you have addressed the reviewer's feedback, please send us a clean and final document, so we can provide it to JIC for their records.

JIC OS Content Comment.

 Very informative study. It is approved with minor comments, see attached

Thanks,

Audrey

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM) From: Kasen Riemersma
To: Peter Halfmann

 Subject:
 Re: New England Journal of Medicine - 21-14060

 Date:
 Friday, September 10, 2021 9:28:24 AM

 Attachments:
 Specimens for culture 20210910.xlsx

I handed them off at the door, so hopefully they make their way to you. I've attached the full specimen manifest with both sets of 24.

Kasen

From: Peter Halfmann <peter.halfmann@wisc.edu>
Date: Friday, September 10, 2021 at 9:04 AM
To: Kasen Riemersma <riemersma@wisc.edu>

Subject: RE: New England Journal of Medicine - 21-14060

If you leave them by the door that's fine - thanks

From: Kasen Riemersma <riemersma@wisc.edu>
Sent: Friday, September 10, 2021 9:04 AM
To: Peter Halfmann <peter.halfmann@wisc.edu>

Subject: Re: New England Journal of Medicine - 21-14060

Hi Peter, I'm about to walk over the second set of 24 specimens for virus titration. Please let me know if I should come at a different time.

Thanks, Kasen

From: Peter Halfmann < peter.halfmann@wisc.edu > Date: Thursday, September 9, 2021 at 9:12 AM

To: Kasen Riemersma < riemersma@wisc.edu >

Subject: RE: New England Journal of Medicine - 21-14060

Got them; thanks! Sounds good.

From: Kasen Riemersma < riemersma@wisc.edu>
Sent: Thursday, September 9, 2021 9:05 AM
To: Peter Halfmann < peter.halfmann@wisc.edu>

Subject: Re: New England Journal of Medicine - 21-14060

Hey Peter,

I'm about to walk over with the first set of 24 more recent specimens. I need a bit more time today to pull the set of 24 older specimens, but will get them to you by the end of the day or first thing tomorrow morning.

I've attached the specimen manifest for the first set of 24.

Kasen

From: Peter Halfmann < pate: Tuesday, September 7, 2021 at 2:30 PM

To: Kasen Riemersma < riemersma@wisc.edu>

Subject: RE: New England Journal of Medicine - 21-14060

Early Thursday is good; thanks

From: Kasen Riemersma < riemersma@wisc.edu > Sent: Tuesday, September 7, 2021 2:30 PM
To: Peter Halfmann < peter.halfmann@wisc.edu >

Subject: Re: New England Journal of Medicine - 21-14060

Thanks, Peter! Would you prefer I drop off the 48 specimens on Wednesday or early Thursday?

Kasen

From: Peter Halfmann < peter.halfmann@wisc.edu>
Date: Tuesday, September 7, 2021 at 12:02 PM
To: Thomas Friedrich < tfriedri@wisc.edu>

Cc: DAVID H O'CONNOR dhoconno@wisc.edu, Kasen Riemersma riemersma@wisc.edu, YOSHIHIRO KAWAOKA

<yoshihiro.kawaoka@wisc.edu>, Katarina Grande <kgrande@publichealthmdc.com>

Subject: Re: New England Journal of Medicine - 21-14060

We can do 24 samples on Thursday and another 24 samples on Friday.

On Sep 7, 2021, at 9:39 AM, Thomas Friedrich < tfriedri@wisc.edu > wrote:

Like Dave, I can see this going either way. Perhaps we could do a set of specimens from within the same time period that is covered in the submitted paper, and then also a more recent batch? This would cover our bases. However, I don't want to burden Peter too much, so I think he and Yoshi should comment also.

Best,

-Tom

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

Dave O'Connor wrote on 2021-09-07 08:42:

Hi all,

I could see it going either way. I don't think we need to add them to the existing dataset. It might even be better to use recent samples because it shows that the trend is stable over time. But I don't feel strongly about it.

dave

Kasen Riemersma wrote on 9/7/21 8:40 AM:

Hi all,

I can definitely provide more samples for Peter to test. Peter, once I know how many you can process, I should be able to send them over quickly.

Tom, if these culture data may be added to our study, I'm inclined to select specimens from the same study period instead of more recent specimens. Do you agree?

Cheers, Kasen

From: Thomas Friedrich tfriedri@wisc.edu
Date: Sunday, September 5, 2021 at 12:43 PM

To: YOSHIHIRO KAWAOKA <<u>voshihiro.kawaoka@wisc.edu></u> **Cc:** DAVID H O'CONNOR <<u>dhoconno@wisc.edu></u>, Peter Halfmann

<peter.halfmann@wisc.edu>, Katarina Grande <kgrande@publichealthmdc.com>,

Kasen Riemersma riemersma@wisc.edu>

Subject: Re: New England Journal of Medicine - 21-14060

Hi all.

Okay, I agree with all this. In our emails last week, I was not sure whether you guys wanted to respond to Vincent as soon as possible. I completely agree that we would need to generate new titration data with samples that have not undergone multiple freeze-thaw cycles.

Luckily we are getting a large number of samples from Exact each week.

Kasen, can we identify a set of fresh samples that can be aliquoted for Peter to test?

Peter, what is a good number of samples for you to receive?

Best,

-Tom

YOSHIHIRO KAWAOKA wrote on 2021-09-03 19:33:

If we are going to respond to Vincent by sharing our new data, we should do the virus isolation with new samples that have not been thawed several times. I am concerned about the data showing that the number of no-virus-recovery samples from vaccinated individuals is higher than that from unvaccinated individuals. He will criticize this point if we send him the current data. Best,

Yoshi

From: DAVID H O'CONNOR dhoconno@wisc.edu

Sent: Saturday, September 4, 2021 8:11 AM **To:** Thomas Friedrich <u><tfriedri@wisc.edu></u>

Cc: Peter Halfmann peter.halfmann@wisc.edu>; YOSHIHIRO KAWAOKA

<yoshihiro.kawaoka@wisc.edu>; Katarina Grande

<kgrande@publichealthmdc.com>

Subject: Re: New England Journal of Medicine - 21-14060

Hi Tom,

I updated Medrxiv with the NEJM submission. I didn't update with this week's data. I suggest waiting until we get a disposition on the NEJM paper before updating Medrxiv again.

