From: b6
Sent: 3/13/2022 10:51:46 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6
Subject: Re: [EXTERNAL] Follow up to b6 conversation
Attachments: Peripheral Neuropathy Evaluations of Patients With Prolonged Long COVID Neurology Neuroimmunology & Neuroinflammation.pdf

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Sent from my iPhone

On Mar 13, 2022, at 4:30 PM, b6 wrote:

That is what most of us vaccine injured have along with b6 which I also have. I know you all have done autonomic testing there as well as b6 Why can't you do it for me?

Sent from my iPhone

On Mar 13, 2022, at 2:29 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Dear b6
Sorry to hear of your ongoing illness. Unfortunately, neuropathies are not my area of expertise. I might suggest b6 at b6 or b6 b6 at b6 Sorry, I cannot be of more help.
Best.
Avi

From: b6
Date: Sunday, March 13, 2022 at 2:14 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: [EXTERNAL] Follow up to b6 conversation

Dr. Nath,
Since you talked with b6 from b6 on my behalf I have b6 b6 I don't hardly sweat anymore

and I know this was acute onset due to the covid shot. b6 b6 My system was working great. Now I have dizziness and autonomic symptoms since the injection. I'm having trouble getting anyone to treat me with any sort of speed at all. I have b6 b6 and am desperate to try and get this under control. b6 won't see me and it is taking 6 months to get into different places who then say they can't help me. b6 doesn't have an autonomic specialist either. Can you bring me to the NIH for testing and treatment? I have also been talking to b6 and she said it is at your discretion. Please help me. I know you have treated others as I have talked with them.

Regards,
b6

Sent from my iPhone

Neurology® Neuroimmunology & Neuroinflammation

May 2022; 9 (3) CLINICAL/SCIENTIFIC NOTE

OPEN ACCESS

Peripheral Neuropathy Evaluations of Patients With Prolonged Long COVID

Anne Louise Oaklander, Alexander J. Mills, Mary Kelley, Lisa S. Toran, Bryan Smith, Marinos C. Dalakas, Avindra Nath

First published March 1, 2022, DOI: https://doi.org/10.1212/NXI.0000000000001146

Abstract

Background and Objectives Recovery from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection appears exponential, leaving a tail of patients reporting various long COVID symptoms including unexplained fatigue/exertional intolerance and dysautonomic and sensory concerns. Indirect evidence links long COVID to incident polyneuropathy affecting the small-fiber (sensory/autonomic) axons.

Methods We analyzed cross-sectional and longitudinal data from patients with World Health Organization (WHO)-defined long COVID without prior neuropathy history or risks who were referred for peripheral neuropathy evaluations. We captured standardized symptoms, examinations, objective neurodiagnostic test results, and outcomes, tracking participants for 1.4 years on average.

Results Among 17 patients (mean age 43.3 years, 69% female, 94% Caucasian, and 19% Latino), 59% had ≥1 test interpretation confirming neuropathy. These included 63% (10/16) of skin biopsies, 17% (2/12) of electrodiagnostic tests and 50% (4/8) of autonomic function tests. One patient was diagnosed with critical illness axonal neuropathy and another with multifocal demyelinating neuropathy 3 weeks after mild COVID, and ≥10 received small-fiber neuropathy diagnoses. Longitudinal improvement averaged 52%, although none reported complete resolution. For treatment, 65% (11/17) received immunotherapies (corticosteroids and/or IV immunoglobulins).

Discussion Among evaluated patients with long COVID, prolonged, often disabling, small-fiber neuropathy after mild SARS-CoV-2 was most common, beginning within 1 month of COVID-19 onset. Various evidence suggested infection-triggered immune dysregulation as a common mechanism.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) can cause long-term disability (long COVID) with new neurologic manifestations after even mild infections.[1] Reports of peripheral neuropathy include Guillain-Barré syndrome, mononeuritis multiplex, brachial plexitis, cranial neuropathies, and orthostatic intolerance, although some studies included patients with potentially contributory conditions. Various long COVID symptoms overlap with those of small-fiber polyneuropathy (SFN).[2,3] Hence, we prospectively analyzed a cross-section of patients with long COVID evaluated for incident neuropathy.

Methods

Standard Protocol Approvals, Registrations, and Patient Consents

This retrospective analysis was approved by the hospitals' ethical review committee (1999P009042). Although participant consent was not required, all 17 provided verbal consent and 16 signed agreements for participation and publication of anonymized results.

Study Design

Inclusion required no known prior neuropathy or risks plus confirmation of SARS-CoV-2 infection according to guidelines of the World Health Organization (WHO). COVID severity classification followed WHO guidelines. Inclusion required meeting the WHO definition of long COVID (onset of symptoms within 90 days of the first day of COVID symptoms that last for >2 months).[1] Participants were enrolled upon COVID

confirmation and neuromuscular referral before record review or most testing and treatment. Participants documented neuropathy symptoms via online REDCap surveys, and their neurologists documented standardized in-person and occasional telehealth neuropathy examinations.[4,5] Because most participants had received symptom-relieving medications at varying doses, we analyzed only potentially preventive treatments, all of which were immunotherapies. Parametric analyses were used with variability represented by standard errors.

Data Availability

Any anonymized data not published within the article will be shared by request from any qualified investigator.

Results

Among 17 patients with SARS-CoV-2 onset between February 21, 2020, and January 19, 2021, treated in 10 states/territories (Table 1), 16 had mild COVID. The one (#9) with severe COVID (1 month stay in intensive care with ventilatory support) had electrodiagnostically confirmed sensorimotor polyneuropathy ascribed to critical care illness in addition to SFN. Medical histories and comprehensive blood screening (not shown) identified none with conventional neuropathy risks nor evidence of systemic dysimmunity. Imaging of the brain or spine, if performed, was unrevealing.

Table 1

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Participants, Objective Tests, and Treatments

Participants' ages averaged 43.3 ± 3.3 years on COVID D1, and 68.8% were female; 18.8% were Latino, and 94.1% were Caucasian. Diagnostic tests for neuropathy (Table 1) revealed that 16.7% electrodiagnostic studies were abnormal, whereas 62.5% (10/16) of lower leg skin biopsies pathologically confirmed SFN, as corroborated by 50% of upper thigh biopsies and autonomic function tests.[2] Initial SFN symptom scores (Table 2) were abnormal—reduced to 40.7% of ideal on average—with pain scores averaging 4.8/10. Initial neuromuscular examinations (Table 3) averaged 77.0% of ideal, with reduced/abnormal distal pin and vibration sensations and absent Achilles reflexes most prevalent.[4,5] Participants 9 and 15 had distal muscle weakness and atrophy. Some patients were initially evaluated early in the course and others later, and investigations continued for months. Sixteen participants with 2020 onset had >1 year follow up, with the latest onset on 1/19/21. See Figure 1 (case 15) and eFigure 1, links.lww.com/NXI/A697, (case 13) for longitudinal details.

Table 2

View inline View popup

Initial Symptom Scores

Table 3

View inline View popup

Neuropathy Examination Scores

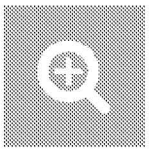

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Figure 1

Case 15: Prolonged COVID-Incident Multifocal Motor Neuropathy

CMAP = compound motor action potential; D = day; EDX = electrodiagnostic testing; IVIg = IV immunoglobulin therapy; MMN = multifocal motor neuropathy; SNAP = sensory nerve action potential. Three weeks after 12/04/1920 onset of mild COVID-19, this previously healthy 65-year-old developed progressive R > L hand weakness and atrophy. Three months later, he could not hold eating utensils or a pen and noted hand "limpness" tingling and pain, and finger cramps without lower limb symptoms. Neurosurgical referral prompted cervical MRI showing unrelated degenerative changes. A local neurologist's EDX suggesting MMN or lower motor neuron disease prompted our neuromuscular evaluation on post-COVID D67. This revealed weakness in the distal ulnar and median nerve distributions, 4/5 finger abduction strength, and R > L interosseus and thenar

eminence atrophy. He could not make a fist or hold utensils; sensory self-examination was normal. EDX on D122 documented demyelinating neuropathy with conduction blocks in both ulnar nerves at the forearms and across the elbows and prolonged latencies and reduced conduction in both median nerves. F waves were prolonged in the upper and lower limbs, and the right peroneal CMAP was low amplitude. SNAP velocities were normal, with slightly diminished amplitude in the median, ulnar, and sural nerves. Serum immunoglobulins and immunofixation were normal, and GM1 antibodies were absent. He met the diagnostic criteria for MMN and began standard treatment, IVIg 2 g/kg/4 weeks, on D146. A few weeks later, he noticed improved hand dexterity with ability to fully open hands and use utensils and decreased hand cramps, with 90% improvement after the 3rd cycle. Then, expiration of IVIg orders caused regression. After 2 missed cycles, D292 evaluation documented R > L increasing difficulty opening his hands and return of hand and forearm tingling. He self-reported hair loss on legs, muscle difficulties, skin color changes, tingling, itching, and needing to move legs for comfort (eFigure 1, links.lww.com/NXI/A697). Same-dose IVIg was restarted, and after 2 cycles with improvement, clinic return on D341 documented 80% improved weakness, hand opening, finger dexterity, and hand cramps. He had bilateral 4/5 finger abduction strength, and this image documented significant remaining R > L interossei muscle atrophy. IVIg was continued, and he was referred for interosseus exercises.

Treatments comprised corticosteroids in 35.3% (6/17) and IV immunoglobulins (IVIg) in 35.3% (6/17). Five were initially dosed at 2.0 g/kg/4 weeks and 1 at 1.6 g/kg/4 weeks. The 5 patients who received repeated IVIg, and their neurologists, reported benefit (e.g., Figure 1, Table 1). eFigure 1 reports patient 13's graphed symptom and examination scores before and during IVIg. Patients' impressions of recovery varied (averaging 51.8 ± 6.7%), reflecting varying illness severity, treatment status, and assessment timing.

Discussion

Neuromuscular evaluations proved useful in most of these patients with long COVID. However some symptoms, exam changes and test results may have been false-negative, given that assessments were not often optimally timed (e.g., #6) and many patients reported care delays. This reported case of multifocal motor neuropathy (Figure 1) increases the spectrum of COVID-associated dysimmune neuropathies. Critical illness neuropathy—reported in approximately 10% of intubated patients with COVID—is attributed to various prolonged insults including intense inflammation and nerve

compressions.[6] Inherent study limitations include bias toward referrals for sensory neuropathy and underpowering. The initial evaluations reported occurred at varying times during the illness and treatment, whereas longitudinal assessments at standardized intervals are ideal for diagnostic and treatment decisions. Timing also complicates analysis of blood testing for immune markers (not shown). We screened patients with newly diagnosed neuropathy for all common established causes of distal sensory neuropathy, including routinely measuring ANA, ESR, IgG anti–SS-A/SS-B antibodies, and complement components C3 and C4, the most productive markers of dysimmunity in initially idiopathic SFN.[7] We did not detect evidence of Sjögren syndrome, and other inflammatory markers were only occasionally elevated. Interpretation is complex as early elevations could be nonspecifically associated with acute COVID, and many months later, inflammation and markers might have subsided leaving residual axonopathy as the proximate cause of current symptoms. Regeneration can take up to 2 years or be incomplete.

These results identify small-fiber neuropathy as most prevalent in this small group of patients with long COVID, also known as post-acute sequelae of SARS CoV-2 infection.[2] In SFN, the small-diameter unmyelinated and/or thinly myelinated sensory and autonomic fibers are predominantly affected, although most patients with severe or advanced polyneuropathy, e.g., case 9, develop large- and small-fiber damage. The small fibers are disproportionately vulnerable, with their lack of myelin exposing them to environmental stressors including immunity, while inability to use saltatory conduction increases metabolic demand, and cytoplasmic paucity limits axonal regeneration. However, small-fiber axons grow throughout life to reinnervate continuously dividing tissues such as the skin and to help repair injuries. If toxic conditions improve, axon elongation and sprouting accelerate to increase the probability of reinnervating enough target cells to resolve symptoms.

Here, most patients treated with sustained IVIg, the primary treatment for inflammatory neuropathy, with preliminary evidence of effectiveness for dysimmune SFN,[8] perceived improvement (e.g., Figure 1, eFigure 1, links.lww.com/NXI/A697). Some treated only with corticosteroids did as well; participant 3 reported that prednisone helped her toward 90% improvement and was discontinued only because of adverse effects. Others improved substantially without immunotherapy (e.g., case 17), documenting spontaneous recovery and need to individualize treatment decisions.

The hypothesis that some long COVID symptoms reflect underlying small-fiber pathology is supported by research observation of small-fiber loss applying in vivo corneal confocal microscopy to patients with long COVID.[9] As with other post-COVID neurologic illnesses, susceptibility to inflammatory mediators appears essential. Autopsy study of post-COVID patients identified neuritis with perivascular macrophage infiltrates but no viral antigens, implicating inflammatory immune responses rather than direct infection. In addition, 1/4th of human DRG neurons express mRNA for SARS-CoV-2–associated receptors and deploy ACE2 protein. Thus, virus or spike protein fragments may attach to them, promoting formation of antibodies that can also target adjacent neural epitopes. Here, the slightly delayed onsets, prolonged postinfectious courses, and apparent responses to continued immunotherapy suggested dysimmune mechanisms.

This report strengthens evidence linking several idiopathic multisymptom conditions—including SFN and fibromyalgia—with dysimmunity, sometimes incident to infections or vaccinations.[2] As with COVID-incident Guillain-Barré syndrome and all referral-based case series, the current cases neither confirm causality nor the clinical significance or magnitude of any association. However, identifying small-fiber neuropathy and

multifocal motor neuropathy in 1 small sample of patients with WHO-defined long COVID provides rationale and preliminary data for larger investigations and may influence interim medical evaluations of similar patients.

Study Funding

Supported in part by the National Institutes of Health; R01NS093653 (ALO). Division of Intramural Research, NINDS (AN) and the Department of Neurology of Thomas Jefferson University (MCD).

Disclosure

The authors report no disclosures. Go to Neurology.org/NN for full disclosures.

Acknowledgment

The authors gratefully acknowledge patient contributions including details from medical personnel. They also thank many colleagues who referred patients, facilitated studies, or contributed data including Heather M. Downs, BS, Lisa Paul, NP, Shibani Mukerji, MD, PhD, Khosro Farhad, MD, Pedro Steven Buarque de Macedo, MD, Yancy Seamans, FNP, Joseph Tornabene, MD, Matthew P. Wicklund, MD, Jennifer Curtin, MD, Yair Mina, MD, Sara Dehbashi, MD, and Madeleine C. Klein, BS.

Appendix Authors

Footnotes

↵* Co–senior authors.

The Article Processing Charge was funded by the NIH.

Go to Neurology.org/NN for full disclosures. Funding information is provided at the end of the article.

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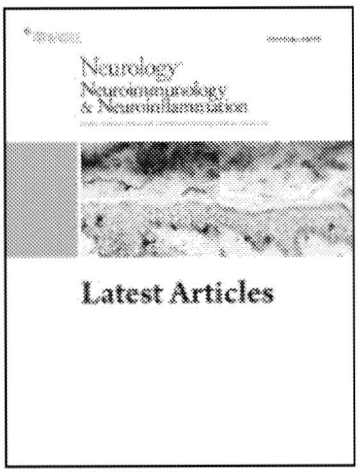

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From: b6
Sent: 3/13/2022 11:18:13 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6-b6
Subject: Re: [EXTERNAL] Follow up to b6 conversation

Sure

Sent from my iPhone

On Mar 13, 2022, at 6:17 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Is it Ok for me to forward your email to her?
Avi

From: b6
Date: Sunday, March 13, 2022 at 7:16 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Re: [EXTERNAL] Follow up to b6 conversation

Is there any way you can introduce us then? I'm sure she is overwhelmed with people contacting her all the time. Thanks!

Sent from my iPhone

On Mar 13, 2022, at 6:06 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Yes, that is why I mentioned b6 her expertise is in peripheral neuropathies. I provide expertise in virology.
Avi

From: b6
Date: Sunday, March 13, 2022 at 6:53 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Re: [EXTERNAL] Follow up to b6 conversation

Is this not your article you co authored?

Sent from my iPhone

On Mar 13, 2022, at 4:30 PM, b6 b6 wrote:

That is what most of us vaccine injured have along with b6 which I also have. I know you all have done autonomic testing there as well as b6 Why can't you do it for me?

Sent from my iPhone

On Mar 13, 2022, at 2:29 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Dear b6
Sorry to hear of your ongoing illness. Unfortunately, neuropathies are not my area of expertise. I might suggest b6 at b6 b6 or b6 at b6 Sorry, I cannot be of more help.
Best.
Avi

From: b6
Date: Sunday, March 13, 2022 at 2:14 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: [EXTERNAL] Follow up to b6 conversation

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dr. Nath,
Since you talked with b6 from b6 on my behalf I have b6 b6 I don't hardly sweat

anymore and I know this was acute onset due to the covid shot. b6 b6 My system was working great. Now I have dizziness and autonomic symptoms since the injection. I'm having trouble getting anyone to treat me with any sort of speed at all. I have b6 and am desperate to try and get this under control. b6 won't see me and it is taking 6 months to get into different places who then say they can't help me. b6 doesn't have an autonomic specialist either. Can you bring me to the NIH for testing and treatment? I have also been talking to b6 and she said it is at your discretion. Please help me. I know you have treated others as I have talked with them.

Regards,
b6

Sent from my iPhone

From: Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246-b6

Sent: 3/17/2021 10:38:18 PM

To: b6 Togias, Alkis (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8b85408814d496194bed8d69d6143eb-b6 Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-b6 b6 Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6-b6 Beavers, Suzanne (CDC/DDPHSS/CSELS/DSEPD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ffcb980af3a40189a0746a453e44921-b6 Walensky, Rochelle (CDC/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=971e7c2ce7f94e67a13565f9bfaef055-b6 b6 Richards, Paul (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0eb3f7c91f947cca52b7e191ff1c984-b6 b6

Subject: Re: Neurological reactions to the Covid vaccines

Dear b6

We started this effort and trying our best to gather information from patients with vaccine side effects to thoughtfully organize the information and report them.

If you look at VARES database there are more than 1000 neurological side effects already reported but in order to present it to scientific community we have to gather as much information as we can before sending it out.

I promise you we will report your issue and other cases that we are reviewing now and I really appreciate if you kindly give us 1-2 weeks to collect comprehensive information before publicizing it.

I would be happy to answer any question definietely will keep you in the loop when our report is ready.
Thank you for your patience.

Warm Regards,
Farinaz

From: b6

Sent: Wednesday, March 17, 2021 6:14:53 PM

To: b6 Safavi, Farinaz (NIH/NINDS) [E] b6 Togias, Alkis (NIH/NIAID) [E] b6 Marks, Peter (FDA/CBER) b6 Nath, Avindra (NIH/NINDS) [E] b6 Beavers, Suzanne (CDC/DDPHSS/CSELS/DSEPD) b6 Walensky, Rochelle (CDC/OD) b6 b6 Richards, Paul (FDA/CBER) b6

Subject: Neurological reactions to the Covid vaccines

Hello,
My name is b6 and many of you know me or have heard from me before. Briefly, I am b6 b6 who developed a severe reaction to the Pfizer Covid vaccine 30 minutes after receiving it and have been very ill for the past three months with severe paresthesias. In my search for information, I wrote several comments after articles I read in journals stating that there were no neurological adverse reactions to the vaccines. I have been contacted by many people from around the world now who have had very similar reactions to mine. Unfortunately, we are unable to find medical care as the medical community knows nothing about these reactions. This group of people is

getting too large for me to handle and correspond with. I wonder if any of you have any recommendations as to where I should go from here. We have all reported our reactions many times to VAERS and the appropriate agencies with no response. At this point, I appear to be the only resource in the world for people suffering like I have been. Maybe it is time for these reactions to be taken seriously and addressed appropriately. I would really appreciate some input and guidance from those of you who should be getting involved with this problem. It is really not a problem that I should be dealing with alone if at all.
Thank you,

b6

Sent from my iPhone

From: b6
Sent: 4/16/2021 5:05:05 PM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject: Re: COVID Vaccine Side Effect Potential
Attachments: Request for Medical Information.jpg

Hi Amanda,

Apologies for the delay, it took longer to print the form than anticipated. I am set up to come down on Tuesday next week, but wanted to get you the authorization.