In terms of Vincent, I'm fine if someone else wants to connect with him and Daniel on the data. I'm not enthusiastic about doing it myself.

dave

--

I often work on email outside of work hours, but you don't have to! If you're receiving this outside of your work hours, I don't expect a response until you are back in the office.

http://dho.pathology.wisc.edu

608.890.0845

From: Thomas Friedrich < tfriedri@wisc.edu>

Sent: Friday, September 3, 2021 18:04

To: DAVID H O'CONNOR < dhoconno@wisc.edu>

Cc: Peter Halfmann < peter.halfmann@wisc.edu>; YOSHIHIRO KAWAOKA

<<u>yoshihiro.kawaoka@wisc.edu</u>>; Katarina Grande

< KGrande@publichealthmdc.com>

Subject: Re: New England Journal of Medicine - 21-14060

Thanks Dave.

Did we update the medrxiv paper with the titration data? If so I can update my Twitter thread on the paper and include it. As you guys have said, even through the samples have undergone multiple freeze-thaw cycles, it is clear that titers are not systematically lower in vaccinees vs. unvaccinated.

Would you guys also email Daniel and Vincent directly to call their attention to these data?

-T

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 3 Sep 2021, at 17:15, DAVID H O'CONNOR < dhoconno@wisc.edu wrote:

What will come first, an NEJM decision on a 400 word letter or Kat's return from Iceland? Nonetheless, I pinged the editor (see below) and offered the titer data should it be helpful.

dave

--

I often work on email outside of work hours, but you don't

have to! If you're receiving this outside of your work hours, I don't expect a response until you are back in the office.

http://dho.pathology.wisc.edu

608.890.0845

From: Letter < letter@nejm.org>
Sent: Friday, September 3, 2021 14:05

To: DAVID H O'CONNOR < dhoconno@wisc.edu>

Subject: RE: New England Journal of Medicine - 21-14060

Hello Dr. O'Connor,

Thank you for your email. Your letter is currently with the editor and a decision regarding possible publication has not yet been made. You will be informed of the final editorial decision via email.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: NEJM Editorial < editorial@nejm.org>
Sent: Friday, September 3, 2021 2:58 PM

To: Letter < letter@nejm.org>

Subject: FW: New England Journal of Medicine - 21-14060

From: Dave O'Connor dhoconno@wisc.edu Sent: Friday, September 3, 2021 10:17 AM
To: NEJM Editorial editorial@nejm.org

Subject: Re: New England Journal of Medicine - 21-14060

To whom it may concern,

I am writing on behalf of our co-authors to ask if there are any updates on the status of the 400 word correspondence we submitted to NEJM on August 23. We are keenly aware that this is timely data given the current landscape of SARS-CoV-2 infection despite vaccination.

One small note: some vocal scientists have criticized our work on social media. The primary claim they make is that virus culture in low Ct samples does not mean that there is similar amounts of replication-competent virus in these samples. Subsequent to our August 23 submission, we re-thawed these samples and showed that virus titers are similar in those who are unvaccinated and infected despite infection (see attached), generally tracking with PCR RNA levels. We would likely want to include a version of this plot in a revised NEJM correspondence to silence this inaccurate criticism.

Thanks in advance for your consideration,

New England Journal of Medicine wrote on 8/23/21 1:39 PM:

Dear Ms. Grande and co-authors,

Thank you for submitting your manuscript, "Shedding of Infectious SARS-CoV-2 Despite Vaccination" to the New England Journal of Medicine.

Your manuscript has been forwarded to members of our editorial staff, who will make an initial evaluation and decide whether it merits further consideration. You will be notified of the decision as soon as possible.

Your manuscript ID is 21-14060.

Please mention the above manuscript ID in all future correspondence or when calling the office for questions. If there are any changes in your street address or e-mail address, please log in

appropriate. You may also view the status of your manuscript at any time by checking For Authors section of the site.

We are undertaking evaluation of your manuscript with the understanding that neither the substance of the article nor the figures or tables have been published or will be submitted for publication elsewhere during the period of review.

Please provide the editors with copies of other manuscripts by you or your coauthors addressing similar or related research questions that are in preparation or under consideration at other journals. This does not apply to abstracts published in connection with scientific meetings or to news reports based on presentations at such meetings.

The Journal's policy is explained more fully at https://www.nejm.org/about-nejm/editorial-policies.

Please call us at 617-734-9800 if you have any questions.

Sincerely,

New England Journal of Medicine 10 Shattuck Street Boston, MA 02115 (617) 734-9800 Fax: (617) 739-9864 http://www.nejm.org

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http://dho.pathology.wisc.edu @dho • 608-890-0845

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Tube_ID	N1_Ct	Collection_Date
1THKW	15.06350109	9/2/2021 11:07
1THGD	19.98705395	9/2/2021 10:58
1THI1	19.58691028	9/2/2021 14:57
1THG9	18.32912604	9/2/2021 11:19
1TFJR	21.29209604	9/2/2021 14:36
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1TMU0	18.79827618	9/4/2021 11:44
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1TKWD	19.85761006	9/3/2021 11:34
1TKV7	16.62752271	9/3/2021 10:02
1TN5K	18.54030436	9/4/2021 11:33
1TJZ5	19.31552845	9/3/2021 12:34
1TJWD	20.73535029	9/3/2021 11:21
1TJUV	15.49592228	9/3/2021 16:23
1TJUA	16.47786494	9/3/2021 16:04
1SEH2	21.08310128	8/24/2021 8:47
1SHM6	21.58934574	8/24/2021 12:38
1SHPW	21.54627886	8/24/2021 13:12
1SE2X	15.7339903	8/24/2021 9:41
1SHRU	16.50421287	8/24/2021 17:01
1SHSV	18.87103606	8/24/2021 16:51
1SHJN	18.28345724	8/24/2021 12:10
1SHS3	21.74136158	8/24/2021 16:57
1SHJV	12.59247242	8/24/2021 13:20
1SHFS	18.57897209	8/24/2021 13:41
1SHLF	14.6042653	8/24/2021 13:21
1SHLU	24.83442105	8/24/2021 12:40
1SHKY	17.43457586	8/24/2021 12:37
1SHAK	23.66621923	8/24/2021 13:54
1SHIC	16.69530582	8/24/2021 16:49
1SJEK	15.23684453	8/25/2021 12:33
1SIY5	21.10522528	8/25/2021 14:22
1SDYB	20.30754385	8/24/2021 13:43
1SHPG	15.97163045	8/24/2021 14:08
1SIZF	15.64100204	8/25/2021 14:41
1SKHE	18.25545253	8/25/2021 9:55
1SIX6	19.99673466	8/24/2021 9:28
1SJ6J	22.95399616	8/25/2021 10:07
1SIZP	17.3381538	8/25/2021 10:47

 From:
 Kasen Riemersma

 To:
 Peter Halfmann

 Cc:
 YOSHIHIRO KAWAOKA

Subject: Re: New England Journal of Medicine - 21-14060

Date: Wednesday, September 15, 2021 12:42:17 PM

Ok, sounds good. Thanks for clarifying.

Kasen

Sent from my iPhone

On Sep 15, 2021, at 12:39 PM, Peter Halfmann peter.halfmann@wisc.edu> wrote:

We got that sample; from what the wells look like there was (bacterial) contamination so I don't to say it was negative.

From: Kasen Riemersma < riemersma@wisc.edu>
Sent: Wednesday, September 15, 2021 12:37 PM
To: Peter Halfmann < peter.halfmann@wisc.edu>

Cc: YOSHIHIRO KAWAOKA <yoshihiro.kawaoka@wisc.edu> **Subject:** Re: New England Journal of Medicine - 21-14060

Thanks, Peter! Was the specimen whose titer was "ND" missing from the drop off?

Cheers, Kasen

Sent from my iPhone

On Sep 15, 2021, at 12:31 PM, Peter Halfmann < peter.halfmann@wisc.edu > wrote:

Kasen,

Here are the titers for the 2nd group of samples.

From: Kasen Riemersma <<u>riemersma@wisc.edu</u>>
Sent: Friday, September 10, 2021 9:28 AM
To: Peter Halfmann <<u>peter.halfmann@wisc.edu</u>>

Subject: Re: New England Journal of Medicine - 21-14060

I handed them off at the door, so hopefully they make their way to you. I've attached the full specimen manifest with both sets of 24.

Kasen

From: Peter Halfmann < peter.halfmann@wisc.edu > Date: Friday, September 10, 2021 at 9:04 AM
To: Kasen Riemersma < riemersma@wisc.edu >

Subject: RE: New England Journal of Medicine - 21-14060

If you leave them by the door that's fine - thanks

From: Kasen Riemersma <<u>riemersma@wisc.edu</u>>
Sent: Friday, September 10, 2021 9:04 AM
To: Peter Halfmann <<u>peter.halfmann@wisc.edu</u>>
Subject: Re: New England Journal of Medicine - 21-14060

Hi Peter, I'm about to walk over the second set of 24 specimens for virus titration. Please let me know if I should come at a different time.

Thanks, Kasen From: Peter Halfmann < peter.halfmann@wisc.edu > Date: Thursday, September 9, 2021 at 9:12 AM

To: Kasen Riemersma < riemersma@wisc.edu >

Subject: RE: New England Journal of Medicine - 21-14060

Got them; thanks! Sounds good.

From: Kasen Riemersma <<u>riemersma@wisc.edu</u>>
Sent: Thursday, September 9, 2021 9:05 AM
To: Peter Halfmann <<u>peter.halfmann@wisc.edu</u>>
Subject: Re: New England Journal of Medicine - 21-14060

Hey Peter,

I'm about to walk over with the first set of 24 more recent specimens. I need a bit more time today to pull the set of 24 older specimens, but will get them to you by the end of the day or first thing tomorrow morning.

I've attached the specimen manifest for the first set of 24.

Kasen

From: Peter Halfmann < peter.halfmann@wisc.edu > Date: Tuesday, September 7, 2021 at 2:30 PM
To: Kasen Riemersma < riemersma@wisc.edu >

Subject: RE: New England Journal of Medicine - 21-14060

Early Thursday is good; thanks

From: Kasen Riemersma <<u>riemersma@wisc.edu</u>>
Sent: Tuesday, September 7, 2021 2:30 PM
To: Peter Halfmann <<u>peter.halfmann@wisc.edu</u>>
Subject: Re: New England Journal of Medicine - 21-14060

Thanks, Peter! Would you prefer I drop off the 48 specimens on Wednesday or early Thursday?

Kasen

From: Peter Halfmann < peter.halfmann@wisc.edu > Date: Tuesday, September 7, 2021 at 12:02 PM
To: Thomas Friedrich < triedri@wisc.edu >

Cc: DAVID H O'CONNOR < dhoconno@wisc.edu, Kasen Riemersma < riemersma@wisc.edu, YOSHIHIRO KAWAOKA < yoshihiro.kawaoka@wisc.edu, Katarina Grande kgrande@publichealthmdc.com>

Subject: Re: New England Journal of Medicine - 21-14060

We can do 24 samples on Thursday and another 24 samples on Friday.

On Sep 7, 2021, at 9:39 AM, Thomas Friedrich <<u>tfriedri@wisc.edu</u>> wrote:

Like Dave, I can see this going either way. Perhaps we could do a set of specimens from within the same time period that is covered in the submitted paper, and then also a more recent batch? This would cover our bases. However, I don't want to burden Peter too much, so I think he and Yoshi should comment also.

Best,

-Tom

Thomas Friedrich

Professor
Dept. of Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

Dave O'Connor wrote on 2021-09-07 08:42:

Hi all,

I could see it going either way. I don't think we need to add them to the existing dataset. It might even be better to use recent samples because it shows that the trend is stable over time. But I don't feel strongly about it.

dave

Kasen Riemersma wrote on 9/7/21 8:40 AM:

Hi all,

I can definitely provide more samples for Peter to test. Peter, once I know how many you can process, I should be able to send them over quickly.

Tom, if these culture data may be added to our study, I'm inclined to select specimens from the same study period instead of more recent specimens. Do you agree?

Cheers, Kasen

From: Thomas Friedrich < tfriedri@wisc.edu>
Date: Sunday, September 5, 2021 at 12:43 PM

To: YOSHIHIRO KAWAOKA <u><yoshihiro.kawaoka@wisc.edu></u>
Cc: DAVID H O'CONNOR <u><dhoconno@wisc.edu></u>, Peter Halfmann

<peter.halfmann@wisc.edu>, Katarina Grande
<kgrande@publichealthmdc.com>, Kasen Riemersma
<riemersma@wisc.edu>

Subject: Re: New England Journal of Medicine - 21-14060

Hi all.