Thanks,
b6

On Mon, Apr 12, 2021 at 8:39 AM Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

> Hello b6
>
> Attached is a medical records release form. Please fill out the sections highlighted in yellow and return to us. If you have not had any scans or biopsies done you can write NA in sections 2 and 3. Please fill out a separate form for each facility you were seen at.
>
> Our scheduler will be reaching out to you to get you scheduled to come in for our study. I am also attaching a copy of our protocol consent for the study. Please review an let me or Dr. Safavi know if you have any questions. This is just for your review and does not get signed at this time.
>
> Thanks,
>
> *Amanda Wiebold, BSN, RN, CNRN*
>
> Research Nurse Specialist
>
> NINDS Section of Infections of the Nervous System
>
> 10 Center Drive, Building 10/7C107, MSC 1430
>
> Bethesda, Maryland 20892
>
> Office: b6

Cell: b6

Fax: 301-402-1137

Email: b6

From: b6
Sent: Tuesday, April 6, 2021 9:58:17 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Cc: b6
Subject: Re: COVID Vaccine Side Effect Potential

Great, I sent it to my work email as well - Teams is connected to that email, so I will join from there - in case you need it b6 See you at 3pm.

Thanks,
b6

On Tue, Apr 6, 2021 at 9:33 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

> Fantastic!Will send you Microsoft Teams link shortly.
>
> Farinaz Safavi MD, PhD
>
> Division of Neuroimmunology and Neurovirology
>
> NINDS, NIH, Bethesda, MD

From: b6
Sent: Tuesday, April 6, 2021 9:31 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Cc: b6
Subject: Re: COVID Vaccine Side Effect Potential

I am pretty open this afternoon as well, let's do 3pm if that works.

Thanks,

b6

On Tue, Apr 6, 2021 at 9:25 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

Thank you very much for contacting me. We have started a research effort at NIH to look into neurological complications of COVID vaccine. It would be great if we can meet through the televisit and discuss your symptoms. I have an availability today after 3pm ET. What time works for you?

Please let me know

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Tuesday, April 6, 2021 9:16 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: COVID Vaccine Side Effect Potential

Hi Dr. Safavi,

My neurologist b6 at b6 recommended reaching out to you regarding my recent potential reaction to the COVID vaccine. He noted you may be interested in speaking to me directly and taking some additional blood work etc. I am happy to help and provide you access to any of my information if it would help with your research.

Please feel free to reach out. You can reach me at this email b6 or call me at b6

Kind Regards, b6

REQUEST FOR MEDICAL INFORMATION FROM SOURCE OUTSIDE THE NATIONAL INSTITUTES OF HEALTH

INSTRUCTIONS: Complete this form in its entirety and forward directly to the requesting facility.

CC PATIENT IDENTIFICATION

b6 (Patient Name) _____ (Patient Number) b6 (Date of Birth)

SOURCE OF INFORMATION REQUESTED

b6 (Name of Health Care Organization or Physician) b6 (Phone Number) (Fax Number)

b6 (Street Address) b6 (City) b6 (State) b6 (Zip Code)

INFORMATION REQUESTED

The purpose or need for disclosure: Review of clinical care and consideration for research study

NIH Requestor/Point of Contact: Amanda Wiebold b6 or b6

Identify the specific items and related dates pertaining to the information to be released.

1. Medical Reports:

Laboratory results, clinic notes, and brain MRI or head CT reports from b6 a)

Send to: National Institutes of Health Clinical Center
National Institute of Neurological Disorders and Stroke
Building 10, Room 7C103
10 CENTER DRIVE MSC 1430
BETHESDA, MD 20892-1430
ATTENTION: Amanda Wiebold/ Dr. Bryan Smith

OR
Fax to: (301) 402-1137
Attn: Amanda Wiebold or
Dr. Bryan Smith

2. MRI scans on CD from b6 date(s).

Send to: National Institutes of Health Clinical Center
National Institute of Neurological Disorders and Stroke
Building 10, Room 7C103
10 CENTER DRIVE MSC 1430
BETHESDA, MD 20892-1430
ATTENTION: Amanda Wiebold/ Dr. Bryan Smith

3. Tissue/Pathology Slides from _____ date(s).

Send to: National Institutes of Health Clinical Center
Laboratory of Pathology
Building 10, Room 2B50
10 CENTER DRIVE MSC 1500 BETHESDA,
MD 20892-1500

AUTHORIZATION

I hereby authorize the release of the above-requested medical information.

b6 b6 (Printed Name of Patient) b6 (Date Signed)

b6 (Street Address) b6 (City) b6 (State) b6 (Zip Code)

From: Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540 b6
Sent: 4/12/2021 12:39:02 PM
To: b6
Subject: RE: COVID Vaccine Side Effect Potential
Attachments: 15N0125 Standard Consent.pdf; NIH-1208 Authorization for the Release of Medical Information modified.pdf

Hello b6

Attached is a medical records release form. Please fill out the sections highlighted in yellow and return to us. If you have not had any scans or biopsies done you can write NA in sections 2 and 3. Please fill out a separate form for each facility you were seen at.

Our scheduler will be reaching out to you to get you scheduled to come in for our study. I am also attaching a copy of our protocol consent for the study. Please review an let me or Dr. Safavi know if you have any questions. This is just for your review and does not get signed at this time.

Thanks,

Amanda Wiebold, BSN, RN, CNRN
Research Nurse Specialist
NINDS Section of Infections of the Nervous System
10 Center Drive, Building 10/7C107, MSC 1430
Bethesda, Maryland 20892
Office: b6
Cell: b6
Fax: 301-402-1137
Email: b6

From: b6
Sent: Tuesday, April 6, 2021 9:58:17 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Cc: b6
Subject: Re: COVID Vaccine Side Effect Potential

Great, I sent it to my work email as well - Teams is connected to that email, so I will join from there - in case you need it b6 See you at 3pm.

Thanks,
b6

On Tue, Apr 6, 2021 at 9:33 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

> Fantastic!Will send you Microsoft Teams link shortly.

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Tuesday, April 6, 2021 9:31 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Cc: b6
Subject: Re: COVID Vaccine Side Effect Potential

I am pretty open this afternoon as well, let's do 3pm if that works.

Thanks,

b6

On Tue, Apr 6, 2021 at 9:25 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

> Hi b6
>
> Thank you very much for contacting me. We have started a research effort at NIH to look into neurological complications of COVID vaccine. It would be great if we can meet through the televisit and discuss your symptoms. I have an availability today after 3pm ET. What time works for you?
>
> Please let me know
>
> Farinaz Safavi MD, PhD
>
> Division of Neuroimmunology and Neurovirology
>
> NINDS, NIH, Bethesda, MD

From: b6
Sent: Tuesday, April 6, 2021 9:16 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: COVID Vaccine Side Effect Potential

Hi Dr. Safavi,

My neurologist b6 at b6 recommended reaching out to you regarding my recent potential reaction to the COVID vaccine. He noted you may be interested in speaking to me directly and taking some additional blood work etc. I am happy to help and provide you access to any of my information if it would help with your research.

Please feel free to reach out. You can reach me at this email b6 or call me at b6

Kind Regards, b6

PRINCIPAL INVESTIGATOR: Avindra Nath, MD

STUDY TITLE: Natural History Study of Inflammatory and Infectious Diseases of the Nervous System

STUDY SITE: NIH Clinical Center

Cohort: Adult/Guardian Consent

Consent Version: 03/17/2020

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Avindra Nath, MD, b6

Study Coordinator: Amanda Wiebold, RN,

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers. Taking part in research at the NIH is your choice.

If the individual being enrolled is a minor then the term "you" refers to "you and/or your child" throughout the remainder of this document.

If the individual being asked to participate in this research study is not able to give consent to be in this study. Therefore, you are being asked to give permission for this person as their decision-maker. The term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research, throughout the remainder of this document.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn more about how inflammation and infections hurt the brain and nervous system so we can develop better tests and treatments for them.

BACKGROUND

Inflammation is the way your body reacts to infection or injury. Signs of inflammation can include swelling, pain, redness or heat. Infections or inflammation in the brain can cause major health problems. Brain and nerve infections can be hard to find because we do not always have good tests for them. Sometimes inflammation in the brain can happen and doctors do not know what caused it. We would like to learn more about how diseases affect the brain and nerves so we can figure out better ways to test for them and treat them. We hope that with better and earlier testing and treatment, we can help people avoid serious health problems and death.

STUDY POPULATION

Up to 1000 people will take part in this study.

VISIT SCHEDULE

For this study, you may have several visits to the NIH Clinical Center in Bethesda, MD. The number of visits and the visit schedule depends on your individual case. In general, there will

be an initial evaluation period where we may see you as often as every week for the first weeks or months. The frequency of visits during this period depends on how much testing you will need at the beginning and if you agree to the extra visits. After this initial evaluation period, we may ask to see you again, regularly or occasionally, depending on your condition and the research needs of this study.

During one or more of your visits, you may have a brief interview with a Clinical Research Advocate (CRA) from the Human Subjects Protection Unit. The interview will see whether you understand about being in this research study. It will help decide whether you need to have someone else give consent for you to be in the study. The CRA will talk to you and the research team about the interview results.

OVERVIEW

During your study visits we will ask you about your history and do a physical exam. You will have a variety of tests. These tests are explained below. We may ask you to do additional research tests if we think that they would help us better understand your disease processes. This could include additional MRI testing, a special eye exam called optical coherence tomography (OCT), or a brain wave test called an electroencephalogram (EEG). You do not have to do these optional research tests if you do not want to. You can still be part of the study. There are no experimental drugs or devices used in this study.

BASELINE STUDY PROCEDURES:

The following procedures will be required for all adults in the study. The research team may decide some of these procedures are not required based on your health status. For children, these studies will be done only if they are tolerated easily.

History and Physical Exam:

We will ask you for your medical, social, and family history. We will ask you about your medications. You will also have a thorough physical and neurological exam. This physical exam is for research purposes only and does not replace any examination you may receive from you own doctors.

Blood Draw

Blood will be drawn through a needle in your arm. We will draw no more than 2.3 cups of blood over 8 weeks for adults and no more than 2 cups of blood over 8 weeks for children.

HIV Test

As part of this study, we may test you for infection with the human immunodeficiency virus (HIV), the virus that causes AIDS. If you are infected with HIV you will still be able to participate in this study.

Genetic Testing

Your blood may be used for genetic research purposes. The genetic material, DNA, will be taken from the sample. Different types of genetic testing may be done, depending on your condition:

1. It may be analyzed to identify the genes that might be causing your condition. This will help us understand how changes in the genes may cause symptoms. Genetic testing can be helpful in establishing a diagnosis. It may eventually lead to improved treatment or prevention.

2. To try to identify genetic changes that may be associated with your condition we may sequence the part of the DNA that provides instructions for making proteins, called the "exome." The exome makes up about 1% of your DNA.

3. We may analyze the DNA and do "whole genome" sequencing. Whole genome sequencing provides information on most of your DNA. Sequencing takes months to complete. It may take even longer for us to analyze the results of the sequencing and to understand which genes might be involved in your condition.

After the genetic sequencing and analysis are complete, you may meet again with the study team and the genetic counselor to discuss the results. Results about known or likely disease-causing gene variations will be given to you as part of genetic counseling.

The genetic testing for this study will not detect all gene changes that are associated with known diseases. However, we will tell you if we find gene changes in your DNA that are known to have major and direct medical significance and are associated with illnesses or conditions that could benefit from early treatment. We call these "reportable gene changes." We suggest you share this

information with your own doctors and that you have a clinical laboratory confirm the "reportable gene change" before you take any action on this information.

We will find individual DNA variations in everyone. We will not inform you of all gene variations, as not all of them have health implications. For example, we will not tell you about gene changes that only predispose to a particular disease--like a gene change that influences the risk for heart disease, but where the development of heart disease depends on other factors (such as diet and smoking). We will also not tell you if you are a carrier of a recessive mutation, which means that you have one copy of a recessive mutation and one copy of the normal gene, if being a carrier causes no known health problems for you.

The results from this research study will be preliminary. Further research may be necessary before they are fully understood. We do not plan to provide you with research results. However, if we obtain information that may be important for your health, we will share it with you. By participating in this study, you do not waive any rights that you may have regarding access to and disclosure of your records.

MRI

Magnetic resonance imaging (MRI) uses a strong magnetic field and radio waves to take pictures of your brain. The MRI scanner is a metal cylinder surrounded by a strong magnetic field. During the MRI, you will lie on a table that can slide in and out of the cylinder. You will be in the scanner about 60-90 minutes. You may be asked to lie still for up to eight minutes at a time. While in the scanner you will hear loud knocking noises, and you will be fitted with earplugs or earmuffs to muffle the sound. You will be able to communicate with the MRI staff at all times during your scan, and you may ask to be moved out of the machine at anytime.

During the MRI scan you will receive gadolinium, a contrast agent, through an intravenous (IV) catheter. A needle will be used to guide a thin plastic tube (catheter) into one of your arm veins. The needle will be removed, leaving only the catheter in the vein. The catheter will be taped to the skin to hold it in place.

During part of the MRI you will receive gadolinium, a contrast agent, through an intravenous (IV) catheter. It will be done for both research and medical purposes.

It is not known if MRI with contrast is completely safe for a developing fetus. Therefore, all women of childbearing potential will have a pregnancy test performed no more than 24 hours before each MRI scan with contrast. The scan will not be done if the pregnancy test is positive.

Lumbar puncture

For the lumbar puncture, you will lie on your side, curled up with your knees at your chest, or you will sit upright. Your lower back will be washed and a local anesthetic will be injected into your back to make it numb, which may sting for a few seconds. A needle will be inserted through the numbed skin and into the space between the bones in your back.

You may feel a sensation of pressure. About 1.5 tablespoons of cerebrospinal fluid (CSF) will be removed. It usually takes 5 to 20 minutes to collect the CSF. After the fluid is collected, the needle will be removed and you may get up and move around as soon as your doctor says you may.

If we cannot safely do your lumbar puncture without the help of an x-ray, your lumbar puncture will be done in the Radiology Department. If you are under 18 years of age the lumbar puncture (either at the bedside or in the Radiology Department) will only be done if it is needed for your clinical care.

Banking and Sharing

Your blood, saliva, urine, tissue sample, spinal fluid or blood cells samples and MRI and other clinical data will be stored securely on the NIH campus. Your data and samples may be sent to a repository for storage and may be released for research purposes. Your name and identifying information will not be on the samples and data. A code will be assigned. The key to the code will be kept at NIH in a separate, secure area.

If you withdraw from this research study before it is complete, you may ask that your remaining samples be destroyed. Results obtained before you withdraw will be kept. Your privacy will be protected as much as possible.

Your blood, saliva, urine, tissue sample, spinal fluid or blood cells samples and MRI and other clinical data may be used for other research projects, including those not related to your current condition. If you do not want your samples and data used for other projects, you should not participate in this study.

OPTIONAL STUDY PROCEDURES

The following procedures will be done depending on your symptoms and diagnosis:

Optical coherence tomography (OCT)

OCT is short for optical coherence tomography. It is a test that measures the thickness of the nerve in the eye. This works similarly to an ultrasound, but instead of measuring sound, it measures the reflection of infrared light. It takes about 15 to 30 minutes. This test is optional. You don't have to have to do this test to take part in this study.

Evoked Potentials

You may be asked to have evoked potential testing. Evoked potentials measure the how fast signals travel along pathways of sensation, hearing or vision. You will have a few electrodes placed on top of the skin your head and you will receive sensory stimulation, listen to clicks or look at pattern. No hair is removed for this testing. The electrodes will be removed after the study. Evoked potentials typically take 1 hour.

Electromyogram (EMG) and Nerve Conduction Study (NCS)

You may be asked to have an EMG and NCS done to study how the muscles and nerves in your arms or legs work. During the EMG a small needle will be inserted into the muscles or an arm and/or leg and the activity of the muscle will be measured. NCS is a test during which small electric shocks are applied to the nerves in your arms or legs and the ability of your nerves to conduct signals is measured. EMG and NCS take 30 minutes to 1 hour.

Neuropsychological Testing

Neuropsychological testing may include tests of your memory, attention, concentration, and thinking. This may include an interview, questionnaires, and a pen-and-paper or a computerized test. It takes 2-4 hours.

Electroencephalogram (EEG)

During an EEG, the electrical activity of your brain ("brain waves") will be recorded by placing small metal disc electrodes on your scalp with either glue, paste or an electrode cap. A conductive gel will be placed in the space between the electrodes and your scalp to make sure there is good contact between them. Your brain waves will be recorded while you are lying quietly, breathing deeply, watching bright flashes of light, or sleeping. The EEG usually takes 1 to 2 hours. The electrodes will be taken off once the EEG is completed.

Skin biopsy (adults only)

A small area of skin will be washed with iodine and alcohol. We will inject a local anesthetic to numb the area. Then we will remove a 1/4-inch piece of skin with a biopsy tool. After the biopsy, the site will be covered by a dressing. You will receive instructions on how to care for area.

Urine Collection

We will collect urine to look for viruses or other signs of infection. We will also do a urine

pregnancy test for women and girls who are able to get pregnant. If you are a minor and have a positive pregnancy test, we will inform both you and your parents. If you object to having this required pregnancy test, you should not participate in this study.

Saliva Collection

We would like to see if certain viruses are found in the saliva of people with inflammation in the brain and nervous system. You will need to chew on a piece of sterile cotton for one minute.

RISKS, INCONVENIENCES AND DISCOMFORTS OF MAIN STUDY PROCEDURES:

History and Physical Exam

There is minimal risk with doing history and physical exam; there could be minimal discomfort.

Blood Draw

You may have some discomfort and bruising at the site of needle entry. There is a very small risk of fainting. Infection in the area of the needle insertion is rare.

Genetic Testing

Genetic testing can provide information about how illness is passed on within a family. This knowledge may affect your emotional wellbeing. You might feel differently about your life if you learned that you or your children were at increased risk of a disease, especially if there were no treatment. Your children, brothers or sisters may find out that they are at risk for health problems because of your genetic information. This might affect your relationships. Other family members may also be affected by uncovering risks they did not want to know about. This information can cause stress, anxiety, or depression.

Some genetic testing shows if people are directly related. Some genetic tests can show that people were adopted or that their biological parent is someone other than their legal parent. If these facts were not known previously, they could be troubling. Genetic counseling is available at NIH to help you understand the implications of your genetic testing.

Because of the emotional risk, some people do not want to know the results of genetic testing. It is our policy to not disclose the results of research genetic testing unless it may have direct medical implications for you or your family.

Results of the research genetic testing in this study are often difficult to interpret because the testing is being done for research purposes only and the laboratories are not clinically certified. You may be referred to a CLIA certified laboratory, possibly outside of NIH, for additional testing or confirmation of the research results. NIH will not cover the cost of the additional testing. You or your insurer will be responsible for the cost.

Your genetic information will be kept confidential to the extent possible. The results of your genetic testing will be kept in a locked and secured manner at the NIH.

HIV Testing

If you test positive for HIV, this could be distressing news for you and your partner. We will tell

you what the results mean and how we report newly diagnosed HIV infection. We will also tell you how to find care. We will tell you how to avoid infecting others and the importance of informing your partners at possible risk because of your HIV infection.

Urine Collection

There are no risks associated with urine collection.

Saliva Collection

There are no medical risks and minimal discomfort with saliva testing.

MRI

People are at risk for injury from the MRI magnet if they have pacemakers or other implanted electrical devices, brain stimulators, some types of dental implants, aneurysm clips (metal clips on the wall of a large artery), metallic prostheses (including metal pins and rods, heart valves, and cochlear implants), permanent eyeliner, implanted delivery pump, or shrapnel fragments. Welders and metal workers are also at risk for injury because of possible small metal fragments in the eye of which they may be unaware. You will be screened for these conditions before having any scan, and if you have any, you will not receive an MRI scan. If you have a question about any metal objects being present in your body, you should inform the staff. In addition, all magnetic objects (for example, watches, coins, jewelry, and credit cards) must be removed before entering the MRI scan room.

It is not known if MRI is completely safe for a developing fetus. Therefore, all women of childbearing potential will have a pregnancy test performed no more than 24 hours before each MRI scan. The scan will not be done if the pregnancy test is positive.

People with fear of confined spaces may become anxious during an MRI. Those with back problems may have back pain or discomfort from lying in the scanner. The noise from the scanner

is loud enough to damage hearing, especially in people who already have hearing loss. Everyone having a research MRI scan will be fitted with hearing protection. If the hearing protection comes loose during the scan, you should let us know right away. Please notify the investigators if you have hearing or ear problems. You will be asked to complete an MRI screening form for each MRI scan you have. There are no known long-term risks of MRI scans.

The risks of an IV catheter include bleeding, infection, or inflammation of the skin and vein with pain and swelling.

Mild symptoms from gadolinium infusion occur in fewer than 1% of those who receive it and usually go away quickly. Mild symptoms may include coldness in the arm during the injection, a metallic taste, headache, and nausea. In an extremely small number, fewer than one in 300,000 people, more severe symptoms have been reported including shortness of breath, wheezing, hives, and lowering of blood pressure. You should not receive gadolinium if you previously had an allergic reaction to it. You will be asked about such allergic reactions before gadolinium is given.

People with kidney disease are at risk for a serious reaction to gadolinium contrast called "nephrogenic systemic fibrosis" which has resulted in a very small number of deaths. A blood test of your kidney function may be done within the month before an MRI scan with gadolinium contrast. You will not receive gadolinium for a research MRI scan if your kidney function is not normal or if you received gadolinium within the previous month.