Okay, I agree with all this. In our emails last week, I was not sure whether you guys wanted to respond to Vincent as soon as possible. I completely agree that we would need to generate new titration data with samples that have not undergone multiple freeze-thaw cycles.

Luckily we are getting a large number of samples from Exact each week.

Kasen, can we identify a set of fresh samples that can be aliquoted for Peter to test?

Peter, what is a good number of samples for you to receive?

Best,

-Tom

YOSHIHIRO KAWAOKA wrote on 2021-09-03 19:33:

If we are going to respond to Vincent by sharing our new data, we should do the virus isolation with new samples that have not been thawed several times. I am concerned about the data showing that the number of no-virus-recovery samples from vaccinated individuals is higher than that from unvaccinated individuals. He will criticize this point if we send him the current data.

Best,

Yoshi

From: DAVID H O'CONNOR <a href="mailto:sedu

Cc: Peter Halfmann <u><peter.halfmann@wisc.edu>;</u> YOSHIHIRO KAWAOKA <u><poshihiro.kawaoka@wisc.edu></u>; Katarina Grande <u><peterphasekarande@publichealthmdc.com></u>

Subject: Re: New England Journal of Medicine - 21-14060

Hi Tom,

I updated Medrxiv with the NEJM submission. I didn't update with this week's data. I suggest waiting until we get a disposition on the NEJM paper before updating Medrxiv again.

In terms of Vincent, I'm fine if someone else wants to connect with him and Daniel on the data. I'm not enthusiastic about doing it myself.

dave

--

I often work on email outside of work hours, but you don't have to! If you're receiving this outside of your work hours, I don't expect a response until you are back in the office.

http://dho.pathology.wisc.edu

608.890.0845

From: Thomas Friedrich <tfriedri@wisc.edu>
Sent: Friday, September 3, 2021 18:04
To: DAVID H O'CONNOR <dhoconno@wisc.edu>

Cc: Peter Halfmann < <u>peter.halfmann@wisc.edu</u>>; YOSHIHIRO KAWAOKA < <u>yoshihiro.kawaoka@wisc.edu</u>>; Katarina Grande

< KGrande@publichealthmdc.com>

Subject: Re: New England Journal of Medicine - 21-14060

Thanks Dave.

Did we update the medrxiv paper with the titration data? If so I can update my Twitter thread on the paper and include it. As you guys have said, even through the samples have undergone multiple freeze-thaw cycles, it is clear that titers are not systematically lower in vaccinees vs. unvaccinated.

Would you guys also email Daniel and Vincent directly to call their attention to these data?

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 3 Sep 2021, at 17:15, DAVID H O'CONNOR < dhoconno@wisc.edu wrote:

What will come first, an NEJM decision on a 400 word letter or Kat's return from Iceland? Nonetheless, I pinged the editor (see below) and offered the titer data should it be helpful.

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http://dho.pathology.wisc.edu 608.890.0845

From: Letter < letter@nejm.org>
Sent: Friday, September 3, 2021 14:05

To: DAVID H O'CONNOR < dhoconno@wisc.edu > **Subject:** RE: New England Journal of Medicine - 21-

14060

Hello Dr. O'Connor,

Thank you for your email. Your letter is currently with the editor and a decision regarding possible publication has not yet been made. You will be informed of the final editorial decision via e-mail.

Best,

Vivian Vu Editorial Assistant New England Journal of Medicine

From: NEJM Editorial < editorial@nejm.org Sent: Friday, September 3, 2021 2:58 PM

To: Letter < letter@nejm.org>

Subject: FW: New England Journal of Medicine - 21-

14060

From: Dave O'Connor < dhoconno@wisc.edu>
Sent: Friday, September 3, 2021 10:17 AM
To: NEJM Editorial < editorial@nejm.org>

Subject: Re: New England Journal of Medicine - 21-14060

To whom it may concern,

I am writing on behalf of our co-authors to ask if there are any updates on the status of the 400 word correspondence we submitted to NEJM on August 23. We are keenly aware that this is timely data given the current landscape of SARS-CoV-2 infection despite vaccination.

One small note: some vocal scientists have criticized our work on social media. The primary claim they make is that virus culture in low Ct samples does not mean that there is similar amounts of replication-competent virus in these samples. Subsequent to our August 23 submission, we re-thawed these samples and showed that virus titers are similar in those who are unvaccinated and infected despite infection (see attached), generally tracking with PCR RNA levels. We would likely want to include a version of this plot in a revised NEJM correspondence to silence this inaccurate criticism.

Thanks in advance for your consideration,

dave

New England Journal of Medicine wrote on 8/23/21 1:39 PM:

Dear Ms. Grande and co-authors,

Thank you for submitting your manuscript, "Shedding of Infectious SARS-CoV-2 Despite Vaccination" to the New England Journal of Medicine.

Your manuscript has been forwarded to members of our editorial staff, who will make an initial evaluation and decide whether it merits further consideration. You will be notified of the decision as soon as possible.

Your manuscript ID is 21-14060.

Please mention the above manuscript ID in all future correspondence or when calling the office for questions. If there are any changes in your street address or e-mail address, please log in to

information as appropriate. You may also view the status of your manuscript at any time by checking For Authors section of the site.

We are undertaking evaluation of your manuscript with the understanding that neither the substance of the article nor the figures or tables have been published or will be submitted for publication elsewhere during the period of review.

Please provide the editors with copies of other manuscripts by you or your coauthors addressing similar or related research questions that are in preparation or under consideration at other

journals. This does not apply to abstracts published in connection with scientific meetings or to news reports based on presentations at such meetings.

The Journal's policy is explained more fully at https://www.nejm.org/about-nejm/editorial-policies.

Please call us at 617-734-9800 if you have any questions.

Sincerely,

New England Journal of Medicine 10 Shattuck Street Boston, MA 02115 (617) 734-9800 Fax: (617) 739-9864 http://www.nejm.org

--

http://dho.pathology.wisc.edu @dho • 608-890-0845

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<Copy of Specimens_for_culture_20210910 PH.xlsx>

To: Thomas Friedrich

Re: New England Journal of Medicine - 21-14060 Cc:

Subject: Tuesday, September 7, 2021 10:05:35 PM

Yep, will do.

Kasen

On Sep 7, 2021, at 9:49 PM, Thomas Friedrich < tfriedri@wisc.edu> wrote:

Okay, Kasen, can you and Luis identify 2 batches of 24 samples for Peter to test Thursday and Friday?

T

Sent from my iPhone

On Sep 7, 2021, at 12:02, Peter Halfmann peter.halfmann@wisc.edu> wrote:

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Best, Yoshi

From: DAVID H O'CONNOR dhoconno@wisc.edu

Sent: Saturday, September 4, 2021 8:11 AM **To:** Thomas Friedrich <u><tfriedri@wisc.edu></u>

Cc: Peter Halfmann <u><peter.halfmann@wisc.edu></u>; YOSHIHIRO KAWAOKA <u><poshihiro.kawaoka@wisc.edu></u>; Katarina Grande <u><kgrande@publichealthmdc.com></u>

Subject: Re: New England Journal of Medicine - 21-14060

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__

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http://dho.pathology.wisc.edu

608.890.0845

From: Thomas Friedrich <tfriedri@wisc.edu>
Sent: Friday, September 3, 2021 18:04
To: DAVID H O'CONNOR <dhoconno@wisc.edu>

Cc: Peter Halfmann < <u>peter.halfmann@wisc.edu</u>>; YOSHIHIRO KAWAOKA < <u>yoshihiro.kawaoka@wisc.edu</u>>; Katarina Grande

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http://dho.pathology.wisc.edu 608.890.0845

From: Letter < letter@nejm.org> Sent: Friday, September 3, 2021 14:05

To: DAVID H O'CONNOR < dhoconno@wisc.edu> Subject: RE: New England Journal of Medicine - 21-

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Best,

Vivian Vu **Editorial Assistant** New England Journal of Medicine

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To: Letter < letter@neim.org>

Subject: FW: New England Journal of Medicine - 21-

14060

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Your manuscript ID is 21-14060.

Please mention the above manuscript ID in all future correspondence or when calling the office for questions. If there are any changes in your street address or e-mail address, please log in to

on as appropriate.
You may also view the status
of your manuscript at any time
by checking For Authors
section of the site.

We are undertaking evaluation of your manuscript with the understanding that neither the substance of the article nor the figures or tables have been published or will be submitted for publication elsewhere during the period of review.

Please provide the editors with copies of other manuscripts by you or your coauthors addressing similar or related research questions that are in preparation or under consideration at other journals. This does not apply to abstracts published in connection with scientific meetings or to news reports based on presentations at such meetings.

The Journal's policy is explained more fully at https://www.nejm.org/about-nejm/editorial-policies.

Please call us at 617-734-9800 if you have any questions.

Sincerely,

New England Journal of Medicine 10 Shattuck Street Boston, MA 02115 (617) 734-9800 Fax: (617) 739-9864 http://www.nejm.org

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email and delete the original message from all computer systems. Thank you.

From: Thomas Friedrich
To: Segaloff, Hannah E - DHS

Cc: Kasen Riemersma; DAVID H O"CONNOR; Katarina Grande; Westergaard, Ryan P - DHS

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Date: Friday, August 20, 2021 4:15:49 PM

Attachments: Riemersma Viral loads in vaccinees NEJM revised 2 tracked 2021-08-20.docx

Hi Hannah.

The comments were indeed minimal. I have made the requested changes in the attached document.

The one comment I don't know how to address is the one asking whether the CDC ethics statement should be included. I do not feel comfortable adding it in if CDC has not in fact done this review. Do you have advice on that?

Best,

-T

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 20 Aug 2021, at 16:07, Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov > wrote:

Also noteworthy that the clearance coordinators are on call over the weekend but only in the office official until 6pm eastern so best bet is getting this back to them in the next \sim 30 min.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu>

Sent: Friday, August 20, 2021 3:44 PM

To: Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov **Cc:** Kasen Riemersma < riemersma@wisc.edu; DAVID H O'CONNOR

<dhoconno@wisc.edu>; Katarina Grande <kgrande@publichealthmdc.com>;

Westergaard, Ryan P - DHS < ryan.westergaard@dhs.wisconsin.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah.

Do you have any updates on the CDC clearance process? Can you see if others have been able to look at the paper?

Thanks,

-T

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 19 Aug 2021, at 18:51, Thomas Friedrich < tfriedri@wisc.edu> wrote:

Okay, fingers crossed!

Sent from my iPhone

On Aug 19, 2021, at 18:02, Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov > wrote:

Though on second thought I can see that the STLT TF is reviewing now- so maybe this is moving faster than I thought.

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov

Qdz0@cdc.gov

From: Thomas Friedrich < tfriedri@wisc.edu Sent: Thursday, August 19, 2021 5:44 PM

To: Segaloff, Hannah E - DHS

hannah.segaloff@dhs.wisconsin.gov

Cc: Kasen Riemersma < <u>riemersma@wisc.edu</u>>; DAVID H O'CONNOR < <u>dhoconno@wisc.edu</u>>; Katarina Grande

< kgrande@publichealthmdc.com>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite

Vaccination when the Delta Variant is Prevalent

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Thanks Hannah.

I really hope they can return comments tomorrow so we can submit. I will be heading up north on Saturday and won't have WiFi for a week. Do you think that is at all possible?

Best,

Tom

Sent from my iPhone

On Aug 19, 2021, at 15:20, Segaloff, Hannah E - DHS < hannah.segaloff@dhs.wisconsin.gov > wrote:

Thanks Tom,

I will send these along and the note. I'm hoping we can switch over to a Google drive format for comments.

Best, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

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To: Segaloff, Hannah E - DHS

< hannah.segaloff@dhs.wisconsin.gov>

Cc: Kasen Riemersma < <u>riemersma@wisc.edu</u>>; DAVID H O'CONNOR < <u>dhoconno@wisc.edu</u>>; Katarina Grande

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Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah.

Attached please find clean (well, clean-ish) and tracked versions of the revised manuscript. We addressed all the comments and made the changes requested. I hope this can be approved quickly.