Most of the gadolinium contrast leaves the body in the urine. However, the FDA recently issued a safety alert that indicates small amounts of gadolinium may remain in the body for months to years. The effects of the retained gadolinium are not clear. At this time, retained gadolinium has not been linked to health risks in people whose kidneys work well. Some types of gadolinium contrast drugs are less likely to remain than others. In this study, we will use the gadolinium contrast drugs that are less likely to remain, whenever possible.

Please tell your research team if you have had any MRI scans in the past 12 months. We will also give you additional information called a "Medication Guide." Upon request, we will give you individual information about retained gadolinium we see on your studies

Lumbar Puncture

You may feel a brief pain or tingling sensation in your legs during the LP if the needle brushes against a nerve. If this happens, please let the doctor or nurse practitioner know right away. They will adjust the needle. You may have a mild backache after the LP at the place the needle was inserted. About one- third of people have a headache for a few days after a lumbar puncture. Usually the headache is not severe and improves without treatment other than a mild pain reliever. Headaches that last longer than 7 days happen with one in 50 to 200 lumbar punctures. They usually improve gradually over 2 weeks. In rare cases headaches have lasted longer. Prolonged headaches may be due to continued leakage of CSF from the area of the LP. You and your clinician may decide to perform a "blood patch" if your headache is prolonged. A blood patch requires removing blood with a needle from a vein in your arm and then injecting it into the area of your back where the lumbar puncture was done to seal off the leak of CSF. If you have your LP with an x-ray, you will be exposed to a small amount of radiation.

Radiation Risk

This research study may involve exposure to radiation from up to 2 lumbar punctures under X-ray. This radiation exposure is not required for your medical care and is for research purposes only. The amount of radiation you will receive in this study is 0.026 rem which is below the guideline of 5 rem per year allowed for research subjects by the NIH Radiation Safety Committee. The average person in the United States receives a radiation exposure of 0.3 rem per year from natural sources, such as the sun, outer space, and the earth's air and soil. If you would like more information about radiation, please ask the investigator for a copy of the pamphlet, An Introduction to Radiation for NIH Research Subjects.

While there is no direct evidence that the amount of exposure received from participating in this study is harmful, there is indirect evidence it may not be completely safe. There may be a very slight increase in the risk of cancer.

Please tell your doctor if you have had any radiation exposure in the past year, either from other research studies or from medical tests or care, so we can make sure that you will not receive too much radiation. Radiation exposure includes x-rays taken in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine scans in which radioactive materials were injected into your body.

If you are pregnant or breast feeding, you may not undergo LP under X-ray. It is best to avoid radiation exposure to unborn or nursing infants since they are more sensitive to radiation than adults.

Banking and Sharing

We will remove any information that could identify you from data and samples that are sent to repositories or shared. Data and samples will be sent with a code. This linking code will be kept at NIH. However, there is a very small chance that the data or samples could be identified as yours.

Research using data or samples from this study may lead to new tests, drugs, or devices with commercial value. You will not receive any payment for any product developed from research using your data or samples.

RISKS, INCONVENIENCES AND DISCOMFORTS OF ADDITIONAL STUDY PROCEDURES:

OCT

There are no known risks of OCT.

Evoked Potentials

The skin needs to be lightly rubbed to place the electrodes, which may cause mild irritation. You may also have slight discomfort of pain from the shock stimulation. If it is too uncomfortable, let us know and we will try to turn down the stimulus intensity. You may stop the test at any time.

EMG and NCS

You may have pain when the needles are inserted. There is a very small risk of infection or bleeding. The nerve stimulation may cause discomfort or pain. If it is too uncomfortable, you can ask to have the test stopped.

Neuropsychological Testing

The neuropsychological tests are not harmful but may be frustrating or stressful. We only ask that you try your best. No one performs perfectly on these tasks. You may refuse to answer any question or to stop a test at any time and for any reason.

EEG

There is no risk associated with having an EEG. You may feel uncomfortable while the electrodes are attached to your scalp. The conductive gel sometimes causes some mild irritation You may not like the smell of the paste or the glue remover, but they are not harmful. If an electrode cap is used instead of the glue or paste, the cap may be uncomfortably tight and cause a headache.

Skin Biopsy

Pain at the biopsy site is usually minimal; bleeding and infection are rare. The biopsy site usually heals with a very small, nearly unnoticeable scar, but may leave a raised scar or visible lump.

INDUCED PLURIPOTENT STEM CELLS (IPS)

We may use your skin or blood cells to create adult stem cells, also called iPS (induced pluripotent stem) cells. Stem cells can be turned into different cell types. Studying different cell types from the iPS cells may help us better understand the conditions we are studying. The iPS cells will not be used for cloning. iPS cells cannot currently be used to grow artificial organs or organisms, but this may change in the future.

ADDITIONAL RISKS

Sedation

You may request medicine to help relax you during your MRI or lumbar puncture. This medicine may have side effects. These side effects include upset stomach, vomiting, headache, dizziness, and mild allergic reactions. Some people may stay sedated (groggy, disoriented) for a longer time than others. Some people may not feel relaxed even after taking the medicine. You may feel irritable or restless. More serious risks are rare. These rare risks include slowed breathing, drop in blood pressure, change in your heart rate or rhythm, or death. We will ask you questions about your medical history to try to pick the best medicine to give you if you request it for your MRI or LP. We will watch you closely during your test if you are given a sedating medicine.

ANTICIPATED BENEFITS

If you are an adult, all procedures will be done for research purposes and there are no expected direct benefits for you in this study.

If you are a child, some procedures will be done only if it will help to diagnose your condition. This information may help your doctor treat your illness better.

For both adults and children, this study will likely increase our general knowledge of how infections and immune conditions affect the brain, and will probably help us to diagnose brain infections and immune disorders earlier and manage patients better. The study results may help to develop new treatments in the future.

RIGHT OF WITHDRAWAL AND CONDITIONS FOR EARLY WITHDRAWAL

You may withdraw from the study at any time and for any reason without loss of benefits or privileges to which you are otherwise entitled. The investigator can remove you from the study at any time if she or he believes that continuation is not in your best medical interest or if you are unable to comply with the requirements of the study.

ALTERNATIVES TO PARTICIPATION OR TREATMENT

The alternative is not to participate.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will not receive compensation for participation in this study.

Will you receive reimbursement or direct payment by NIH as part of your participation?

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

Reimbursement of travel will be offered consistent with NIH guidelines.

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain

federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Avindra Nath, MD, b6 You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

REQUEST FOR MEDICAL INFORMATION FROM SOURCE OUTSIDE THE NATIONAL INSTITUTES OF HEALTH

INSTRUCTIONS: Complete this form in its entirety and forward directly to the requesting facility.

CC PATIENT IDENTIFICATION

(Patient Name) (Patient Number) (Date of Birth)

SOURCE OF INFORMATION REQUESTED

(Name of Health Care Organization or Physician) (Phone Number) (Fax Number)

(Street Address) (City) (State) (Zip Code)

INFORMATION REQUESTED

The purpose or need for disclosure: Review of clinical care and consideration for research study

NIH Requestor/Point of Contact: Amanda Wiebold b6

Identify the specific items and related dates pertaining to the information to be released.

1. Medical Reports:

   Laboratory results, clinic notes, and brain MRI or head CT reports from _____ date(s).

   Send to: National Institutes of Health Clinical Center
   National Institute of Neurological Disorders and Stroke
   Building 10, Room 7C103
   10 CENTER DRIVE MSC 1430
   BETHESDA, MD 20892-1430
   ATTENTION: Amanda Wiebold/ Dr. Bryan Smith

   OR
   Fax to: (301) 402-1137
   Attn: Amanda Wiebold or
   Dr. Bryan Smith

2. MRI scans on CD from _____ date(s).

   Send to: National Institutes of Health Clinical Center
   National Institute of Neurological Disorders and Stroke
   Building 10, Room 7C103
   10 CENTER DRIVE MSC 1430
   BETHESDA, MD 20892-1430
   ATTENTION: Amanda Wiebold/ Dr. Bryan Smith

3. Tissue/Pathology Slides from _____ date(s).

   Send to: National Institutes of Health Clinical Center
   Laboratory of Pathology
   Building 10, Room 2B50
   10 CENTER DRIVE MSC 1500 BETHESDA,
   MD 20892-1500

AUTHORIZATION

I hereby authorize the release of the above-requested medical information.

(Signature of Patient/Legal Guardian) (Printed Name of Patient) (Date Signed)

(Street Address) (City) (State) (Zip Code)

From: Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246-b6
Sent: 4/17/2021 4:09:34 PM
To: b6
Subject: Re: myself

Im sorry you need to speak with your internist.I am a neuroligist and practice medicine through emails does not make any sense.

Farinaz

From: b6
Sent: Saturday, April 17, 2021 12:09:01 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: myself

Farinaz, I just received b6 and my b6 I am very worried. Is there anyway we could speak briefly?

Sent from my iPhone

> On Apr 17, 2021, at 9:03 AM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:
>
> Even as a case series we need some objective findings.I am not talking about basic immunology work.When you try to publish a case series, people need evidence(at least clinical ones).I have a couple of people with b6
> b6 but 4 out of 40 is not enough in this kind of reports or for any reviewer.
>
> Additionally,case series do not give enough epidemioligical information.People can say 70 cases out of 210 million vaccinated individuals meaning 1 in 30 million.Is it really more than a baseline incidence of small fiber neuropathy?!!!!!!
>
> thats why we need to make a very strong case to show the importance if this findings.
>
> I understand your frustration but we need to be patient and scientifically follow the appropriate path to br able to push this work forward.
>
> You can give my email to her and we can discuss it with her if she is interested.
>
> Have a good weekend!
>
> Farinaz
>
> ---
>
> **From:** b6
> **Sent:** Saturday, April 17, 2021 11:50:41 AM
> **To:** Safavi, Farinaz (NIH/NINDS) [E] b6
> **Subject:** Re: myself

Thank you Farinaz. Why is there nothing been written about just the observation that so many people are having these reactions? Just that in itself will inform the medical community so they can try to help these people. Instead, they are being labeled with "anxiety" and functional disease. I understand your desire to work out the scientific basis of these reactions. This will take time. The medical community needs to know about this now! There are many many people who need help.
Can I give Dr Janet Woodcock your name? She is the acting commissioner of the fda. If she is so inclined, could she contact you?

Sent from my iPhone

On Apr 17, 2021, at 8:41 AM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

I am really glad that your visit went well with new neurologist.I completely agree with him and actually I find it very helpful since b6 show us sone footprint of disease we easily can discuss treatment plan.
You definietely can give my email to physicians contact you but I will be very selective to meet people for now because our protocol has approval for limited number of patients.
I am trying to put together the information but in order to convince medical community we really need objective information.I have confirmatory results in some patients but I need more to build a strong case.
I believe all of you and I really think there is a reaction causing neuropathic features post vaccine that usually slowly get better by its own or with apropriate treatment and trying my best to share this information in a proper scientific manner.
Let me know about the results of b6 since it might be very helpful.

Farinaz

From: b6
Sent: Saturday, April 17, 2021 11:14:05 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: myself

Hi Farinaz, I had a nice visit with b6 yesterday.
He is a very kind man who patiently listened to my story. He told me that he has one other female patient who had a similar reaction and is slowly improving after three months. I told him your impression of what is going on and he agreed it probably is a small fiber neuropathy. He said this is often related to underlying autoimmune disease such as rheumatoid arthritis and scleroderma. I explained to him that b6 b6 He really had no other ideas about my vaccine reaction. He did schedule me for b6 I need to have b6 b6 before I can do these tests in his office and was unable to get one late yesterday so it will have to be scheduled next week. He said I could receive b6 if I don't improve, as you recommended.

He recommended that I b6 I will try it again. He drew more labwork including b6 b6 I asked him if he would speak to you and he said he will copy you on his consult note. If you would like to contact him, I can forward you his phone number. Like everyone else, he is unaware of what is going on or what to do about it. I did not find the visit helpful, but at least I have some one who is willing to offer me medical care. With your help, hopefully I will get better. My symptoms fluctuate from day to day. My last bad day was 3 days ago. I am keeping my fingers crossed that my symptoms will subside.

In the meantime Farinaz, I am being contacted daily by people experiencing similar neurological reactions to the vaccines. b6

b6

Unfortunately, there is nothing else you can read on the Internet about these reactions as nothing has been published. I believe there are thousands of people who have had similar reactions to mine. I am even being contacted now by physicians in b6 who have heard about my reaction and are asking for advice for their patients as they can't find any information to read about. I spoke with two physicians yesterday. I believe you are the only resource In the country who has had any experience or has any theories about what is occurring. So many of the people that have joined my group (over 70 now) have seen doctors at excellent centers such as Stanford, UCSF, Harvard etc. and these doctors are uninformed. b6 is now a member of my group with a severe vaccine reaction. She can't get help! I'm sure she will be contacting you.

I wrote another letter to Drs. Peter Marks and Janet Woodcock at the FDA pleading for them to take these reactions seriously and stop ignoring them so the medical world will know about them and try to help all of these poor patients who are not getting help. Janet Woodcock responded quickly that she would like to help but then responded again saying:

"I am so very sorry for your ordeal. It seems what is missing is what they call a "research definition", in other words a syndromic framework to describe what is being experienced, since it may not fit into current diagnostic categories. Possibly one of the academic researchers you have consulted could work on that. I don't have insight into how this could be approached from a treatment standpoint". Janet Woodcock

In otherwords, they are not interested in hearing about these reactions. It is shocking to me that they completely blow off these reports of 100's and 1000's suffering with severe reactions. I would think they would want to know as much as possible about these reactions. Something is very wrong and these adverse reactions to the vaccines are being covered up. It is a great disservice to so many who are suffering like me.

I know you are getting close to publishing and I hope you are in touch with Peter Marks and Janet Woodcock. Hopefully they will pay attention to you. From the

large number of people contacting me, I can only imagine how many more people there are out there suffering. This is not a rare problem.

With great thanks,
b6

Sent from my iPhone

On Apr 17, 2021, at 5:39 AM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6
Please update me with your neuroligy visit.Would be happy to help.
Farinaz

Farinaz

From: b6
Sent: Monday, April 12, 2021 7:15:04 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re:

Thank you Farinaz. I assumed that would be your answer but I told her I would ask. She contacted me out of the blue today. Obviously there is a lot of resistance to publish anything that is negative about the vaccines. Our group is still having great difficulty getting medical care. I hope I can get treatment with this new neurologist, with your help. I really need help. My facial paresthesias are incapacitating and at times excruciating. They seem to be getting worse. I am not functioning. It is a very hard way to live. I wonder what I did to deserve this punishment. I will be seeing him on Friday. Thank you for all your help.
b6

Sent from my iPhone

On Apr 12, 2021, at 4:02 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

Thank you for your email. We prefer to complete our findings with scientific evidence first before getting to any press release.Please be patient,I am really working hard to prepare this information in

the organized fashion to inform medical community.

Farinaz

PS;please let me know when you see your neurologist and I would be hapoy to discuss with him about next steps.

From: b6
Sent: 4/19/2021 4:40:06 PM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
Subject: Re: Severe reaction to Pfizer Covid vaccine

Thank you Farinaz. I have been feeling much worse the last few days. It's been very difficult. I am b6 on Wednesday. b6 is not scheduled till the following Wednesday. I will try to get it done sooner by my dermatologist. I also have an appointment to see an allergist today and I'm trying to get in to see b6 at b6 who was referred by b6 I think she is a mast cell expert. Over the weekend, a friend allergist started me on b6 and told me to b6 I am very worried about b6 and believe there is a systemic process going on that is quite serious. I will be speaking with a hepatologist hopefully today. b6 b6 They are also helping me with b6 My internist recommended that I b6 I don't think that is great advice.
Thanks,
b6

Sent from my iPhone

On Apr 19, 2021, at 6:34 AM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6
I am sorry to hear about your symptoms and I believe you need to be seen by an internist regarding your b6 unfortunately as a neurologist I am not well qualified to comment on b6
Regarding neurological symptoms,I believe getting the work up b6 ASAP may help us to expedite proceed with potential treatments.
Best Regards,

Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD

From: b6
Sent: Sunday, April 18, 2021 2:31 PM
To: b6
Cc: Togias, Alkis (NIH/NIAID) [E]; Woodcock, Janet (FDA/OC); b6 Safavi, Farinaz (NIH/NINDS) [E]; b6
Subject: Re: Severe reaction to Pfizer Covid vaccine

I'm going to the ER now. I am so ill. My whole body is numb and vibrating.

Sent from my iPhone

> On Apr 18, 2021, at 11:27 AM, b6 wrote:
>
> HI

> I am so sorry to hear. I know that b6 at b6 is great and I hope you can get an appt to see her.
> I hope this helps and please let me know if I can help in any way.
> All the best
> b6
>
>
> -----Original Message-----
> From: b6
> Sent: Sunday, April 18, 2021 9:15 AM
> To: Togias, Alkis (NIH/NIAID) [E] b6 Janet Woodcock b6
> Cc: b6 b6 Farinaz Safavi b6
> Subject: Re: Severe reaction to Pfizer Covid vaccine
>
> Thank you. I have been seriously ill for b6 now. I am getting worse. I have seen many many doctors who do not know what is wrong with me. I have sought care in b6 where I live as well as b6 and NIH. I have spoken to many experts. My case was presented at CDC grand rounds. I have yet to hear of their recommendations. I have no diagnosis. My illness started 30 minutes after receiving the vaccine. I was fine prior to getting the vaccine.
>
> Yesterday I got b6 b6 I became dramatically worse through the day with burning, numbness, vibration, tremors and twitching throughout my body. I worried that I might die last night. I believe I must have mast cell activation syndrome. b6 b6 Now with b6 b6 I am very alarmed. I fear that I will not survive this.
> I need to find a mast cell expert in b6 I have tried to reach b6 for two weeks now with no luck. I was hoping she could go over the recent labs she ordered on me and give me direction re. my b6 and my unbearable symptoms. I would also like to know what the CDC's recommendations were.
> If anyone can help me I would me so grateful.
> Thank you,
> b6
>
>
> Sent from my iPhone
>
>> On Apr 18, 2021, at 6:22 AM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>>
>> Dear b6
>> I continue to be very sorry hearing that the symptoms you have experienced following your vaccination have not subsided and that none of the clinicians you have consulted has been able to offer a good explanation or a solution. As I have mentioned to you before, I have kept looking for any researcher(s) who may be investigating this matter and I have discussed it with b6 b6 Unfortunately, my searches have not produced anything helpful. I will continue keeping my eyes open.
>> Sincerely,
>> Alkis Togias
>>
>> On 4/15/21, 8:41 PM, b6 wrote:

>>
>> Hi Doctor Togias, Marks and Woodcock,
>> It is now b6 that I have been suffering from severe paresthesias in my face, tongue, scalp, chest wall and limbs as well as tremor, twitching, weakness, headache and imbalance since receiving the Pfizer Covid vaccine on b6 I was previously healthy and am now incapacitated. I have seen many prominent doctors in b6 as well as b6 at b6 at b6 and Dr. Nath's group at the NIH (Farinaz Safavi MD). I am seeing a 4th neurologist tomorrow in b6 and Dr. Safavi plans to help him treat me for b6 b6 She is the only person who acknowledges this reaction to the vaccine.
>>
>> My case has even been presented at the CDC grand rounds on March 23, 2021, but I am yet to get any of their recommendations other than to have b6 follow me. Ironically, she will no longer follow me because I am out of state!
>>
>> My ordeal has been agonizing, but what is even worse is that there are so many others with similar reactions to mine. They contact me from all over the world, finding me through comments I wrote about my reaction. I have a group of close to 100 people with similar reactions. There are thousands more. None of us have been able to get medical care or acknowledgement from the medical community, as they know nothing about this. Most of these poor people have been referred to psychiatrists. We have reported our reactions over and over to VAERS, the FDA, CDC, Pfizer, Astra Zeneca and Moderna with no response. I have been contacted by reporters who want to publish our story but face resistance to publishing anything negative about the vaccines.
>>
>> There are many people with severe neurological reactions to these vaccines. If I know of 100, I can only imagine how many 1000's there are. As my story has started spreading through b6 doctors are actually calling me to get information to help them treat their patients, as they know nothing and can find no information anywhere. Two doctors called me today.
>>
>> It took six blood clots to halt the J+J vaccine. I know there are many other vaccine complications and deaths numbering in the many 1000's.
>>
>> Why is this being kept a secret? When will the public be made aware so we can get treatment? Will we recover? You have no idea the pain and suffering that many people have been going through. I wish you could experience what we are experiencing to understand my pleas. It is very difficult to live this way. b6 It is so shocking to me that this suppression of information and the truth can occur in our country. As a b6 I never imagined this could occur here in the United States, with our great medical system and regulatory agencies.
>> Please bring these reactions public so medical care will be available to the many like me who are suffering agonizing symptoms resulting from these vaccines. Eventually, the truth will be told. We need help now.
>>
>> Sincerely,
>>
>> b6
>>
>>
>> Sent from my iPhone
>>
>>>> On Feb 11, 2021, at 4:48 AM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>>> Dear b6
>>> I am truly very sorry to hear that the problems you experienced after your COVID-19 vaccination have continued. As you must be aware, problems like yours have been reported by other people; so the various agencies and the companies know about them. On the other hand, I am not aware whether any

research is being conducted to understand their nature. I will continue checking with colleagues and if I hear something that could be helpful to you, I will let you know.
>>> With kind regards,
>>> Alkis Togias
>>> Alkis Togias, M.D.
>>> Branch Chief, Allergy, Asthma and Airway Biology DAIT/NIAID/NIH
>>> 5601 Fishers Lane, Room 6B40
>>> Bethesda, MD 20892-9827
>>> email: b6
>>> tel: b6
>>> For Courier Mail please use the following ZIP code: Rockville, MD
>>> 20852
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>>>> On 2/10/21, 3:08 PM, b6 wrote:
>>> Hi Dr. Togias,
>>> Sorry to bother you again. I am just feeling very desperate. I am still very ill with neurological symptoms b6 after receiving the Pfizer vaccine. I think I have told you about my reaction that occurred 30 minutes after receiving the vaccine in prior emails to you. Despite my reporting this to the FDA, CDC, VAER's and Pfizer multiple times, there is no response from any agency or any documentation of my adverse reaction. b6 at b6 has reached out to the NIH as has my neurologist, b6 at b6 in b6 No one seems to know anything about this or what to do for me. I have been completely incapacitated for b6 now with severe paresthesias in my face, tongue, chest wall, limbs as well as headache, dizziness and tremor.
>>> Do you know anyone in the country who is studying these neurological reactions and who might be able to help me in some way recover? I would very much like to return to my prior life which was active and healthy. I feel very despondent over my prognosis. This has been devastating for me.
>>> With great appreciation for any help you can give me, b6
>>>
>>> b6
>>> Sent from my iPhone
>>>>> On Jan 3, 2021, at 9:14 AM, b6 wrote:
>>>> Thank you. I am experiencing some type of immunological/neurological
>>>> reaction to the vaccine. The most prominent symptom is burning and numbness of my face and tongue. I have reached out to many people and no one can help me. b6 has given up on me and I don't feel these symptoms are allergic. b6 do not help. I have reported my symptoms to VAERS, v safe, Pfizer multiple times but have had no response from anyone. This has been a very difficult experience. I just pray that this resolves. I was previously healthy and am very uncomfortable now. I feel very helpless. If you know anyone that might be able to help me I would greatly appreciate it.
>>>> Thank you.
>>>> Sent from my iPhone
>>>>>> On Jan 3, 2021, at 8:56 AM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>>>>> Good morning b6
>>>>> I am so sorry to hear that the problems continue. I have not heard of such a situation but that does not mean anything because we do not get reports from patients at NIH, nor do we see patients. Have you reported this to the VAERS website? It is important that the CDC gets these reports.
>>>>> As I mentioned before, if I hear anything of relevance, I will let you and b6 know.
>>>>> Kind regards,

>>>>> Alkis Togias
>>>>>> On 1/2/21, 7:13 PM, b6 wrote:
>>>>> Hi Dr. Togias, I am so sorry to bother you but I am frightened and don't know what to do. I continue to be ill since I received the Pfizer Covid vaccine on b6 I was healthy prior to the vaccine. I have a remote history of b6 I was also on b6 I developed burning in my face 30 minutes after I received the vaccine and then had a pre-syncopal event with dizziness, tachycardia and chest tightness. I was basically in bed for the next six days with severe malaise, chest tightness, anorexia, burning of my face and tongue and occasional extremities. The malaise and chest tightness have resolved. Symptoms that I am left with are constant burning in my face and intermittent tingling and numbness of my face and tongue. I occasionally get burning in different areas of my arms and legs briefly. No muscle weakness. I have been on b6 b6 doesn't know what to do for me. He has spoken to b6 b6 I spoke with a rheumatologist and immunologist today and will b6 b6 They believe I am having some time of immunological/neurological reaction. Have you heard of this? Do you know of anyone who can help me?
>>>>> Today is b6 and I am feeling worse today.
>>>>> Thank you. I am trying to get help and no one knows what to do for me.
>>>>> Sincerely,
>>>>> b6
>>>>> Sent from my iPhone
>>>>>>> On Dec 29, 2020, at 5:39 PM, b6 wrote:
>>>>>> Thank you so much Dr. Togias. This has been very frightening for me. b6 seems to be easing the burning in my face. Please be in touch if you hear anything new.
>>>>>> Sincerely,
>>>>>> b6
>>>>>> Sent from my iPhone
>>>>>>>> On Dec 29, 2020, at 5:26 PM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>>>>>>> Hi b6
>>>>>>> I am very sorry to hear that things have gotten worse. I called b6 and I think he is doing the best he can for a situation that is very difficult to assess given its unusual nature and our lack of knowledge of a potential mechanism. I told b6 that I will let him know if we hear of more people having developed the type of reaction you had and how their physicians have approached it.
>>>>>>> I hope you feel better soon.
>>>>>>> Kind regards,
>>>>>>> Alkis Togias
>>>>>>>> On 12/29/20, 7:29 PM, b6 wrote:
>>>>>>> Dr Togias, I am so sick. I thought I was better yesterday. Felt fine yesterday evening. Today much worse. Face and legs burning. Face felt numb and swollen. Hard to get a deep breath but b6 b6 Symptoms come in waves. I am really afraid. Today is b6 since I received the Pfizer vaccine. This all started about 30 minutes after receiving it. I was fine prior. b6 b6 is helping me but I don't think anyone knows what to do. He has spoken to b6 I have left her 2 messages. I am on b6 I have been b6 b6 I have b6 No other meds. I have a remote history of b6 I have been b6 b6 I just started b6 If you have any other thoughts, please let me or b6 know. His number is b6 This has been very scary for me. I am fearful that something worse will happen to me and don't know how long this will last for. So sorry to bother you.
>>>>>>> Thank you,
>>>>>>> b6

>>>>>>> Sent from my iPhone
>>>>>>>> On Dec 28, 2020, at 4:48 AM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>>>>>>>> I am glad you are seeing b6 I know him well. He may be able to contact b6 as well.
>>>>>>>> I hope this goes away soon!
>>>>>>>> Alkis
>>>>>>>> On 12/27/20, 8:46 PM, b6 wrote:
>>>>>>>> Thank you for your kind response. I have been very ill today. An allergist, b6 has been helping me. I believe he knows you. I have had burning in my face and extremities, headache, chills, chest tightness, malaise. No fever or cough. b6 I have been taking b6 b6
>>>>>>>> I will contact b6 and get labs drawn tomorrow. I hope this reaction that I am having ends soon. I hope I survive it. It has been quite severe.
>>>>>>>> Sincerely,
>>>>>>>> b6
>>>>>>>> Sent from my iPhone
>>>>>>>>> On Dec 27, 2020, at 5:04 PM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>>>>>>>> Dear b6
>>>>>>>> Thank you very much for your note. I am sorry to hear you experienced such a reaction with the Pfizer vaccine and I can understand your hesitancy for receiving the second dose. Not being able to assess your situation in more detail, I do not want to risk an interpretation or a recommendation. Your reaction does not sound as typical anaphylaxis although hypertensive systemic allergic reations have been described. As you have heard, we have not identified a mechanism behind reactions to the Pfizer vaccine (there has also been at least one case with the Moderna) and we hope that, if various logistical issues are addressed, we will be able to conduct the study you have probably heard about to help get more insights. Due to your reaction you would probably not qualify for that study, but I suggest you contact a specialist who may be able to do some testing that may help assess some hypotheses. The person that I know in b6 who has been actively working in this field, is b6 at b6 It may be worth contacting her.
>>>>>>>> With kind regards,
>>>>>>>> Alkis Togias, M.D.
>>>>>>>> Branch Chief, Allergy, Asthma and Airway Biology DAIT/NIAID/NIH
>>>>>>>> 5601 Fishers Lane, Room 6B40
>>>>>>>> Bethesda, MD 20892-9827
>>>>>>>> email: b6
>>>>>>>> tel: b6
>>>>>>>> For Courier Mail please use the following ZIP code: Rockville,
>>>>>>>> MD 20852
>>>>>>>> Disclaimer: The information in this e-mail and any of its attachments is confidential and may be sensitive. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error, please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases shall not accept liability for any statements made that are sender's own and not expressly made on behalf of the NIAID by one of its representatives.
>>>>>>>>> On 12/25/20, 2:11 PM, b6 wrote:
>>>>>>>> Hi Dr. Togias,
>>>>>>>> My name is b6 I am a b6 in b6 I received the Pfizer BioNTech Covid vaccine the morning of b6 I left the hospital after 15 minutes feeling fine but 30 minutes after receiving the vaccine, I developed burning and tingling of my face, tightness at the base of my tongue, shortness of breath, heart racing, chest tightness and had a near syncopal event. I immediately took b6 and called 911. By the time the paramedics arrived, I felt alittle better but my BP was b6 My face continued to burn as did my arms and I felt mild chest tightness for 12 hours and stayed on b6 By 10 pm, the symptoms

completely resolved. I felt perfectly fine the next day until 10 pm when all the symptoms recurred as well as swelling and hives on my face. I have continued b6 and continue with tingling of my face and slight chest tightness. I believe I am having a significant allergic reaction to the vaccine. I did notify all the online sites including VAERS, Pfizer. I wonder if I have b6 b6 If you are interested in my case, I am happy to help. I am also very nervous about receiving the second dose of the vaccine. If you are not the appropriate person to receive this info, would you direct me to who would be interested in this info?

>>>>>>>>> Thanks so much,

>>>>>>>>> b6

>>>>>>>>>

>>>>>>>>> Sent from my iPhone

From: b6
Sent: 4/17/2021 4:28:31 PM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
Subject: Re: myself

I don't know what to do or who can help me. I am very very worried .

b6

Sent from my iPhone

On Apr 17, 2021, at 9:09 AM, b6 wrote:

Farinaz, I just received my b6 and my b6 b6 I am very worried. Is there anyway we could speak briefly?

Sent from my iPhone

On Apr 17, 2021, at 9:03 AM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Even as a case series we need some objective findings.I am not talking about basic immunology work.When you try to publish a case series, people need evidence(at least clinical ones).I have a couple of people with b6 b6 but 4 out of 40 is not enough in this kind of reports or for any reviewer.

Additionally,case series do not give enough epidemioligical information.People can say 70 cases out of 210 million vaccinated individuals meaning 1 in 30 million.Is it really more than a baseline incidence of small fiber neuropathy?!!!!!!

thats why we need to make a very strong case to show the importance if this findings.

I understand your frustration but we need to be patient and scientifically follow the appropriate path to br able to push this work forward.

You can give my email to her and we can discuss it with her if she is interested.

Have a good weekend!

Farinaz

From: b6
Sent: Saturday, April 17, 2021 11:50:41 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: myself

Thank you Farinaz. Why is there nothing been written about just the observation that so many people are having these reactions? Just that in itself will inform the medical community so they can try to help these people. Instead, they are being labeled with "anxiety" and functional disease. I understand your desire to work out the scientific basis of these reactions. This will take time. The medical community needs to know about this now! There are many many people who need help.

Can I give Dr Janet Woodcock your name? She is the acting commissioner of the fda. If she is so inclined, could she contact you?

Sent from my iPhone

On Apr 17, 2021, at 8:41 AM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

I am really glad that your visit went well with new neurologist.I completely agree with him and actually I find it very helpful since if b6 show us sone footprint of disease we easily can discuss treatment plan.
You definietely can give my email to physicians contact you but I will be very selective to meet people for now because our protocol has approval for limited number of patients.
I am trying to put together the information but in order to convince medical community we really need objective information.I have confirmatory results in some patients but I need more to build a strong case.
I believe all of you and I really think there is a reaction causing neuropathic features post vaccine that usually slowly get better by its own or with apropriate treatment and trying my best to share this information in a proper scientific manner.
Let me know about the results of b6 since it might be very helpful.

Farinaz

From: b6
Sent: Saturday, April 17, 2021 11:14:05 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: myself

Hi Farinaz, I had a nice visit with b6 yesterday. He is a very kind man who patiently listened to my story. He told me that he has one other female patient who had a similar reaction and is slowly improving after three months. I told him your impression of what is going on and he agreed it probably is a small fiber neuropathy. He said this is often related to underlying autoimmune disease such as rheumatoid arthritis and scleroderma. I explained to him that b6 b6 He really had no other ideas about my vaccine reaction. He did schedule me for b6 I need to have b6 b6 before I can do these tests in his office and was unable to get one late yesterday so it will have to be scheduled next week. He said I could receive b6 if I don't improve, as you recommended.

He recommended that I b6 b6 I will try it again. He drew more labwork including b6 b6 b6 I asked him if he would speak to you and he said he will copy you on his consult note. If you would like to contact him, I can forward you his phone number. Like everyone else, he is unaware of what is going on or what to do about it. I did not find the visit helpful, but at least I have some one who is willing to offer me medical care. With your help, hopefully I will get better. My symptoms fluctuate from day to day. My last bad day was 3 days ago. I am keeping my fingers crossed that my symptoms will subside.

In the meantime Farinaz, I am being contacted daily by people experiencing similar neurological reactions to the vaccines. b6

b6

b6 Unfortunately, there is nothing else you can read on the Internet about these reactions as nothing has been published. I believe there are thousands of people who have had similar reactions to mine. I am even being contacted now by physicians in b6 who have heard about my reaction and are asking for advice for their patients as they can't find any information to read about. I spoke with two physicians yesterday. I believe you are the only resource In the country who has had any experience or has any theories about what is occurring. So many of the people that have joined my group (over 70 now) have seen doctors at excellent centers such as Stanford, UCSF, Harvard etc. and these doctors are uninformed. b6 b6 is now a member of my group with a severe vaccine reaction. She can't get help! I'm sure she will be contacting you.

I wrote another letter to Drs. Peter Marks and Janet Woodcock at the FDA pleading for them to take these reactions seriously and stop ignoring them so the medical world will know about them and try to help all of these poor patients who are not getting help. Janet Woodcock responded quickly that she would like to help but then responded again saying:

"I am so very sorry for your ordeal. It seems what is missing is what they call a "research definition", in other words a syndromic framework to describe what is being experienced, since it may not fit into current diagnostic categories. Possibly one of the academic researchers you have consulted could work on that. I don't have insight into how this could be approached from a treatment standpoint". Janet Woodcock

In otherwords, they are not interested in hearing about these reactions. It is shocking to me that they completely blow off these reports of 100's and 1000's suffering with severe reactions. I

would think they would want to know as much as possible about these reactions. Something is very wrong and these adverse reactions to the vaccines are being covered up. It is a great disservice to so many who are suffering like me.

I know you are getting close to publishing and I hope you are in touch with Peter Marks and Janet Woodcock. Hopefully they will pay attention to you. From the large number of people contacting me, I can only imagine how many more people there are out there suffering. This is not a rare problem.

With great thanks,
b6

Sent from my iPhone

On Apr 17, 2021, at 5:39 AM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6
Please update me with your neuroligy visit.Would be happy to help.
Farinaz

Farinaz

From: b6
Sent: Monday, April 12, 2021 7:15:04 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
b6
Subject: Re:

Thank you Farinaz. I assumed that would be your answer but I told her I would ask. She contacted me out of the blue today. Obviously there is a lot of resistance to publish anything that is negative about the vaccines. Our group is still having great difficulty getting medical care. I hope I can get treatment with this new neurologist, with your help. I really need help. My facial paresthesias are incapacitating and at times excruciating. They seem to be getting worse. I am not functioning. It is a very hard way to live. I wonder what I did to deserve this punishment. I will be seeing him on Friday. Thank you for all your help.
b6

Sent from my iPhone

On Apr 12, 2021, at 4:02 PM,
Safavi, Farinaz (NIH/NINDS) [E]
b6 wrote:

Hi b6

Thank you for your email. We prefer to complete our findings with scientific evidence first before getting to any press release.Please be patient,I am really working hard to prepare this information in the organized fashion to inform medical community.

Farinaz

PS;please let me know when you see your neurologist and I would be hapoy to discuss with him about next steps.

From: b6
Sent: 3/31/2021 5:51:35 AM
To: b6 Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246-b6
b6
b6
Subject: RE: Myself

HI
Thanks and let's see what your doctors say and I am happy to weigh in through a research capacity.
All the best and hope you are feeling better,
b6

From: b6
Sent: Tuesday, March 30, 2021 1:11 PM
To: b6 Farinaz Safavi b6
b6
b6
Subject: Myself

Here are my recent lab results. b6
b6

I am overall better with occasional flareups. I do have constant milder paresthesias in my face, scalp, tongue and chest wall which are not as severe as they were previously.

My case was supposed to have been presented to CDC grand rounds last week and I am waiting to hear the outcome of this.

I am concerned that b6 I will await b6 input on this.

I am also concerned that b6
b6
b6 Could this be related to my vaccine reaction or b6

Thank you for all of your help.

Sincerely,

b6

Sent from my iPhone

From: b6
Sent: 3/30/2021 8:11:04 PM
To: b6 Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
b6
b6
Subject: Myself
Attachments: Business Card Mar 30, 2021.pdf

Here are my recent lab results. b6
b6

I am overall better with occasional flareups. I do have constant milder paresthesias in my face, scalp, tongue and chest wall which are not as severe as they were previously.

My case was supposed to have been presented to CDC grand rounds last week and I am waiting to hear the outcome of this.

I am concerned that b6 I will await b6 input on this.

I am also concerned that b6
b6
b6 Could this be related to my vaccine reaction or b6

Thank you for all of your help.

Sincerely,

b6

Sent from my iPhone

b6

b6

b6

b6

b6

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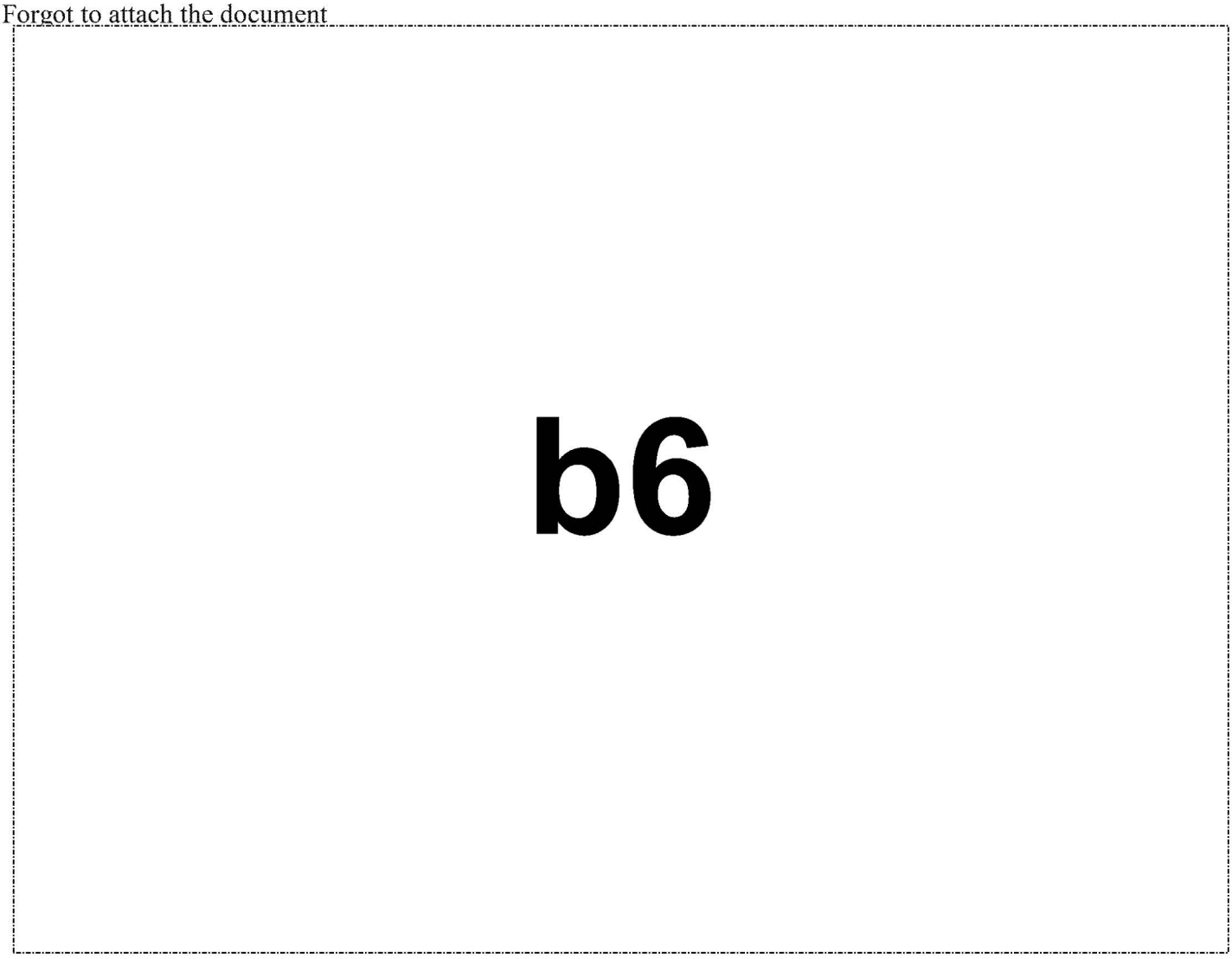
b6

b6

b6

From: b6
Sent: 9/23/2021 12:15:15 AM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
Subject: Re: Moderna Adverse Reaction

Forgot to attach the document



On Wed, Sep 22, 2021 at 5:01 PM b6 wrote:

Hi Dr. Farinaz,

I reached out earlier this year about my internal vibration and other side effects from the Moderna vaccine. I asked two different neurologist and one allergist to reach out to you but I don't believe they have. I have my VAERS ID# b6 which now says serious and permanent disability. Unfortunately my doctors are still treating me like I have a psychological issue. Do you know any resources I can reach out too? I'm going on b6 b6 like this and still have symptoms. Any information would be appreciated. I also attached my 14 panel

blood cytokine test that's shows b6 Just thought I share just in case you might have some insights.

Thank you for your time, b6

On Tue, May 11, 2021 at 2:28 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Ho b6
I am so glad your symptoms have been improving.I will be happy to speak with your neuroligist when you see her/him and share our understanding about these adverse events.
Hope it helps

Farinaz

From: b6
Sent: Tuesday, May 11, 2021 2:48:00 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: Moderna Adverse Reaction

Hello Dr. Farinaz,

We haven't had the opportunity to touch base yet but I was wondering if you had any information on what test to have done for these issues. I'm on b6 and luckily my internal tremor isn't as intense anymore. I see a neurologist on the 17th. Any tips or info would be appreciated.

Thank you, b6

On Sat, Apr 3, 2021 at 1:43 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Dear b6
Sorry to hear about your illness.
We are in the process of some change and improvement in our workforce.I will get back to you in a week to coordinate a televisit with you.
Best

Farinaz

From: b6
Sent: Tuesday, March 30, 2021 5:21:21 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Moderna Adverse Reaction

My name is b6 and I am writing to you in regards my Moderna adverse reaction. I got your information from a small Facebook group that's going through the same issues as me. On b6 I received my first shot of Moderna. I was told to stay 30min because b6 I also received a flu shot 3 weeks prior. After 15 min I started to feel tingling in my face and throat tightness. As time passed, I started to feel like I couldn't breathe at one point. As I continued to have issues breathing and started getting nauseous and lightheaded, they informed a nurse to look over me. The nurse had a student nurse do my vitals manually. She gives out b6 heart rate and b6 blood pressure. My normal blood pressure is b6 I had to be picked up due to feeling unwell. I went home took Tylenol and slept.

The next few weeks I kept feeling zaps of sharp pain in my chest area. On the 12th day after the vaccine, I had a panic attack. The panic attack started with a sharp pain in my neck and when I inhaled it hurt. I got heart palpitations and again felt like I couldn't breathe. I never suffered from a panic attack, so we called 911. The EMTs came my blood pressure was b6 b6 It was suggested I go to the ER since b6 In the ER I told the doctor about my vaccine incident. They b6 b6 My b6 b6 I was then diagnosed with b6 I was sent home and after a few hours I started to feel an internal tremor.

I describe the tremor as having a cell phone on vibrate its usually is in my lower abdomen to pelvic area. My blood pressure b6 I kept reaching out for help by going to ER once more, 3 urgent care visits and my primary. No one could help me, and I kept getting labeled as b6 b6 My primary doctor said I could be having adverse reaction to the vaccine, but I just have to wait it out. The internal tremor I feel constantly and sometimes it's in my chest. I have muscle twitching, tingling in my lower limbs, muscle pain, and b6 I do feel like my symptoms cause anxiety because ill have these spells where I feel adrenaline running through me which will cause anxiousness. b6 is getting better, but I still b6 and have had another panic attack.

I have been on b6 During that time, my symptoms have not improved. b6 I never had any of these issues prior. I don't drink, smoke or do any drugs besides the medication prescribed.

On 3/30/21, I reached out to my psychiatrist again and went into more detail about everything and she said she believes me about the vaccine side effects. She recommended I go back to my primary care doctor and ask to be referred to UCSD covid long haulers study to see if they can help me.
I wanted to share my information to see if it might be help to your research.

Thank you for your time, b6 Here is my phone number if you need anymore information b6 b6

From: b6
Sent: 10/1/2021 7:03:10 AM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
Subject: Re: Quick question
Attachments: WHO scale post-COVID september.docx

Hi Dr.Safavi,

Attached is the WHO scale with my updated scores. For an update of my symptoms: the paresthesias in my face has really progressed as compared to when it first started in terms of intensity. It feels like someone is pouring acid onto my face and yesterday it spread into my ears and scalp too. It's incredibly uncomfortable; hopefully I can get b6 relatively quickly to take the edge off soon. I had initially planned to only take it at night to start but took it TID today to try and help with the pain in my face. I feel like some of my autonomic symptoms are worsening. Since Saturday I feel like my temperature regulation is off, or at least my perception of temperature. What I mean here are things like wearing winter clothes in the house for 4 days and then yesterday evening/today switching to being hot. I've been having night sweats as well. My b6 issues which I hadn't had in a month or so has come back this week, last night I couldn't sleep and early in the morning I noticed my HR was in the b6 for hours for no good reason. I've also noticed my HR jumping up with standing/walking today intermittently and a couple other times earlier this week too. I've been having some GI issues this week which are unusual for me.

Today I b6 I really hope to see an improvement soon. It's surprising, frustrating, and if I'm being honest a bit scary too, to have my symptoms continue to progress with time.

Best Regards,
b6

On Wed, Sep 29, 2021 at 5:49 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Dear b6
Thank you very much for update.I am very glad that your headaches have improved significantly.
Please let me know if I can be any help.
Best

Farinaz

From: b6
Sent: Wednesday, September 29, 2021 5:46:27 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: Quick question

Hi Dr.Safavi,

Good news about my headache; it was mild yesterday and thus far today I haven't had it at all. Today has been wonderful, I'm really happy to be back at my level of functioning b6 I did talk about it with my local neurologist today in the event that the headache were to come back this evening for example and he recommended continued conservative management, things are clearly healing and there's no reason for it not to continue.

I had a good appointment with my neurologist overall and it's in large part due to having the documentation and diagnostic testing from you and your team. The b6 in particular helped open doors for conversation. I have now been prescribed b6 and we are also going to try b6 to see if it helps with the brain fog. It's been a long b6 I'm really thankful to try different things to help me get my life back.

Best Regards,
b6

PS-tomorrow I will send you the updated WHO post-COVID scale scores

On Wed, Sep 29, 2021 at 12:45 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

Hope all is well.Can you update me with status of your low pressure headache and your discussion with your health care provider?

Thank you

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Monday, September 27, 2021 5:52 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Quick question

All sounds good to me, my next local appt is this Wednesday, I will keep you posted.

Thanks!

b6

On Mon, Sep 27, 2021 at 5:00 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Nothing to be worried b6

The reason I said you may speak with your local physicians was that you might be able to get it much faster than us coordinating it. Otherwise I can discuss with the team and see how we can proceed with it here. However your headaches are not that severe and might go away soon but still I will speak with Dr.Nath and the team to see what their thoughts are.Please you also inform me when you discuss it with your physicians and we can find the best way.

From: b6
Sent: Monday, September 27, 2021 4:46 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Quick question

Hi Dr.Safavi,

I usually lay down once the headache's get to a 5 and then they improve quickly. I will try and push through them more today and tomorrow than what I did this weekend and see how it goes. I do worry about whether I need b6 or not, I've been conflicted about it, it's always hard to have clarity when the health issues are your own. It sounds like you recommend that I should talk about it more with my local physicians. It's disheartening to hear that because I remember during the research consent process that you told me if I needed b6 that the NIH would do that for me. I hope it wasn't anything that I did on my end that has made things different; if I did anything that upset you or the team, please accept my apologies for that. I am incredibly grateful for what you and everyone else has done to find diagnostic answers as well as treatment solutions to help me get my life back.

b6

On Mon, Sep 27, 2021 at 4:22 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

> Hi,
>
> How bad are your headaches from 1-10?
>
> I discussed it with the team and they said if it is very severe you may go to ED to get b6 If not that severe, then it will go away with hydration and rest eventually.
>
> Farinaz

From: b6
Sent: Monday, September 27, 2021 4:18 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Quick question

Hi Dr.Safavi,

Thank you for answering my questions, all makes sense to me. I'm still having issues with positional headaches unfortunately. I'm still spending a ton of time on the couch due to them.

b6

On Mon, Sep 27, 2021 at 3:06 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi,

b6 does not show any findings consistent with b6 b6 so that we b6 Additionally Anti TS-HDS Ab is kind of new Ab was found to be associated with small fiber neuropathy.We b6 b6 since as long as I know it has not become commercialized in reliable labs yet(i checked afew weeks ago though).We did a very extensive research lab measuring for every single antigen in the body from a pooled sera of post vaccine patients and no Ab was detected so that we incline to say the process is less likely Ab mediated however we are working on many more methods to confirm this findings.

BTW,How is your headache?feeling better?

Farinaz

From: b6
Sent: Monday, September 27, 2021 2:52:11 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Quick question

Hi,

I have a quick question for you. I was wondering if b6 b6 I've connected with many others with similar health issues to mine- There is a b6 that reported that she tested positive for b6 and a second person reported that she tested positive for b6 With their health stories being extremely similar to mine, it made me wonder if it was something that I had already been tested for.

Thanks!

b6

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b6

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b6

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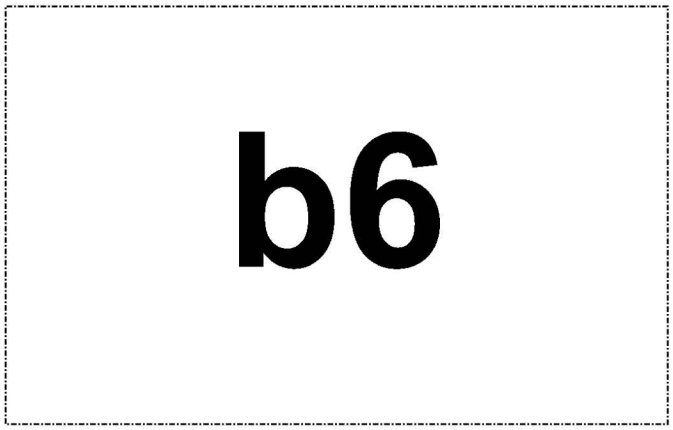
b6

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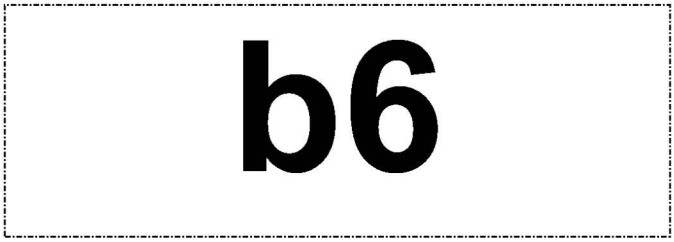
b6

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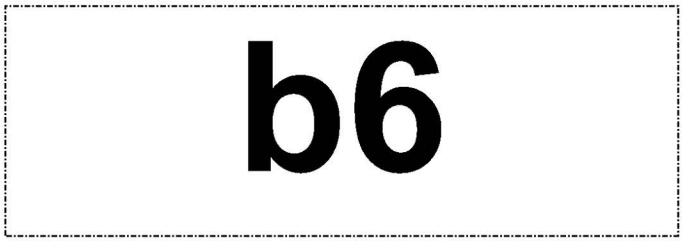
b6

b6

From: Fouanta, Ladifatou (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A5EBAA8D0DA84114AB631D6A3B913706-b6
Sent: 12/27/2021 6:27:49 PM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246-b6
b6
Subject:
Attachments: b6

Hi Dr Safavi and b6
I have attached some info about b6
Thanks,

Ladifatou (Ladi) Fouanta, BSN, RN, CNRN
Research Nurse Specialist
NINDS Section of Infections of the Nervous System
10 Center Drive, Building 10/7C103, MSC 1430
Bethesda, Maryland 20892
Office: b6
Fax: 301-480-5594
Email: b6

From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Monday, December 27, 2021 12:57 PM
To: Fouanta, Ladifatou (NIH/NINDS) [E] b6
b6
Subject: b6

Hi Ladi,
I had a televisit with b6 g.I am wondering whether we have any information pamphlet that can be sent to her for her own information.
Thank you

Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD

b6

b6

b6

From: b6
Sent: 1/24/2022 8:05:47 PM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
CC: b6
Subject: [EXTERNAL] Pfizer Vaccine Death Confirmed Via Autopsy Report
Attachments: b6

Dear Dr. Farinaz Safavi,

Greetings. My name is b6 along with my parents b6 We are emailing to discuss my b6 who passed away on b6 We have received an extensive autopsy report and the findings concurred that his death was caused directly due to the Pfizer booster vaccine that he had received on b6 The pathologist performed scans of his heart and gathered 22 slides which confirmed that b6 had severe myocarditis from the Pfizer booster vaccine that led to his death.

Please give us answers and follow up to why this occurred. We are devastated.

Lot #'s
Pfizer 1st dose - b6
Pfizer 2nd dose
Pfizer booster -

Autopsy, death certificate, vaccine cards, and apple watch heart rate data are attached

Thank you,

b6
b6

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b6

From: Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246-b6
Sent: 6/13/2021 1:32:12 AM
To: b6
Subject: Re: a couple of questions

Hi b6
Thanks for the update. Have you discussed your new symptoms with your physicians?I believe the best course of action is speaking with your physicians and discuss your new symptoms plus asking for further evaluation if there is a concern about dysautonomia.
I would be more than happy to speak with any of your physicians as needed.
Best

Farinaz

From: b6
Sent: Sunday, May 30, 2021 7:48:09 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: a couple of questions

I apologize it was b6

On Sun, May 30, 2021 at 11:13 AM b6 wrote:

Hi Dr. Safavi,

I wanted to update my review of symptoms since I last saw you as things have changed.

CV: b6 (my HR is fluctuating and b6 , i cannot seem to control it, it changes from rest, to standing to moving. When my HR reaches b6 But for the most part- my HR is b6 R hand and R foot is still swollen- but it has gone down since when I got the vaccine. When I was at the weakest I have ever been I was having shortness of breath after every activity. Yesterday, I had to go to advanced urgent care due to chest pain and exhaustion, I barely did anything all day but I think walking to the mailbox may have triggered the chest pain. He checked b6 b6 b6 I am getting really tired after every activity, I have to take a break and rest. I'm not sure what is going on with b6 b6

GI: b6 b6

Neuro: generalized muscular weakness/muscular fatigue/tightness and the symptoms I had with it are b6 I have noticed the difference it makes when off of it twice and restarting on b6 I feel like my muscular weakness b6
Still have:+tremors +paraesthesias- burning, tingling

Symptoms in general get worse with exercise/activity. Each time that I became more mobile with b6 is when I started experiencing the other symptoms more which explains why in the beginning it was just in the background.

I am suspecting this might be partly due to autonomic dysfunction, I also watched a youtube video that also explained autonomic dysfunction in long haulers (except I think mine was caused by vaccine). This doctor explains things very well even for a provider!
https://www.youtube.com/watch?v=DgJKAgxpF4k

I'm not sure if the chest pain I am having is related to b6 Many people are getting b6 checked and I was wondering if this can be checked for me now that my symptoms have changed, I know you b6 b6 I am speaking with a father whose young son was in the ICU for weeks after pfizer vaccine and on him they b6 b6

Thanks!

b6

On Wed, Apr 14, 2021 at 10:47 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Dear b6

Thank you for your email. Of course,I already forwarde your email to b6 team in order to schedule you.They will reach out for next step.

Regarding b6 you definietely can think about it and let me know.

Best

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Tuesday, April 13, 2021 7:50 PM

To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: a couple of questions

Dear Dr. Safavi,

Apologies for not getting back sooner, I had been thinking about the best course of action and I for now will start with b6 team for work-up with b6 do you know what kind of testing is done or what he is evaluating for? However, I would like a chaperone on that visit. I started a treatment plan a medical friend helped me with and my weakness has been getting a lot better but is still there. I have new neurological symptoms developing like tingling in my legs that are recurring more and burning sensations the more normal I try to be. I would like to talk to my doctor about whether b6 would be necessary and take into consideration both of your opinions.

I will look out for the email to schedule the appointment.

Thank you for your time and all that you are doing!

b6

On Wed, Mar 31, 2021 at 9:21 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

> Unfortunately tomorrow is a very busy day for me.
>
> here is the outline of our discussion
>
> We believe you have developed some symptoms post vaccine and we would be happy to try our best to help you.
>
> We all agreed that the cause of your weakness is less likely due to immune mediated process.In order to test and make sure this is correct,there are a couple of tests available that can be done in b6 lab.You can get both tests to evaluate b6 with him in one visit.
>
> It was another discussion about your fatiguibility and exercise intolerance that might be due to some immune mediated process.For that we can bring you back and b6
> b6
> b6
>
> everyone agreed that physical therapy would help you to return to your normal function and enourage you to continue.
>
> Please kindly think through our suggestions and let me know how you like to proceed and we can coordinate accordingly.
>
> Best Regards,
>
> Farinaz

From: b6
Sent: Wednesday, March 31, 2021 4:57:55 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: a couple of questions

Good afternoon,

I am not available on Friday. Just tomorrow afternoon (04/01) or next week.

Some updates/clarification:

1. I had my grip strength measured with the device Physical Therapist has- b6 b6

2. When I mean I have to rest after activity, it means discontinue use of muscle. I do not go to sleep or nap.

3. I tried b6 for two days. Day 1- before bedtime the front of my thighs started burning. I fell asleep and woke up with the back of my neck burning. As I was doing my at home exercises, more muscles started to burn. Day 2: same exact thing happened again along with some impairment of coordination. Upon discussion with my Doctor we discontinued use. He also did not know why my muscles would burn when taking that.

Thanks Dr. Safavi!

b6

On Tue, Mar 30, 2021, 9:27 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

> Dear b6
>
> We discussed our case in our group.There are afew things that I would like to communicate with you.
>
> We can do a short televisit on Friday at 9am ET.

Please let me know if this time works for you.

Best

Farinaz

From: b6
Sent: Monday, March 22, 2021 1:28:04 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: a couple of questions

Dear Dr. Safavi,

Here are some of the symptoms I have:

Daily Baseline weakness (even with rest) post-vaccine:
UE
- objects feeling heavier than normal which this morning I stumbled on "if you can't hold onto something, you can't lift it" which now makes sense, goes back to when I initially complained of having to squeeze hard in order to lift gatorade and spoon and why I have difficulty lifting a mug off the table when it's full of milk, and it is true, I experimented today- if I squeeze really hard it's easier to lift, but still feels very heavy. I cannot go about lifting like a normal person would on everyday objects.had a couple of episodes of clumsiness, +poor grip strength
- difficulty with fine motor movements- clipping nails, the smaller the object is the harder it is to pick up, opening up ziploc bags, etc
-doing activities over shoulder activities is difficult (no issues with range of motion)

LE
-limping (which b6 but when left weakness started was limping again)
-doing leg movements standing up are difficult
-delay in initiating muscles to move on command when sitting down or laying down, once gets past that with assistance the rest of the motion is easier.

Head
- no mental fatigue
-no vision changes
-no headache
-wakes up fully rested every morning

With activity (pain usually comes last as a symptom-when I've done too much, weakness usually stops me before I get there):
UE
- flexion of right arm with continuous repetition and/or sustained flexion causes burning at deltoid which gets worse with continuous activity
-sustained use of grip causes inability of hand to close all the way and pain

-ROM activities/exercises with repetition causes popping/clicking of joints, pain, heaviness, tightness, and may lead to decreased ROM and having shoulder lower than normal (have to hold arm upwards as if getting it back into place)

LE
-walking for long periods of time causes further limping, slowing down of pace, leg does not want to physically move, difficulty standing for long, foot pain, foot swelling
-ROM activities/exercises with repetition causes popping/clicking, slowing down of pace, pain
-muscles become tight when lifting leg from laying down position

Neck/upper back/chest- repetitive ROM and sustained use causes tightness to the point that the muscles cannot support the weight of head, affects throat, (thinking from the pressure of the tight muscles), once felt a burning sensation at back of neck when it was really really tight

Symptoms that arise due to activity, feel better after rest. Baseline weakness remains. Stopping ROM exercises and starting Isometric exercises is helping to still be functional with baseline weakness without the other symptoms that come along with activity. My muscles fatigue quickly, the stiffness comes after prolonged sustained use. I think I have difficulty with both, initiating mostly in the legs and sustaining with all muscles.