Note: As you know, to edit collaboratively, we uploaded the Word doc with CDC comments to Google Drive. I re-downloaded the edited version as a Word doc — this is the "clean" version and preserves CDC comments and our responses. To make the "tracked" version I had to compare that downloaded document to the Word doc you forwarded from CDC. When I did that I noticed that it duplicated several comments from CDC folk. For the sake of readability I

tried to delete duplicates, but there are still a lot of comments in a small space. It also appears that replies within comments were not recognized, so now they just appear as comments on top of other comments. I hope that all makes sense.

If these copies do not come through, you can download them from the shared Google drive here:

Best,

-Tom

Thomas Friedrich

Professor
Dept. Pathobiological Sciences
University of Wisconsin
School of Veterinary Medicine
@tcfriedrich
@tcf-lab
www.vetmed.wisc.edu/friedrichlab

On 19 Aug 2021, at 09:41, Segaloff, Hannah E - DHS <<u>hannah.segaloff@dhs.wisconsin.gov</u>> wrote:

Hi All,

Here are the first round of comments. We should get all responses within 24 to 48 hours of our submission. It looks like this needs to be approved by Lab TF, cross clearance and the response. Let me know if I can help with comments.

Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

From: CDC IMS 2019 NCOV Response Lab TF Clearance < eocevent216@cdc.gov >

Sent: Thursday, August 19, 2021

9:24 AM

To: Segaloff, Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<qdz0@cdc.gov>

Cc: CDC IMS 2019 NCOV Response

Lab TF Clearance

<<u>eocevent216@cdc.gov</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Caution: Message from external sender. Do not click on links or open attachments unless you recognize the sender.

Hi Hannah,

Please address the mandatory comments and return for rereview.

Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance <u>eocevent216@cdc.gov</u>

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Segaloff, Hannah (CDC/DDPHSS/CSELS/DSEPD)

<adz0@cdc.gov>

Sent: Wednesday, August 18,

2021 9:18 AM

To: CDC IMS 2019 NCOV Response Lab TF Clearance <<u>eocevent216@cdc.gov</u>>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hello,

Thank you for the quick work getting this approved for DIM expedited clearance. I haven't had a manuscript in expedited clearance before. Does it have the same steps as standard? How much time should I anticipate for the clearance process?

Thank you! Hannah

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021

11:51 AM

To: Kools, John J.

(CDC/DDID/NCEZID/OD)

<czk7@cdc.gov>; CDC IMS 2019 NCOV Response Lab TF Clearance

<<u>eocevent216@cdc.gov</u>>;

Dunworth, Soumya

(CDC/DDPHSS/CSELS/OD)

<<u>kya6@cdc.gov</u>>

Cc: Limbago, Brandi (CDC/DDID/NCIRD/OD)

<<u>bbl7@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>; Segaloff,

Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<<u>qdz0@cdc.gov</u>>; Moon,

Jonathan L.

(CDC/DDID/NCEZID/DSR)

<iki5@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

NP! Glad we were able to turn this around so quickly.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist Laboratory and Testing Task Force

COVID-19 Emergency Response

Centers for Disease Control and

Prevention

Lab TF Communications

Mailbox: eocevent503@cdc.gov

Cell:

From: Kools, John J. (CDC/DDID/NCEZID/OD)

<czk7@cdc.gov>

Sent: Tuesday, August 17, 2021

12:47 PM

To: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<aqv9@cdc.gov>; CDC IMS 2019

NCOV Response Lab TF Clearance

<<u>eocevent216@cdc.gov</u>>;

Dunworth, Soumya

(CDC/DDPHSS/CSELS/OD)

< kya6@cdc.gov>

Cc: Limbago, Brandi

(CDC/DDID/NCIRD/OD)

<<u>bbl7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>; Segaloff,

Hannah

(CDC/DDPHSS/CSELS/DSEPD)

<adz0@cdc.gov>; Moon,

Jonathan L.

(CDC/DDID/NCEZID/DSR)

<iki5@cdc.gov>

Subject: RE: Shedding of

Infectious SARS-CoV-2 Despite

Vaccination when the Delta

Variant is Prevalent

Thanks Shelbi!

From: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021

12:43 PM

To: CDC IMS 2019 NCOV

Response Lab TF Clearance

<eocevent216@cdc.gov>; Kools,

John J. (CDC/DDID/NCEZID/OD)

<<u>czk7@cdc.gov</u>>; Dunworth,

Soumya (CDC/DDPHSS/CSELS/OD)

<kya6@cdc.gov>

Cc: Limbago, Brandi

(CDC/DDID/NCIRD/OD)

<<u>bbl7@cdc.gov</u>>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR)

<<u>xhg9@cdc.gov</u>>; Segaloff,

Hannah

(CDC/DDPHSS/CSELS/DSEPD) <adz0@cdc.gov>; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) <iki5@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Afternoon,

This has been approved for expedited clearance.

Thanks, Shelbi Davis Communication Lead Health Communication Specialist Laboratory and Testing Task Force COVID-19 Emergency Response Centers for Disease Control and Prevention Lab TF Communications Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021

12:40 PM

To: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<aqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thank you. I approve expedited clearance.

Stephanie Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021

12:16 PM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hey Stephanie,

Please see attached for the updated draft.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and
Prevention
Lab TF Communications

Mailbox: eocevent503@cdc.gov
Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021

11:05 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H.

(CDC/DDPHSS/CSELS/OD)

<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Sure thing, working on the updated draft now.

Thanks,

Shelbi Davis

Communication Lead

Health Communication Specialist Laboratory and Testing Task Force COVID-19 Emergency Response Centers for Disease Control and

Prevention

Lab TF Communications
Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021

10:56 AM

To: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Yes, please request an updated draft with Hannah's name on it and then I approve it going for expedited clearance.
Stephanie
Stephanie R. Bialek MD MPH
Deputy Incident Manager
COVID-19 Response
CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<aqv9@cdc.gov>

Sent: Tuesday, August 17, 2021

10:56 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

< iwg7@cdc.gov>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hey Stephanie,

From correspondence with ADS and STLT Hannah was inadvertently left off the manuscript but WI has confirmed that she is a co-author but her name is not on this draft. Should we request an updated draft with Hannah information on there as the co-author?

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and

Prevention

Lab TF Communications

Mailbox: eocevent503@cdc.gov

Cell:

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021

10:51 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H.