I hope that helps- I was reading about multifocal motor neuropathy, I'm not sure if this is something similar.

b6

On Sun, Mar 21, 2021 at 9:36 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

I have a couple of questions for you.

Do you feel any stiffness in your extremities leading you weakness feeling?

Does activity aggravate your symptoms?if so do you have any achiness with symptoms?

Do you feel your issue is to initiate or sustaining use of muscle?

Please let me know

Thanks

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246 b6
Sent: 4/12/2021 12:16:43 PM
To: b6
Subject: RE: Pfizer reaction follow up - b6

b6
We all have been learning about the process.If the symptoms now last for more than a month,I think it would be reasonable to b6
Where are you located?

Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD

From: b6
Sent: Monday, April 12, 2021 8:13 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Pfizer reaction follow up - b6

Dear Dr. Safavi,

No, I have not b6 I was under the assumption that you thought these reactions were going to disappear with time- so I wanted to hold off on b6 if I didn't need too/ if the doctors thought it was going to go away. Please let me know your thoughts.

Sincerely, b6

On Mon, Apr 12, 2021 at 7:24 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

> Unfortunately, I do not have any comment about b6 and its effect on your disease. We really do not have that much information about these reactions.Can you remind me whether you b6
> Thank you
>
> Farinaz
>
> **From:** b6
> **Sent:** Thursday, April 8, 2021 8:45:04 AM
> **To:** Safavi, Farinaz (NIH/NINDS) [E] b6
> **Cc:** Wiebold, Amanda (NIH/NINDS) [E] b6
> **Subject:** Re: Pfizer reaction follow up - b6
>
> Dear Dr. Farinaz,
>
> Ok, what do you think about me b6 Do you think that would be beneficial for the symptoms? I just don't want to aggravate any symptoms and possibly make it worse, however not sure b6 is positive either. Please let me know your thoughts on this.
>
> Sincerely,

b6

On Wed, Apr 7, 2021 at 6:32 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6
Sorry to hear your symptoms continue.Actually I think it woukd be helpful to be evaluated by neurologist again and get the work up like b6 if your symptoms are bothersome which may guide us through sone disgnosis or treatment.

I cc Amanda in this email to send you medical record release form and consent you for sample only.I believe she will contact you.

Farinaz

From: b6
Sent: Wednesday, April 7, 2021 4:00:08 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Pfizer reaction follow up - b6

Dear Dr. Safavi,

Hope all is well. My name is b6 and I previously emailed you regarding my adverse COVID 19 pfizer reaction last week. I spoke with b6 we had a telehealth visit where she collected some medical information from me. The reason I am following up with you is because I feel completely lost in terms of what I should be doing/how I should be getting treated at this point. I went to a neurologist who referred me to another neurologist- both saying its anxiety/ stress. I don't feel like my health is being taken seriously and that the pfizer vaccination could be the cause despite my numerous attempts explaining this and I do not know where else to turn.

My neurologist just wanted to prescribe me b6 and I picked up the medication but refused to take it. Most of my b6 She claims nobody else has come into her office with these symptoms from the vaccination. She didn't day she didn't believe me but she recommended I speak with a psychologist regarding "all the things happening in the world". I still have not taken a single ounce of medication since this whole situation began, and I am not looking to mask my symptoms but to help cure what's happening to me. You are the only doctor that seems to understand what is happening to others from the vaccination and I really need some guidance because I do not know who else to turn to anymore. I have been to two different neurologists, a cardiologist, a gastro, my PCP, orthopedist, and will be seeing an allergist later this month. I was thinking of trying to schedule an appointment with a rheumatologist but I don't know if that's even something I need.

Any recommendation would be so helpful. I really want to feel better, but I feel like nobody is prescribing me anything to do so. The symptoms have gotten better with time, but I feel like I could be doing more for my body then nothing. I saw my gynecologist today for a check up and he recommended b6 b6 I think I will take his recommendation but I don't want to cause more havoic in my body.

My Story:
I am a b6 from b6 I received your email addresses from the facebook group I'm a part of regarding reactions to various COVID 19 vaccinations.

I have no past medical history, I have always been a super healthy person. I played sports in college, I work out pretty consistently, not a big drinker or anything like that, and a VERY healthy eater. I have been taking b6

I received my first Pfizer vaccination on b6 I didn't experience any sort of reaction from the first dose the next day. Shortly after (maybe 2-3 days after the first dose) I experienced a bit of an itch on my right foot, but went away. Then felt it again the next day. It traveled out of my foot and I started feeling these tingling sensations on my right leg. Thought maybe I had sciatica b6 b6 The tingling would come and go. It moved to my left leg and then my arms. I also felt the tingling in my elbows, fingers, neck, boob area, abdomen. My lower back was a bit sore and felt tight. I didn't totally put the vaccine and these symptoms together. I was also experiencing chest pains, like pressure on my chest that would come on and I feel that my heart rate would increase. I would just breathe through these pains and they would disappear in about a minute. I figured maybe it had to do with stress.

I received the second dose of Pfizer on b6 and experienced the "typical" symptoms I've heard: body aches, fatigue, low grade fever. The symptoms disappeared within 24 hours, and I did not feel any tingling. The following day at night, I started experiencing severe tingling. My stress/anxiety went up immediately; crying a lot and not understanding what was happening to me. The following day I felt the tingling all over my body: legs, torso, forehead, back of head, vagina, tongue, back, etc. I got super scared. It's like my nerves were firing off with nowhere to go. I went to the ER two days later, and they basically told me to go home, saying I should see a neurologist and that I wasn't dying. Days afterwards, I felt this horrible pin pricking sensation down my spine and topical numbness in my right leg that went away. I also began experiencing some muscle twitching. It started in my right leg but I can feel it in various parts of my body (thighs, buttock, calves, arms, hand, and right underneath armpit on my back). I went to a neurologist and she told me it was "anxiety paresthesia" and to de-stress my life. I had a bad flare up a week and a half after that (no idea what it was from).

My current situation: I have a burning sensation mostly in my thighs, forearms (near elbows area), and upper shoulders. I have pin pricking sensations around my body. And I have muscle twitching in my arms, legs, and hand. I also have been experiencing diarrhea for the past month and a half. (almost two months now). My neurologist told me b6 b6

To be completely honest, I am quite frightened of this whole situation and just looking for some clarity. I have b6 from my neurologist that I could easily send you if need be. b6 assistant has not reached out to me yet regarding b6

My email address is: b6 my phone number is b6 Please feel free to reach out to me in whatever fashion suits you. I look forward to your response!

Any recommendation would be so kind of you.

Thank you,
b6

From: Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246-b6]
Sent: 10/1/2021 6:13:17 PM
To: b6
Subject: RE: Quick question

Yes It is correct but I suggest you b6 to see the real effect of it before taking b6

Let me know if I can be any of help

Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD

From: b6
Sent: Friday, October 1, 2021 2:09 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Quick question

Hi Dr. Safavi,
I will reach out to my neurologist today about it. Thank you for your offer to speak with him if needed, I will pass it along and let you know. Is the dosing that you recommend b6

Best regards,
b6

Sent from my iPhone

On Oct 1, 2021, at 2:03 PM, b6 wrote:

Sent from my iPhone

Begin forwarded message:

From: "Safavi, Farinaz (NIH/NINDS) [E]" b6
Date: October 1, 2021 at 12:14:47 PM EDT
To: b6
Subject: RE: Quick question

Hi b6
Thank you for the update. I discussed your case with Dr.Nath. We suggest you speak with your neurologist whether it is possible to consider b6 for you. I would be more than happy to speak with him and share our understanding with him.
Please let me know
Hope you feel better

Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD

From: b6
Sent: Friday, October 1, 2021 3:03 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Quick question

Hi Dr.Safavi,
Attached is the WHO scale with my updated scores. For an update of my symptoms: the paresthesias in my face has really progressed as compared to when it first started in terms of intensity. It feels like someone is pouring acid onto my face and yesterday it spread into my ears and scalp too. It's incredibly uncomfortable; hopefully I can get b6 b6 relatively quickly to take the edge off soon. I had initially planned to only take it at night to start but took it TID today to try and help with the pain in my face. I feel like some of my autonomic symptoms are worsening. Since Saturday I feel like my temperature regulation is off, or at least my perception of temperature. What I mean here are things like wearing winter clothes in the house for 4 days and then yesterday evening/today switching to being hot. I've been having night sweats as well. My b6 issues which I hadn't had in a month or so has come back this week, last night I couldn't sleep and early in the morning I noticed my HR was in the b6 for hours for no good reason. I've also noticed my HR jumping up with standing/walking today intermittently and a couple other times earlier this week too. I've been having some GI issues this week which are unusual for me.
Today I b6 I really hope to see an improvement soon. It's surprising, frustrating, and if I'm being honest a bit scary too, to have my symptoms continue to progress with time.

Best Regards,
b6

On Wed, Sep 29, 2021 at 5:49 PM Safavi, Farinaz (NIH/NINDS) [E]
b6 wrote:

> Dear b6
> Thank you very much for update.I am very glad that your headaches have improved significantly.
> Please let me know if I can be any help.
> Best
>
> Farinaz
> <FE8757DEE4E34AB0B42656F8348B59E6.png>
> **From:** b6
> **Sent:** Wednesday, September 29, 2021 5:46:27 PM
> **To:** Safavi, Farinaz (NIH/NINDS) [E]
> b6
> **Subject:** Re: Quick question

Hi Dr.Safavi,

Good news about my headache; it was mild yesterday and thus far today I haven't had it at all. Today has been wonderful, I'm really happy to be back at my level of functioning b6 I did talk about it with my local neurologist today in the event that the headache were to come back this evening for example and he recommended continued conservative management, things are clearly healing and there's no reason for it not to continue.

I had a good appointment with my neurologist overall and it's in large part due to having the documentation and diagnostic testing from you and your team. The b6 in particular helped open doors for conversation. I have now been prescribed b6 and we are also going to try b6 to see if it helps with the brain fog. It's been a long b6 I'm really thankful to try different things to help me get my life back.

Best Regards,
b6

PS-tomorrow I will send you the updated WHO post-COVID scale scores

On Wed, Sep 29, 2021 at 12:45 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

Hope all is well.Can you update me with status of your low pressure headache and your discussion with your health care provider?

Thank you

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Monday, September 27, 2021 5:52 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Quick question

All sounds good to me, my next local appt is this Wednesday, I will keep you posted.

Thanks!

b6

On Mon, Sep 27, 2021 at 5:00 PM Safavi, Farinaz (NIH/NINDS) [E]
b6 wrote:

Nothing to be worried b6

The reason I said you may speak with your local physicians was that you might be able to get it much faster than us coordinating it. Otherwise I can discuss with the team and see how we can proceed with it here. However your headaches are not that severe and might go away soon but still I will speak with Dr.Nath and the team to see what their thoughts are.Please you also inform me when you discuss it with your physicians and we can find the best way.

From: b6
Sent: Monday, September 27, 2021 4:46 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Quick question

Hi Dr.Safavi,

I usually lay down once the headache's get to a 5 and then they improve quickly. I will try and push through them more today and tomorrow than what I did this weekend and see how it goes. I do worry about whether I need b6 b6 or not, I've been conflicted about it, it's always hard to have clarity when the health issues are your own. It sounds like you recommend that I

should talk about it more with my local physicians. It's disheartening to hear that because I remember during the research consent process that you told me if I needed b6 that the NIH would do that for me. I hope it wasn't anything that I did on my end that has made things different; if I did anything that upset you or the team, please accept my apologies for that. I am incredibly grateful for what you and everyone else has done to find diagnostic answers as well as treatment solutions to help me get my life back.

b6

On Mon, Sep 27, 2021 at 4:22 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi,

How bad are your headaches from 1-10?

I discussed it with the team and they said if it is very severe you may go to ED to get b6 If not that severe, then it will go away with hydration and rest eventually.

Farinaz

From: b6
Sent: Monday, September 27, 2021 4:18 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Quick question

Hi Dr.Safavi,

Thank you for answering my questions, all makes sense to me. I'm still having issues with positional headaches unfortunately. I'm still spending a ton of time on the couch due to them.

b6

On Mon, Sep 27, 2021 at 3:06 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi,

b6 does not show any findings consistent with b6 b6 so that we b6 b6 Additionally Anti TS-HDS Ab is kind of new Ab was found to be associated with small fiber neuropathy.We b6 b6 since as long as I know it has not become commercialized in reliable labs yet(i checked afew weeks ago though).We did a very extensive research lab measuring for every single antigen in the body from a pooled sera of post vaccine patients and no Ab was detected so that we incline to say the process is less likely Ab mediated however we are working on many more methods to confirm this findings.

BTW,How is your headache?feeling better?

Farinaz

<2357B3EC861F461FBC695033493C7F5C.png>

From: b6
Sent: Monday, September 27, 2021 2:52:11 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Quick question

Hi,
I have a quick question for you. I was wondering if b6 b6 b6 I've connected with many others with similar health issues to mine- There is a b6 that reported that she tested positive for b6 b6 and a second person reported that she tested positive for b6 With their health stories being extremely similar to mine, it made me wonder if it was something that I had already been tested for.

Thanks!
b6

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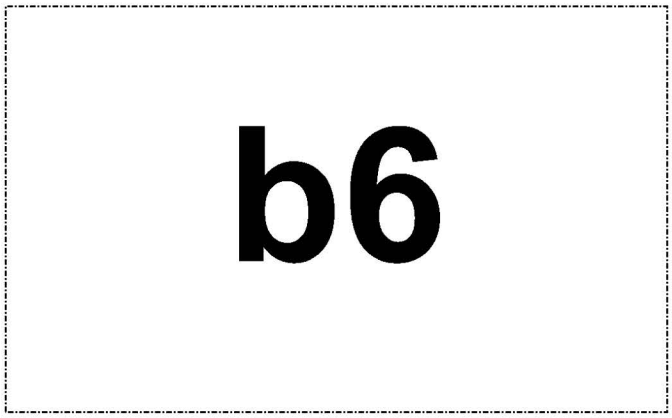
b6

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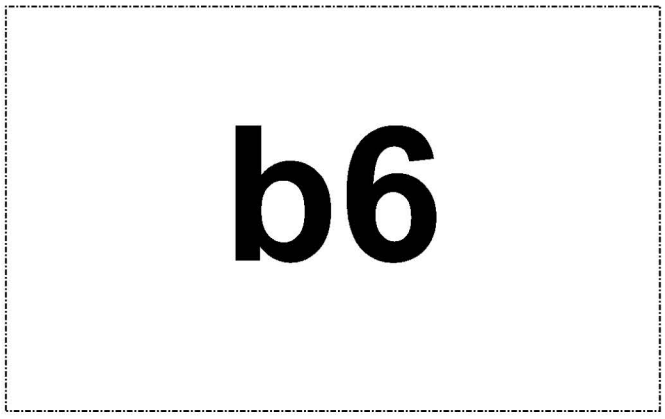
b6

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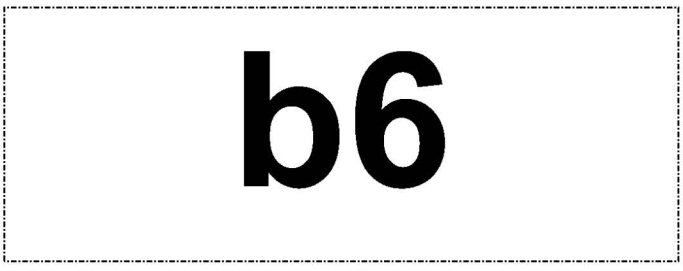
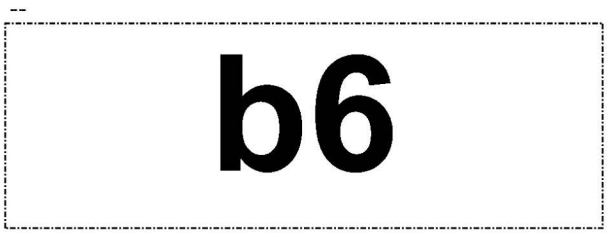
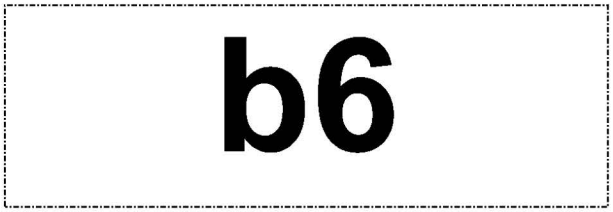

b6


b6


b6


b6

From: Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246 b6
Sent: 10/2/2021 10:14:53 PM
To: b6
Subject: Re: Pfizer reaction follow up - b6

Hi b6
Sorry it seems that I missed replying your email.
We believe the symptoms imptove overtime but all we know so far is anecdotal.We need large scale epidemioligical study to answer these questions.
I also would like to ask you is it possible whether you send us your b6
please let me know

Farinaz

From: b6
Sent: Wednesday, August 18, 2021 2:40:50 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: Pfizer reaction follow up - b6

Dear Dr. Safavi,

Thanks for your reply. Have you noticed people becoming 100% overtime, is that the outlook that I should be getting ? Some doctors say they don't really know what the prognosis will be, others say it should go away over time, so it's a bit confusing what to really think about it.
Is there any medication you recommend that you've found to be helpful?

Thank you,

b6

On Wed, Aug 18, 2021 at 11:11 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Dear b6

Thank you very much for the update. I am glad you feel partly better.Time definietely helps to recover from these symptoms. We have not published the paper yet but of course I can send it to you when it gets published.

In terms of samples,we checked pooled sera from several patients for thousands of autoantibodies but we were not able to find any so that we stopped checking them.If we find more information I will let you know.

Best

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Monday, August 16, 2021 1:26 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Pfizer reaction follow up - b6

Hi Dr. Safavi,

Would you be able to send me the research paper when it is complete ? I never ended up hearing back if I had any markers in my blood that was interesting and/or relevant to the research.

I still feel the paresthesia's everyday, I did get prescribed b6 It helped slightly, i think time has been the most helpful but I am disappointed that I continue to feel the burning/tingling/shock sensations everyday. Some days are better than others. Overall, it has gone from February. My neurologist tried to prescribe me b6 but I didn't end up taking it. So I've just been taking a few vitamins here and there, but overall I haven't been getting treated with medication.

Have you found anything in your research that could be helpful for me- in terms of treatment or just in general? Have you been finding people have been recovering ?

It's hard to try and stay positive when I continue to feel the paresthesia's everyday, do you think it will go away in time ?

Thank you so much.

Sincerely,

b6

On Sun, Aug 15, 2021 at 1:55 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

Hope all is well.

I am in the process of submitting our research paper and I would like to know how is every thing going with you?

Did b6 help you and how are you feeling?

Please let me know

Thanks

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Monday, May 3, 2021 11:07 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Cc: Wiebold, Amanda (NIH/NINDS) [E]
Subject: Re: Pfizer reaction follow up - b6

Yes my cell number is b6

Sincerely, b6

On Mon, May 3, 2021 at 11:05 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

Can you send me your cell phone number?I would like to speak with you

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Monday, May 3, 2021 10:25 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Cc: Wiebold, Amanda (NIH/NINDS) [E]
Subject: Re: Pfizer reaction follow up - b6

Dear Dr. Safavi,

I have sent over my medical release forms and my doctors should have sent over all my current testings performed (the doctors are: neurologist, gastro, cardiologist, and allergist/immunologist). As per your request, I did b6

b6

She has been wanting to prescribe me b6 for the nerve pain, however I would like medication to actually treat what is going on with me, perhaps a more auto-immune approach.

Again, I am b6 no prior medical history, no allergies to anything. Received two doses of pfizer vaccine. I just really do not understand how I was completely healthy before the vaccine and after now I b6 In your professional opinion, do you think this can go away with time?

What should I be taking to try and get rid of b6

My neurologist's name is b6 her phone number is b6 Would you be able to collaborate on a treatment strategy?

I know you have a lot of patients, but I feel totally lost and don't really know what to do anymore.

Sincerely, b6

On Mon, Apr 12, 2021 at 12:33 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

I was speaking with our research nurse and wondering have you sent us the medical release form.

I cc Amanda in this email and appreciate if you contact her for paperwork and consent then we can send you the kit or collecting samples from you.

Thank you

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Monday, April 12, 2021 8:13 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Pfizer reaction follow up - b6

Dear Dr. Safavi,

No, I have not b6 I was under the assumption that you thought these reactions were going to disappear with time- so I wanted to hold off on b6 b6 if I didn't need too/ if the doctors thought it was going to go away. Please let me know your thoughts.

Sincerely, b6

On Mon, Apr 12, 2021 at 7:24 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Unfortunately, I do not have any comment about b6 and its effect on your disease. We really do not have that much information about these reactions.Can you remind me whether you have b6 b6

Thank you

Farinaz

From: b6
Sent: Thursday, April 8, 2021 8:45:04 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Cc: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: Pfizer reaction follow up - b6

Dear Dr. Farinaz,

Ok, what do you think about me b6 Do you think that would be beneficial for the symptoms? I just don't want to aggravate any symptoms and possibly make it worse, however not sure b6 is positive either. Please let me know your thoughts on this.

Sincerely,

b6

On Wed, Apr 7, 2021 at 6:32 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

Sorry to hear your symptoms continue.Actually I think it woukd be helpful to be evaluated by neurologist again and get the work up like b6 if your symptoms are bothersome which may guide us through sone disgnosis or treatment.

I cc Amanda in this email to send you medical record release form and consent you for sample only.I believe she will contact you.

Farinaz

From: b6
Sent: Wednesday, April 7, 2021 4:00:08 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Pfizer reaction follow up - b6

Dear Dr. Safavi,

Hope all is well. My name is b6 and I previously emailed you regarding my adverse COVID 19 pfizer reaction last week. I spoke with b6 we had a telehealth visit where she collected some medical information from me. The reason I am following up with you is because I feel completely lost in terms of what I should be doing/how I should be getting treated at this point. I went to a neurologist who referred me to another neurologist- both saying its anxiety/ stress. I don't feel like my health is being taken seriously and that the pfizer vaccination could be the cause despite my numerous attempts explaining this and I do not know where else to turn.

My neurologist just wanted to prescribe me b6 and I picked up the medication but refused to take it. Most of my blood work has come in- all completely normal. She claims nobody else has come into her office with these symptoms from the vaccination. She didn't day she didn't believe me but she recommended I speak with a psychologist regarding "all the things happening in the world". I still have not taken a single ounce of medication since this whole situation began, and I am not looking to mask my symptoms but to help cure what's happening to me. You are the only doctor that seems to understand what is happening to others from the vaccination and I really need some guidance because I do not know who else to turn to anymore. I have been to two different neurologists, a cardiologist, a gastro, my PCP, orthopedist, and will be seeing an allergist later this month. I was thinking of trying to schedule an appointment with a rheumatologist but I don't know if that's even something I need.

Any recommendation would be so helpful. I really want to feel better, but I feel like nobody is prescribing me anything to do so. The symptoms have gotten better with time, but I feel like I could be doing more for my body then nothing. I saw my gynecologist today for a check up and he recommended I b6 b6 I think I will take his recommendation but I don't want to cause more havoic in my body.

My Story:
I am a b6 from b6 I received your email addresses from the facebook group I'm a part of regarding reactions to various COVID 19 vaccinations.

I have no past medical history, I have always been a super healthy person. I played sports in college, I work out pretty consistently, not a big drinker or anything like that, and a VERY healthy eater. I have been taking b6

I received my first Pfizer vaccination on b6 from work; I am b6 I didn't experience any sort of reaction from the first dose the next day. Shortly after (maybe 2-3 days after the first dose) I experienced a bit of an itch on my right foot, but went away. Then felt it again the next day. It traveled out of my foot and I started feeling these tingling sensations on my right leg. Thought maybe I had sciatica b6 The tingling would come and go. It moved to my left leg and then my arms. I also felt the tingling in my elbows, fingers, neck, boob area, abdomen. My lower back was a bit sore and felt tight. I didn't totally put the vaccine and these symptoms together. I was also experiencing chest pains, like pressure on my chest that would come on and I feel that my heart rate would increase. I would just breathe through these pains and they would disappear in about a minute. I figured maybe it had to do with stress.

I received the second dose of Pfizer on b6 and experienced the "typical" symptoms I've heard: body aches, fatigue, low grade fever. The symptoms disappeared within 24 hours, and I did not feel any tingling. The following day at night, I started experiencing severe tingling. My stress/anxiety went up immediately; crying a lot and not understanding what was happening to me. The following day I felt the tingling all over my body: legs, torso, forehead, back of head, vagina, tongue, back, etc. I got super scared. It's like my nerves were firing off with nowhere to go. I went to the ER two days later, and they basically told me to go home, saying I should see a neurologist and that I wasn't dying. Days afterwards, I felt this horrible pin pricking sensation down my spine and topical numbness in my right leg that went away. I also began experiencing some muscle twitching. It started in my right leg but I can feel it in various parts of my body (thighs, buttock, calves, arms, hand, and right underneath armpit on my back). I went to a neurologist and she told me it was "anxiety paresthesia" and to de-stress my life. I had a bad flare up a week and a half after that (no idea what it was from).

My current situation: I have a burning sensation mostly in my thighs, forearms (near elbows area), and upper shoulders. I have pin pricking sensations around my body. And I have muscle twitching in my arms, legs, and hand. I also have been experiencing diarrhea for the past month and a half. (almost two months now). My neurologist told me b6
b6

To be completely honest, I am quite frightened of this whole situation and just looking for some clarity. I have b6 from my neurologist that I could easily send you if need be. b6 assistant has not reached out to me yet regarding sending over b6

My email address is: b6 my phone number is b6 Please feel free to reach out to me in whatever fashion suits you. I look forward to your response!

Any recommendation would be so kind of you.

Thank you,
b6

From: Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246 b6
Sent: 2/2/2022 5:32:42 PM
To: b6
CC: Nahar, Kymani (NIH/NINDS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f432f899337490ea7cbde0a4b52effb b6 Fouanta, Ladifatou (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5ebaa8d0da84114ab631d6a3b913706 b6
Subject: RE: [EXTERNAL] Re: b6

Hi b6
We bring you back for exam and b6 We do not have any biomarker to follow after b6 because there is no scientific evidence at this point that b6 can be a biomarker to predict patient clinical features.
I will definitely let you know when we have any results but research based assays take months sometime since we have to run all patients samples at the same time.

Farinaz

From: b6
Sent: Wednesday, February 2, 2022 12:29:06 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Cc: Nahar, Kymani (NIH/NINDS) [C] b6 Fouanta, Ladifatou (NIH/NINDS) [E]
b6
Subject: Re: [EXTERNAL] Re: b6

Hi Dr. Safavi,

I very much appreciate your response. Will you keep me updated on the results you find regarding b6 b6 I am not sure if the results will update automatically in the portal.

I am working to reschedule my treatment for hopefully earlier than March with Kymani now. I was wondering what kind of tests I should expect to repeat following b6

Thank you,
b6

On Tue, Feb 1, 2022 at 9:18 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

Sorry for delay respond.We can schedule your b6 in your convenient time and its ok with us whether you see her before or after b6

b6 result has not been back.I will follow up with b6 again.For b6 all the tests we sent was b6 Since this is a research protocol we keep all b6 and b6 so that we b6 (Research aspect of the work usually takes loner than regular medical tests).So far b6 We plan to send for b6 b6

Our b6 We adjust b6

b6

Hope it helps. Kymani and Ladi will kindly help to schedule b6 in mutual convenient time .I plan to go on annual leave in 3rd week of march in case you prefer to be scheduled earlier than that time.

Best Regards

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Wednesday, January 26, 2022 1:00 PM
To: Nahar, Kymani (NIH/NINDS) [C]
Cc: Fouanta, Ladifatou (NIH/NINDS) [E]; Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: [EXTERNAL] Re: b6

Hi Kymani and Dr. Safavi,

I have been working relentlessly to coordinate my leave at work and schedule an appointment with b6 (thank you, Dr. Safavi, for the recommendation - I tremendously appreciate it). Unfortunately, the first available appointment with b6

b6

b6 Is this possible? I'd like to wait a couple more weeks.

I also wanted to follow up on any additional results that may have come in. I was wondering about b6

b6

b6 I know a common trend among those experiencing adverse reactions to the vaccine is elevated ACE2 & MAS1 autoantibodies.

In addition, I wanted to inquire about b6

b6

Thank you,

b6

On Mon, Jan 24, 2022 at 12:50 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Dear b6

Hope all is well.

I discussed your case in our team.We will start the process to b6

b6

Hope it helps you to set up an appointment with a neurologist who takes care of your symptoms.

I emailed b6 and will get back to you as soon as I have any results.

b6

Please let me know if you have any questions/concerns.

Best

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Friday, January 21, 2022 9:34 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Cc: Fouanta, Ladifatou (NIH/NINDS) [E]
Subject: Re: [EXTERNAL] Re: b6

Hello Dr. Safavi (and Ladi!),

I hope your week is going well. I was finally able to meet with a neurologist from b6 I requested a neuro-immunologist but was given the first available doctor from the team given the urgency, b6 b6 He was not very helpful with my case b6 He was confused why I was seeing a neurologist and sent me a referral to a rheumatologist.

I was wondering if you could recommend a neurologist that your other patients have worked with that understands these vaccine side effects? In addition, I was wondering if it would be possible to b6 b6 to see if it helps as I am searching for a neurologist. This process is quite daunting and takes a lot of time to send over test results, identify a doctor, schedule an appointment, etc. I had to call b6 everyday to keep the process moving and it truly exhausted me and the doctor was not even helpful. Is there someone specific I can request that would understand my case?

Also, given the similarity to Long COVID, have any of your patients successfully enrolled into Long COVID clinics? I am continuously turned away by doctors because my symptoms are very multi-system and they say they do not treat this. I feel that I need a team of doctors working with me such as internist, neurologist, rheumatologist, immunologist/allergist, endocrinologist, gastroenterologist, physical therapist, etc. My PCP is also not very useful because he does not understand these vaccine side effects.

Is the NIH able to help with documentation for b6 Have other patients been able to receive this?

Lastly, I wanted to thank you one more time for taking on my case. It really means the world to me and gives me a ray of hope.

Thank you,

b6

On Thu, Jan 6, 2022 at 8:01 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

> You should pick your PCP and neurologist and have a visit with them.In a meanwhile we can start the process and see when can we bring you in for treatment.If your physicians need to speak with us,I would be more than happy to contact them or they can email me(please share it with them) and I will share our understanding about your symptoms with them.

Hope it helps.

Please let us know if you would like to receive the treatment and we can proceed accordingly.

Thanks

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Thursday, January 6, 2022 7:56 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Cc: Fouanta, Ladifatou (NIH/NINDS) [E]
Subject: Re: [EXTERNAL] Re: b6

Thank you very much, Dr. Safavi.

One last question - what is the process to get started? Will I need to arrange a meeting with my new PCP and neurologists and the team at NIH? I am just thinking ahead to what I will need to accomplish before then.

Thank you,

b6

On Thu, Jan 6, 2022 at 7:35 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

Sorry for delayed respond. Last afew days were quite busy for me.

Here is my answers to your questions

Treatment Effectiveness and Durability:

- Dr. Safavi - during our conversation, you mentioned that several of your patients have received this treatment. Could you please clarify if 50% of the patients received the treatment or if 50% of those that received treatment had a positive effect? If the former, have all the patients that received it benefited from the treatment? We can not predict the outcome of treatment in patients or know its efficiency without clinical trials.What I said was our anecdotal experience showed that patients who b6 showed some improvement (some patients more significant than others)
- You also mentioned you are writing a paper. Would you have any preliminary data to share from the patients you have treated so far? We are submitting the paper for publication as case series again this is just observational study not clinical trial
- How many treatments are patients with my condition needing? Dr. Safavi - you mentioned some patients get to 80% and do not return to their baseline and improve from there on their own. Does that mean one treatment can be enough? In reading about this treatment, it seems many patients receive it on some kind of a cadence for life. In what you have seen, how many treatments are typically needed until b6 can be stopped and the patient does not return to original symptoms? From what I understood, one treatment can work or most patients need one or two rounds. However, reading about b6 it seems like it's possible to return to we had patients showed improvement with one round and we had others require more rounds we really can not answer this question based on our limited data.every patient respond differently and we still do not have enough data to come with definite treatment regimen.
- If I end up needing a second round of the treatment, will this be with my neurologist and outside of NIH? Yes
- Will you still be in touch as thought leaders and available for guidance if something comes up? Yes,of course

Treatment Process and Potential Side Effects:

- If I do receive the treatment, will I only need to have a neurologist or also a primary care physician? Dr. Nath also mentioned needing a strong PCP (I currently go to b6 and my PCP is very basic). I believe it would be good to have both PCP and neurologist
- In terms of the treatment itself, did I understand this correctly: it will be b6 b6 Is this correct? You may have some side effects within b6 but again it is individual based I can not really predict how your body react to b6
- This seems like a b6 and I am curious about the rationale. Is the thinking that b6

b6

- How long will I be at risk for the side effects? For example, there is a risk of blood clots, kidney problems, bleeding problems - is this only during treatment or for a longer time? Usually body b6
- How is the brand of medicine determined? Is there a brand that works especially well for vaccine injuries? No, we use the one NIH pharmacy provides us
- I have read that b6 results in fewer side effects. Is this an option? Could it be an option down the line if more treatments are needed? No, b6 has different indications. For b6 is useful.
- How long do I have to make the decision whether to receive this treatment? you need to inform us as early as you can specially now with Omicron situation we are on limited staff and it may take longer than normal to arrange the treatment
- Are there any alternatives to b6 Time? Antihistamines? Supplements? Exercises? Not as we know and even our experience with b6 is very limited too.

Post-Treatment and Considerations:

- For how long will I need to tell doctors that I have used this medication? b6 b6 As I mentioned above b6 b6
- Are there any long-term things to be aware of? For example, things to tell doctors, medication I won't be able to take, other restrictions I need to be aware of if I proceed with b6 You need to inform your physicians you received it but no specific instruction from our standpoint unless your physicians have reason based on their own practice
- Are there any COVID-specific implications? Will this treatment help to have a better outcome if I end up getting COVID? Will it help me fight other infections? (I ask because I seem to handle even the most minor colds with a lot of difficulty now). In other words, will it help my immune system stabilize? Sorry if I am thinking about it incorrectly! I am trying to understand if b6 b6 will make me more or less susceptible to infections / improve my immune response. Basically b6 b6 b6 In terms of COVID, you need to do all precautions to not contract the infection but if you get COVID the process would be the same as other patients. same protocol that your PCP can help you with.
- What were patients receiving this treatment surprised by or brought up as a concern? Is there anything that I haven't thought of to ask that should go into my decision-making process? I do not have any further comment to add. would be happy to answer any further questions if it comes up.

Best wishes and let us know your decision.

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Monday, January 3, 2022 10:07:46 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6 Fouanta, Ladifatou (NIH/NINDS) [E] b6
Subject: [EXTERNAL] Re: b6

Thank you very much, Dr. Safavi and Ladi. I really appreciate the extra information on b6 I hope you both had a nice break and I wish you a Happy New Year!

As I have been reading about this treatment option, a few more questions have come to mind that I was hoping to get your help with. Would it be possible to schedule another appointment? Dr. Safavi - I know you are out next week so I am also including the questions below in case it is easier for you to respond by email. However, I think it would be most helpful to talk through them as you offer so much helpful information and anecdotes from your research.

Treatment Effectiveness and Durability:

- Dr. Safavi - during our conversation, you mentioned that several of your patients have received this treatment. Could you please clarify if 50% of the patients received the treatment or if 50% of those that received treatment had a positive effect? If the former, have all the patients that received it benefited from the treatment?
- You also mentioned you are writing a paper. Would you have any preliminary data to share from the patients you have treated so far?
- How many treatments are patients with my condition needing? Dr. Safavi - you mentioned some patients get to 80% and do not return to their baseline and improve from there on their own. Does that mean one treatment can be enough? In reading about this treatment, it seems many patients receive it on some kind of a cadence for life. In what you have seen, how many treatments are typically needed until b6 can be stopped and the patient does not return to original symptoms? From what I understood, one treatment can work or most patients need one or two rounds. However, reading about b6 it seems like it's possible to return to

- If I end up needing a second round of the treatment, will this be with my neurologist and outside of NIH? Will you still be in touch as thought leaders and available for guidance if something comes up?

Treatment Process and Potential Side Effects:

- If I do receive the treatment, will I only need to have a neurologist or also a primary care physician? Dr. Nath also mentioned needing a strong PCP (I currently go to b6 and my PCP is very basic).
- In terms of the treatment itself, did I understand this correctly: it will be b6 b6 Is this correct?
- This seems like b6 and I am curious about the rationale. Is the thinking that b6 b6
- How long will I be at risk for the side effects? For example, there is a risk of blood clots, kidney problems, bleeding problems - is this only during treatment or for a longer time?
- How is the brand of medicine determined? Is there a brand that works especially well for vaccine injuries?
- I have read that b6 results in fewer side effects. Is this an option? Could it be an option down the line if more treatments are needed?
- How long do I have to make the decision whether to receive this treatment?
- Are there any alternatives to b6 Time? Antihistamines? Supplements? Exercises?

Post-Treatment and Considerations:

- For how long will I need to tell doctors that I have used this medication? If there are b6 b6
- Are there any long-term things to be aware of? For example, things to tell doctors, medication I won't be able to take, other restrictions I need to be aware of if I proceed with b6
- Are there any COVID-specific implications? Will this treatment help to have a better outcome if I end up getting COVID? Will it help me fight other infections? (I ask because I seem to handle even the most minor colds with a lot of difficulty now). In other words, will it help my immune system stabilize? Sorry if I am thinking about it incorrectly! I am trying to understand if b6 b6 will make me more or less susceptible to infections / improve my immune response.
- What were patients receiving this treatment surprised by or brought up as a concern? Is there anything that I haven't thought of to ask that should go into my decision-making process?

I very much appreciate you working with me!

Thank you,

b6

On Mon, Dec 27, 2021 at 1:28 PM Fouanta, Ladifatou (NIH/NINDS) [E] b6 wrote:

Hi Dr Safavi and Anna,

I have attached some info about b6
b6

Thanks,

Ladifatou (Ladi) Fouanta, BSN, RN, CNRN

Research Nurse Specialist

NINDS Section of Infections of the Nervous System

10 Center Drive, Building 10/7C103, MSC 1430

Bethesda, Maryland 20892

Office: b6

Fax: 301-480-5594

Email: b6

From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Monday, December 27, 2021 12:57 PM
To: Fouanta, Ladifatou (NIH/NINDS) [E] b6
b6
Subject: b6

Hi Ladi,

I had a televisit with b6
b6

Thank you

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246 b6
Sent: 7/29/2021 3:37:35 PM
To: b6
CC: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject: RE: Pfizer reaction follow up - b6

From: b6
Sent: Monday, May 3, 2021 11:07 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Cc: Wiebold, Amanda (NIH/NINDS) [E]
Subject: Re: Pfizer reaction follow up - b6

Yes my cell number is b6

Sincerely, b6

On Mon, May 3, 2021 at 11:05 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

> Hi b6
>
> Can you send me your cell phone number?I would like to speak with you
>
> Farinaz Safavi MD, PhD
>
> Division of Neuroimmunology and Neurovirology
>
> NINDS, NIH, Bethesda, MD

From: b6
Sent: Monday, May 3, 2021 10:25 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Cc: Wiebold, Amanda (NIH/NINDS) [E]
Subject: Re: Pfizer reaction follow up - b6

Dear Dr. Safavi,

I have sent over my medical release forms and my doctors should have sent over all my current testings performed (the doctors are: neurologist, gastro, cardiologist, and allergist/immunologist). As per your request, b6

b6

She has been wanting to prescribe me b6 for the nerve pain, however I would like medication to actually treat what is going on with me, perhaps a more auto-immune approach.

Again, I am b6 no prior medical history, no allergies to anything. Received two doses of pfizer vaccine. I just really do not understand how I was completely healthy before the vaccine and after now I b6 In your professional opinion, do you think this can go away with time?

What should I be taking to try and get rid of b6

My neurologist's name is b6 her phone number is b6 Would you be able to collaborate on a treatment strategy?

I know you have a lot of patients, but I feel totally lost and don't really know what to do anymore.

Sincerely, b6

On Mon, Apr 12, 2021 at 12:33 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

I was speaking with our research nurse and wondering have you sent us the medical release form.

I cc Amanda in this email and appreciate if you contact her for paperwork and consent then we can send you the kit or collecting samples from you.

Thank you

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Monday, April 12, 2021 8:13 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Pfizer reaction follow up - b6

Dear Dr. Safavi,

No, I have not b6 I was under the assumption that you thought these reactions were going to disappear with time- so I wanted to hold off on b6 if I didn't need too/ if the doctors thought it was going to go away. Please let me know your thoughts.

Sincerely, b6

On Mon, Apr 12, 2021 at 7:24 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

> Unfortunately, I do not have any comment about b6 and its effect on your disease. We really do not have that much information about these reactions.Can you remind me whether you b6
>
> Thank you
>
> Farinaz

From: b6
Sent: Thursday, April 8, 2021 8:45:04 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Cc: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: Pfizer reaction follow up b6

Dear Dr. Farinaz,

Ok, what do you think about me getting off b6 Do you think that would be beneficial for the symptoms? I just don't want to aggravate any symptoms and possibly make it worse, however not sure b6 is positive either. Please let me know your thoughts on this.