(CDC/DDPHSS/CSELS/OD)

<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hey,

I am working on getting clarification as we speak, update to follow.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and
Prevention
Lab TF Communications

Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021

10:49 AM

To: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Cc: Fisher, Angela H.
(CDC/DDPHSS/CSELS/OD)
<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Hannah Segaloff EISO is listed on the clearance request form as an author but not on the manuscript. Can you clarify that she indeed and author? If so, then my approval for expedited clearance stands.

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

Sent: Tuesday, August 17, 2021

10:40 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD) < iwg7@cdc.gov>; Gartin, Jarrett

(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: Re: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Thanks for the speedy response!

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and

Prevention

Lab TF Communications
Mailbox: eocevent503@cdc.gov

Cell:

From: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Sent: Tuesday, August 17, 2021

10:39 AM

To: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Cc: Fisher, Angela H.

(CDC/DDPHSS/CSELS/OD)

<<u>iwg7@cdc.gov</u>>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: RE: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

I approve.

Stephanie R. Bialek MD MPH Deputy Incident Manager COVID-19 Response CDC

From: Davis, Shelbi (CDC/DDID/NCIRD/DVD)

<qqv9@cdc.gov>

Sent: Tuesday, August 17, 2021

10:38 AM

To: Bialek, Stephanie R. (CDC/DDID/NCIRD/DVD)

<zqg7@cdc.gov>

Cc: Fisher, Angela H. (CDC/DDPHSS/CSELS/OD)

<iwg7@cdc.gov>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Subject: Fw: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Morning Stephanie,

Happy Tuesday! We would like to request DIM1 expedited approval for the attached manuscript. Please refer to the email thread below.

Thanks,
Shelbi Davis
Communication Lead
Health Communication Specialist
Laboratory and Testing Task Force
COVID-19 Emergency Response
Centers for Disease Control and
Prevention
Lab TF Communications
Mailbox: eocevent503@cdc.gov
Cell:

From: CDC IMS 2019 NCOV Response Lab TF Clearance <<u>eocevent216@cdc.gov</u>>

Sent: Tuesday, August 17, 2021

10:32 AM

To: Davis, Shelbi

(CDC/DDID/NCIRD/DVD)

<aqv9@cdc.gov>; Gartin, Jarrett (CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>

Cc: CDC IMS 2019 NCOV Response

Lab TF Clearance

<eocevent216@cdc.gov>

Subject: Fw: Shedding of

Infectious SARS-CoV-2 Despite Vaccination when the Delta

Variant is Prevalent

Hi Shelbi and Jarrett,

Should I begin clearance on this item or wait until you receive the DIM approval?

Thank you, Alexis

CDC IMS 2019-nCoV Lab Task Force Clearance eocevent216@cdc.gov

Hours of Operation:

Monday-Friday 9 AM - 6 PM EST Saturday & Sunday On Call (Check Ins at 10 AM & 3 PM)

From: Kools, John J. (CDC/DDID/NCEZID/OD)

<<u>czk7@cdc.gov</u>>

Sent: Tuesday, August 17, 2021

9:59 AM

To: CDC IMS 2019 NCOV
Response Lab TF Clearance
<<u>eocevent216@cdc.gov</u>>; Davis,
Shelbi (CDC/DDID/NCIRD/DVD)
<<u>qqv9@cdc.gov</u>>; Gartin, Jarrett
(CDC/DDID/NCIRD/OD) (CTR)

<xhg9@cdc.gov>
Cc: Dunworth, Soumya
(CDC/DDPHSS/CSELS/OD)
<kya6@cdc.gov>; Limbago, Brandi
(CDC/DDID/NCIRD/OD)
<bbf?@cdc.gov>; Moon, Jonathan
L. (CDC/DDID/NCEZID/DSR)
<iki5@cdc.gov>; Llewellyn, Anna
C. (CDC/DDID/NCEZID/DPEI)
<gif7@cdc.gov>; Segaloff, Hannah
(CDC/DDPHSS/CSELS/DSEPD)

<<u>qdz0@cdc.gov</u>>

Subject: Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent

Good Morning,

You may have heard but our task

force was asked by STLT, and we agreed, to sponsor this manuscript through clearance. The authors are targeting NEJM and are requesting our task force to request IM approval for expedited clearance. Our main POC for this manuscript is our CDC EISO Hannah Segaloff (Cc'd). Let me know if you have any questions.

Hannah- our clearance team can help shepherd your paper through clearance. I would anticipate our laboratory SMEs to have some questions for your team.

Best regards,

John

John Kools
ADS, Laboratory & Testing Task Force
CDC COVID-19 Response
Phone: 404-217-7258

From: Rose, Dale A. (CDC/DDID/NCEZID/DPEI)

<<u>ido8@cdc.gov</u>>

Sent: Tuesday, August 17, 2021

4:51 AM

To: Kools, John J. (CDC/DDID/NCEZID/OD)

<czk7@cdc.gov>

Subject: FW: Follow up on your

results

Morning John! Thanks for taking this on. We had intensive discussions with WI, IM, and MMWR last week about this. There's strong interest in

supporting and moving this forward quickly in clearance, including securing approval for expedited clearance so it can quickly make it to NEJM for consideration. If you anticipate any issues with the content or timing, please do let me know as our TF is in routine conversation with the state epi and want to make sure we're aligned in our discussions.

Much appreciated, and I hope you are well!

Best, Dale

Dale Rose, Ph.D.
STLT Support Task Force
Cell:

From: Llewellyn, Anna C. (CDC/DDID/NCEZID/DPEI)

<gif7@cdc.gov>

Sent: Monday, August 16, 2021

3:35 PM

To: Segaloff, Hannah (CDC <u>dhs.wisconsin.gov</u>)

< hannah.segaloff@dhs.wisconsin.

gov>; Rose, Dale A.

(CDC/DDID/NCEZID/DPEI) < ido8@cdc.gov>; Westergaard,

Ryan (CDC dhs.wisconsin.gov)

<ryan.westergaard@dhs.wisconsi</pre>

<u>n.gov</u>>; Bisgard, Kris

(CDC/DDPHSS/CSELS/DSEPD)

<<u>kmb6@cdc.gov</u>>

Cc: Ricaldi Camahuali, Jessica (CDC/DDID/NCEZID/DPEI) < mpi7@cdc.gov; Kools, John J. (CDC/DDID/NCEZID/OD)

<<u>czk7@cdc.gov</u>>; Limbago, Brandi (CDC/DDID/NCIRD/OD) <<u>bbl7@cdc.gov</u>>; Moon, Jonathan L. (CDC/DDID/NCEZID/DSR) <iki5@cdc.gov>; CDC IMS 2019 NCOV Response STLT ADS <<u>eocevent410@cdc.gov</u>>; CDC IMS 2019 NCOV Response Lab Task Force <eocevent177@cdc.gov>

Subject: Re: Follow up on your results

Dear Hannah,

Thank you for these additional documents. Due to this manuscript's focus on laboratory data, our Laboratory and Testing Task Force colleagues have agreed to be the sponsoring task force for CDC COVID-19 Response clearance. John Kools is the Lab TF ADS and can assist with next steps.

Best Regards,

Anna

Anna Llewellyn, PhD Associate Director for Science State, Tribal, Local, and Territorial Support Task Force COVID-19 Emergency Response Centers for Disease Control and Prevention

Office: 404-639-1538 | Cell:

eocevent410@cdc.gov

From: Segaloff, Hannah E - DHS <hannah.segaloff@dhs.wisconsin. gov>

Sent: Monday, August 16, 2021

3:13 PM

To: Rose, Dale A.

(CDC/DDID/NCEZID/DPEI)

< ido8@cdc.gov>; Westergaard,

Ryan (CDC dhs.wisconsin.gov)

<ryan.westergaard@dhs.wisconsi</pre>

n.gov>; Bisgard, Kris

(CDC/DDPHSS/CSELS/DSEPD)

<<u>kmb6@cdc.gov</u>>

Cc: Llewellyn, Anna C.

(CDC/DDID/NCEZID/DPEI)

<gif7@cdc.gov>; Ricaldi

Camahuali, Jessica

(CDC/DDID/NCEZID/DPEI)

<mpi7@cdc.gov>

Subject: RE: Follow up on your

results

Thank you. I have attached the concept proposal that was approved from the original MMWR submission as well as a clearance request form.

Sincerely, Hannah

Hannah Segaloff, PhD, MPH | LT, U.S. Public Health Service Epidemic Intelligence Service Officer U.S. Centers for Disease Control and Prevention

Bureau of Communicable Diseases Wisconsin Department of Health Services Currently Teleworking

Cell:

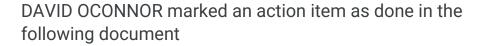
Hannah.Segaloff@dhs.wisconsin.gov Qdz0@cdc.gov

<Reimersma_Viral loads in vaccinees_ NEJM_editedauthorlist_LABTF COMMENTS.docx> From: **DAVID OCONNOR (Google Docs)**

To: Kasen Riemersma

Subject: Viral loads in va... - @tfriedri@wisc.edu I think the title ...

Date: Tuesday, August 10, 2021 1:21:20 PM





Viral loads in vaccinees: MMWR

Infection with Replication-Competent



Kasen Riemersma

@tfriedri@wisc.edu I think the title should say "Shedding of..." not "Infection with..." because our main takeaway is that vaccinated people can transmit, not that they can be infected. Also, I'm not a fan of "replication-competent" for a lay audience. How about "Shedding of Infectious SARS-CoV-2 Despite Vaccination..."?

Assigned to Thomas Friedrich



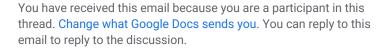
DAVID OCONNOR New



Marked as done

Open

Google LLC, 1600 Amphitheatre Parkway, Mountain View, CA 94043,





From: onbehalfof@manuscriptcentral.com

To: RYAN WESTERGAARD

Subject: New England Journal of Medicine Letter NOT about NEJM Article 21-14060: Account Created for you in

ScholarOne Manuscripts

Date: Monday, August 23, 2021 1:39:09 PM

Dear Dr. Westergaard:

A submission entitled Shedding of Infectious SARS-CoV-2 Despite Vaccination (21-14060) has been submitted by Ms. Katarina Grande to the New England Journal of Medicine.

You are listed as a co-author for this manuscript. The online peer-review system, ScholarOne Manuscripts, automatically created a user account for you. Your USER ID and PASSWORD for your account is as follows:

Site URL:
USER ID:
PASSWORD:

You can use the above USER ID and PASSWORD (once set) to log in to the site and check the status of papers you have authored/co-authored. Please log in to information via the edit account tab at the top right.

If you believe you already have an account with us and this is a duplicate account, or if you do not wish to have an account with the New England Journal of Medicine, please contact us and we will be happy to assist you.

Thank you for your participation.

Sincerely,

Editorial Office

New England Journal of Medicine 10 Shattuck Street Boston, MA 02115 (617) 734-9800

Fax: (617) 739-9864 http://www.nejm.org

Log in to Remove This Account -

From: medicine@us.nature.com
To: RYAN WESTERGAARD

Subject: NMED-BC116676 Receipt of New Paper by Nature Medicine

Date: Tuesday, November 2, 2021 2:05:07 PM

Dear Dr. Westergaard,

Please note that you are listed as a co-author on the manuscript "Shedding of Infectious SARS-CoV-2 Despite Vaccination" (reference number: NMED-BC116676), which was recently submitted to Nature Medicine.

The corresponding author is solely responsible for communicating with the journal and managing communication between co-authors. Please contact the corresponding author directly with any queries you may have related to this manuscript.

You can now use a single sign-on for all your accounts, view the status of all your manuscript submissions and reviews, access usage statistics for your published articles and download a record of your refereeing activity for the Nature journals. Please check your account regularly and ensure that we have your current contact information.

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>these

instructions. Please note that it must be linked prior to acceptance, it will not be possible to add/modify ORCIDs at proof, and you may not receive further notification before an accept decision is made. Please ensure the ORCID is linked to your account associated with this manuscript, and not to any other account you may have on our system.

Login =

If you have any issues attaching an ORCID to your Manuscript Tracking System account, please contact the <u>Platform Support Helpdesk</u>.

Many thanks,

Editorial Assistant Nature Medicine medicine@us.nature.com

Our flexible approach during the COVID-19 pandemic

If you need more time at any stage of the peer-review process, please do let us know. While our systems will continue to remind you of the original timelines, we aim to be as flexible as possible during the current pandemic.

This email has been sent through the Springer Nature Tracking System NY-610A-NPG&MTS

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