Sincerely,

b6

On Wed, Apr 7, 2021 at 6:32 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

Sorry to hear your symptoms continue.Actually I think it woukd be helpful to be evaluated by neurologist again and get the work up b6 if your symptoms are bothersome which may guide us through sone disgnosis or treatment.

I cc Amanda in this email to send you medical record release form and consent you for sample only.I believe she will contact you.

Farinaz

From: b6
Sent: Wednesday, April 7, 2021 4:00:08 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Pfizer reaction follow up - b6

Dear Dr. Safavi,

Hope all is well. My name is b6 and I previously emailed you regarding my adverse COVID 19 pfizer reaction last week. I spoke with b6 we had a telehealth visit where she collected some medical information from me. The reason I am following up with you is because I feel completely lost in terms of what I should be doing/how I should be getting treated at this point. I went to a neurologist who referred me to another neurologist- both saying its anxiety/ stress. I don't feel like my health is being taken

seriously and that the pfizer vaccination could be the cause despite my numerous attempts explaining this and I do not know where else to turn.

My neurologist just wanted to prescribe me b6 and I picked up the medication but refused to take it. Most of my b6 She claims nobody else has come into her office with these symptoms from the vaccination. She didn't day she didn't believe me but she recommended I speak with a psychologist regarding "all the things happening in the world". I still have not taken a single ounce of medication since this whole situation began, and I am not looking to mask my symptoms but to help cure what's happening to me. You are the only doctor that seems to understand what is happening to others from the vaccination and I really need some guidance because I do not know who else to turn to anymore. I have been to two different neurologists, a cardiologist, a gastro, my PCP, orthopedist, and will be seeing an allergist later this month. I was thinking of trying to schedule an appointment with a rheumatologist but I don't know if that's even something I need.

Any recommendation would be so helpful. I really want to feel better, but I feel like nobody is prescribing me anything to do so. The symptoms have gotten better with time, but I feel like I could be doing more for my body then nothing. I saw my gynecologist today for a check up and he recommended I b6 b6 I think I will take his recommendation but I don't want to cause more havoic in my body.

My Story:
I am a b6 from b6 I received your email addresses from the facebook group I'm a part of regarding reactions to various COVID 19 vaccinations.

I have no past medical history, I have always been a super healthy person. I played sports in college, I work out pretty consistently, not a big drinker or anything like that, and a VERY healthy eater. I have been taking b6

I received my first Pfizer vaccination on b6 from work; I am b6 I didn't experience any sort of reaction from the first dose the next day. Shortly after (maybe 2-3 days after the first dose) I experienced a bit of an itch on my right foot, but went away. Then felt it again the next day. It traveled out of my foot and I started feeling these tingling sensations on my right leg. Thought maybe I had sciatica b6 The tingling would come and go. It moved to my left leg and then my arms. I also felt the tingling in my elbows, fingers, neck, boob area, abdomen. My lower back was a bit sore and felt tight. I didn't totally put the vaccine and these symptoms together. I was also experiencing chest pains, like pressure on my chest that would come on and I feel that my heart rate would increase. I would just breathe through these pains and they would disappear in about a minute. I figured maybe it had to do with stress.

I received the second dose of Pfizer on b6 and experienced the "typical" symptoms I've heard: body aches, fatigue, low grade fever. The symptoms disappeared within 24 hours, and I did not feel any tingling. The following day at night, I started experiencing severe tingling. My stress/anxiety went up immediately; crying a lot and not understanding what was happening to me. The following day I felt the tingling all over my body: legs, torso, forehead, back of head, vagina, tongue, back, etc. I got super scared. It's like my nerves were firing off with nowhere to go. I went to the ER two days later, and they basically told me to go home, saying I should see a neurologist and that I wasn't dying. Days afterwards, I felt this horrible pin pricking sensation down my spine and topical numbness in my right leg that went away. I also began experiencing some muscle twitching. It started in my right leg but I can feel it in various parts of my body (thighs, buttock, calves, arms, hand, and right underneath armpit on my back). I went to a neurologist and she told me it was "anxiety paresthesia" and to de-stress my life. I had a bad flare up a week and a half after that (no idea what it was from).

My current situation: I have a burning sensation mostly in my thighs, forearms (near elbows area), and upper shoulders. I have pin pricking sensations around my body. And I have muscle twitching in my arms, legs, and hand. I also have been experiencing diarrhea for the past month and a half. (almost two months now). My neurologist told me b6
b6

To be completely honest, I am quite frightened of this whole situation and just looking for some clarity. I have b6 from my neurologist that I could easily send you if need be. b6 assistant has not reached out to me yet regarding b6

My email address is: b6 my phone number is b6 Please feel free to reach out to me in whatever fashion suits you. I look forward to your response!

Any recommendation would be so kind of you.

Thank you,
b6

From: Safavi, Farinaz (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=94807CE146E045D4B61655DA26A0C246 b6
Sent: 9/29/2021 9:48:03 PM
To: b6
Subject: Re: Quick question

From: b6
Sent: Wednesday, September 29, 2021 5:46:27 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: Quick question

Hi Dr.Safavi,

Good news about my headache; it was mild yesterday and thus far today I haven't had it at all. Today has been wonderful, I'm really happy to be back at my level of functioning b6 I did talk about it with my local neurologist today in the event that the headache were to come back this evening for example and he recommended continued conservative management, things are clearly healing and there's no reason for it not to continue.

I had a good appointment with my neurologist overall and it's in large part due to having the documentation and diagnostic testing from you and your team. The b6 in particular helped open doors for conversation. I have now been prescribed b6 and we are also going to try b6 to see if it helps with the brain fog. It's been a long b6 I'm really thankful to try different things to help me get my life back.

Best Regards,
b6

PS-tomorrow I will send you the updated WHO post-COVID scale scores

On Wed, Sep 29, 2021 at 12:45 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

> Hi b6
>
> Hope all is well.Can you update me with status of your low pressure headache and your discussion with your health care provider?
>
> Thank you
>
> Farinaz Safavi MD, PhD
>
> Division of Neuroimmunology and Neurovirology
>
> NINDS, NIH, Bethesda, MD

From: b6
Sent: Monday, September 27, 2021 5:52 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Quick question

All sounds good to me, my next local appt is this Wednesday, I will keep you posted.

Thanks!

b6

On Mon, Sep 27, 2021 at 5:00 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Nothing to be worried b6

The reason I said you may speak with your local physicians was that you might be able to get it much faster than us coordinating it. Otherwise I can discuss with the team and see how we can proceed with it here. However your headaches are not that severe and might go away soon but still I will speak with Dr.Nath and the team to see what their thoughts are.Please you also inform me when you discuss it with your physicians and we can find the best way.

From: b6
Sent: Monday, September 27, 2021 4:46 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Quick question

Hi Dr.Safavi,

I usually lay down once the headache's get to a 5 and then they improve quickly. I will try and push through them more today and tomorrow than what I did this weekend and see how it goes. I do worry about whether I need a b6 or not, I've been conflicted about it, it's always hard to have clarity when the health issues are your own. It sounds like you recommend that I should talk about it more with my local physicians. It's disheartening to hear that because I remember during the research consent process that you told me if I

needed b6 that the NIH would do that for me. I hope it wasn't anything that I did on my end that has made things different; if I did anything that upset you or the team, please accept my apologies for that. I am incredibly grateful for what you and everyone else has done to find diagnostic answers as well as treatment solutions to help me get my life back.

b6

On Mon, Sep 27, 2021 at 4:22 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi,

How bad are your headaches from 1-10?

I discussed it with the team and they said if it is very severe you may go to ED to get b6 If not that severe, then it will go away with hydration and rest eventually.

Farinaz

From: b6
Sent: Monday, September 27, 2021 4:18 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Quick question

Hi Dr.Safavi,

Thank you for answering my questions, all makes sense to me. I'm still having issues with positional headaches unfortunately. I'm still spending a ton of time on the couch due to them.

b6

On Mon, Sep 27, 2021 at 3:06 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi,

b6 does not show any findings consistent with b6 b6 so that we b6 Additionally Anti TS-HDS Ab is kind of new Ab was found to be associated with small fiber neuropathy.We b6 b6 since as long as I know it has not become commercialized in reliable labs yet(i checked afew weeks ago though).We did a very extensive research lab measuring for every single antigen in the body from a pooled sera of post vaccine patients and no Ab was detected so that we incline to say the process is less likely Ab mediated however we are working on many more methods to confirm this findings.

BTW,How is your headache?feeling better?

Farinaz

From: b6
Sent: Monday, September 27, 2021 2:52:11 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Quick question

Hi,
I have a quick question for you. I was wondering if b6 b6 I've connected with many others with similar health issues to mine- There is a b6 that reported that she tested positive for b6 and a second person reported that she tested positive for b6 With their health stories being extremely similar to mine, it made me wonder if it was something that I had already been tested for.

Thanks!
b6

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b6

b6

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b6

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b6

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b6

b6

From: b6
Sent: 4/19/2021 3:27:06 PM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
Subject: Re: Re :Covid-19 Vaccine Adverse Reaction

Good Morning Doctor,

I just wanted to let you know I had my b6
b6

I am continuing to get better with each passing day, although some days I still have set backs. I feel that I am just on the verge of being "cured," and then the next morning I wake up with the internal tremors in a new location. Recently face and stomach, instead of spine.

I know it is hard for you to really recommend anything since you have not physically seen me, but could I still benefit from b6 There is a lady in our Facebook group that had b6
b6 and had great success. Is this something that you have heard of, and would recommend if I was your physical patient?

My neurologist has basically said that I am "normal" and there is nothing else he can do for me. My Allergist/Immunologist said that he does not recommend anything else, other than what I am doing. I am still
b6
b6

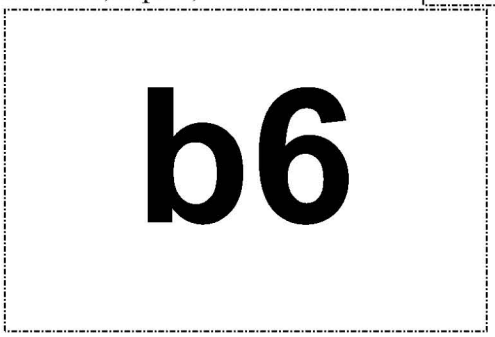
I still have hope in the fact that this will eventually vanish, but I do feel that since you are literally the only doctor that I have talked with that has any clue as to what is going on, I would ask to see if there is anything you can recommend to try and see if I can finally get all the symptoms to completely subside.

As always, I appreciate your responsiveness and attentiveness to this unfortunate event. I know that you have helped so many people that I have connected with via our facebook group. We are a hope for those that are experiencing these same horrible side effects. I know it may be overwhelming, but you are the light in the darkness for many, including myself!

Thanks so much!

b6

On Wed, Apr 7, 2021 at 7:19 PM b6 wrote:



b6

On Wed, Apr 7, 2021, 7:07 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Actually this is a great idea.I would like to speak with your neurologist and discuss your issues.

Can you send me his information

Thanks

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Wednesday, April 7, 2021 8:05 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Re :Covid-19 Vaccine Adverse Reaction

Ok, I was seeing a Neurologist, but he dismissed me and said I looked great neurologically. He has no concerns from any of my tests and wanted me to see the immunologist. I do still have my foot in the door though. He told me to call if I needed anything else from them. Let me see what the immunologist wants to do tomorrow, and I will let you know. It might be a great advantage to have you get with the immunologist or neurologist, so that they can be better educated on what you have seen and heard going on with the vaccine reactions.

On Wed, Apr 7, 2021, 6:40 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

I also thought you may benefir to see a neurologist there and I would be happy to communicate with them.

They are most likely more familiar with post covid type complications.Some one with neuromuscular subspeciality.

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Wednesday, April 7, 2021 7:39 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Re :Covid-19 Vaccine Adverse Reaction

Yes, I have family in b6 I will certainly ask for a referral if we feel this is necessary.

On Wed, Apr 7, 2021, 6:36 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Usually neurologists or cardiologists can do autonomic testing.

Are you close to b6 is a very good.

Farinaz

From: b6
Sent: Wednesday, April 7, 2021 7:31 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Re :Covid-19 Vaccine Adverse Reaction

Ok, I will mention it tomorrow. What type of doctor specializes in autonomic dysfunction? If we don't have someone here, I can find someone in a bigger city near by.

On Wed, Apr 7, 2021, 6:02 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

That really can come from autonomic dysfunction.Now we know post covid infection people develop dysautonomia.I really think you should get autonomic evaluations

Farinaz

From: b6
Sent: Wednesday, April 7, 2021 6:59:25 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: Re :Covid-19 Vaccine Adverse Reaction

I just started having issues after the vaccine. I have always had low to normal blood pressure, like b6 b6 Some days it is b6 or the highest it got was b6

On Wed, Apr 7, 2021, 5:54 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Actually your blood pressure fluctuation does go with autonomic dysfunction.your doctor may refer you to a person who does autonomic testings.How long have you develooed fluctuation in blood pressure?

Thanks

Farinaz

From: b6
Sent: Wednesday, April 7, 2021 6:51:16 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: Re :Covid-19 Vaccine Adverse Reaction

My doctor wanted b6 I have my doctor's appointment tomorrow, so I can ask about the autonomic dysfunction. I was reading that the kidney issues could be due to nerve problems as well. Which is right up the same alley as all the other issues I am having.

Thank you for your response

On Wed, Apr 7, 2021, 5:14 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

Thank you very much for updating me.

Sometimes autonomic dysfunction can present as bowel or urinary symptoms.What were your symptoms originally that get the work up for?

I am not sure what is the availability of autonomic testing in the city you live? You may benefit from it but I really can not comment or practice medicine long distance and through emails.

Best

Farinaz

From: b6
Sent: Wednesday, April 7, 2021 2:01:12 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: Re :Covid-19 Vaccine Adverse Reaction

Hi Dr. Safavi,

I wanted to let you know that I had b6

b6

b6 I was assuming since this is, again, a new symptom since the vaccine, that I should let you

know. I have an appointment with my Immunologist tomorrow, and I was going to ask him about the b6 b6 you had suggested, is there anything else that I should ask?

I am still feeling well enough b6 but the vibrations or pulsing currents that run down my spine never stop. It has lessened in severity, but it is still very noticeable 24/7. My neurologist dismissed me, and did not want to run any other tests. I can ask the Immunologist about b6 or perhaps they will be on the list of things to do now that I am having a kidney issue?...

I appreciate your time always, and the help you are giving to navigate these uncharted waters.

b6

On Fri, Mar 26, 2021 at 12:59 PM b6 wrote:

Ok, I will be sure to ask the Allergist/Immunologist. They may be able to get me in for b6 next week. They just don't have any appointments to visit with the doctor any sooner than April 8th.

On Fri, Mar 26, 2021, 9:37 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

I am so glad b6 which was my expectations as well.I probably check bellow panels in your case to make sure we do not miss any thing but ofcourse leave it to you and your providers.

b6

I am not worried about b6 just recheck it in a few weeks and hopefully it comes down.

We also gonna run many other research assays on the serum you sent us and will let you know if anything comes back abnormal.

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Friday, March 26, 2021 10:01 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Re :Covid-19 Vaccine Adverse Reaction

Good Morning Doctor!

I was going to get with you today also. My neurology visit went fairly well. He just said that there is nothing wrong with me Neurologically. b6 b6 and he wants me to continue to see the Allergist/Immunologist specialist here in town. He told me that he didn't need to see me anymore.

I had an appointment with the Allergist/Immunologist a few weeks ago, and they only did b6 This is one of the reasons I was going to reach out to you today. b6 b6 b6

So, as of now, the A/I has scheduled for me to have b6 I do not see the A/I until April 8. I can have them b6 if necessary?

I was feeling really good for over a week. Very minimal vibrations, more energy, and good overall feeling. Then just last night I started having chills followed by sweats, then more intense vibrations disrupting my sleep.

I am always happy to do whatever I need to do to find answers for this mysterious side effect! Just let me know what you think I should do.

b6

On Fri, Mar 26, 2021, 8:43 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

Hope all is well and your symptoms have been improving.

I would like to know how your neurology appointment went and I am also wondering can your neurologist sends some b6 to investigate your symptoms. I definitely would be more than happy to speak with him/her as well.

Please keep me in the loop.

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: Safavi, Farinaz (NIH/NINDS) [E]
Sent: Monday, March 22, 2021 3:28 PM
To: b6
Subject: RE: :Covid-19 Vaccine Adverse Reaction

Dear b6

Thank you very much for your email and update. Unfortunately, I can not comment about b6 b6 and its correlation to your post vaccine symptoms. As we discussed in our televisit, I also believe post vaccine symptoms gradually improve by decreasing the intensity of immune response so that I really can not comment if this improvement related to medication you have been taking or due to natural course of your vaccine reaction. Either way, I am very glad that you feel better. I would love to hear about your neurology visit and would be happy to provide any assistance.

Thank you very much to send us b6 We plan to run several tests on patient samples and will let you know if we find anything to help your management.

Best Regards,

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Monday, March 22, 2021 2:05 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: :Covid-19 Vaccine Adverse Reaction

Good Afternoon Doctor,

I wanted to let you know that my Neurologist had a cancellation this Wednesday for me to be seen at 2:30 in the afternoon. I will discuss with them face to face about our tele-health visit from March 9th. I have left multiple messages with the nurse, but they just assure me they are putting notes in my file, and I have to wait until I can meet with the Neurologist. I am hopeful!

Second, I recently came across an article about b6 I called my Rheumatologist to talk with them about it, and they said they had never heard of it. Is this something that you have heard of, or know of the procedures for diagnosis? I ask, because after I read the article, things started adding up for me. I had 10 out of 13 symptoms on the list. I also had a yearly dermatologist appt. on March 17 and she noticed I have b6. She said that it was no big deal, usually brought about from some sort of immune response. So, I asked her if it could be the negative reaction I was having to the vaccine. She said with it being so new, she couldn't say for certain. I have never had these lesions on my skin ever, and they just suddenly popped up?!? She put me on b6 and told me that if they didn't go away she would b6 b6 I researched a little more about the b6 and it led me to b6 diagnosis. That is when I realized I had almost every symptom listed. So, I started the recommended treatment of b6 since it is so benign. This was Wednesday March 17, and by Saturday March 20 I was starting to notice my symptoms easing. I am still doing the regimine, as well as adding b6
I am not 100% better by any means, but I would put my functionality at about 30-50% before I started this, and I would put my functionality at about 75-80% now. I am getting more energy daily, the tremors in my hands have almost stopped, the vibrations I have running through my body are still there, but less intense. I still have temperature regulation problems, and a little dizziness, but I feel so much more improved. I don't know if this needs to be explored more, or if my case is just a little

different than others, but I am going to keep doing what I am doing, until someone tells me otherwise. This is the most I have felt like myself since b6 I had b6 b6 I hope this can give some answers? I will let you know how my Neurology appt. goes Wednesday as well.

Thanks,

b6

On Thu, Mar 18, 2021 at 7:15 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

Thank you very much for updating me.Were you able to arrange b6 b6 as soon as possible?

I would be more than happy to speak with the NP you saw and ask her to b6

I think you can definietely b6 How about you speak with one of your providers and b6

We usually can b6 b6

U wish you could see a neurologist earlier than April 20th then I could communicate with her about possible treatments.

Farinaz

PS;It would be great if we have b6 then at least we can some tests to find the cause.

Farinaz

From: b6
Sent: Thursday, March 18, 2021 7:54:59 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: :Covid-19 Vaccine Adverse Reaction

Good Evening Doctor,

I received the kit yesterday, and I have been in touch with Amanda. I have an appointment Monday March 22nd, at 9:00 am. I have had an awful time here lately. My symptoms seem to wax and wane, but there have been more bad days than good recently. I did get in to see the Rheumatologist on March 10, the day after our visit. He placed me on b6 b6 That seemed to help for about a week. My symptoms are just so intense they are still felt 24/7, even through medication. I asked about b6 and he didn't seem interested in that just yet. They did prescribe me b6 because the day of my appt. my blood pressure was b6 I do believe this was due to anxiety about my appointment, and the ever constant pain in my body. I have taken my blood pressure 4 times a day since March 10th, with very normal readings, so I did not start the b6 I have heard that b6 can help with nerve related issues, but I didn't want to chance having my blood pressure bottom out while I am b6 So, I will just continue to monitor my BP. I did start some b6 Do you have any insight on this, or any other medications/combinations that you have heard are working? I am wondering if I should be more adamant about getting started on b6 as you suggested?

I did have b6 on March 10, and they called me the next day to tell me b6 I am still awaiting the results for b6 I just don't know how much longer I can take this. The vibrations run through my body so violently at times, that there is no way to rest. I don't have another appt. with my Rheumatologist until March 30, and the Neurologist April 20. I hate to be a complainer, and don't mean to burden you. I sincerely appreciate all that you are doing! I guess each day I wake up expecting to feel better, or have some encouraging news, but it is always the same. No news, and no changes. I hope for brighter days ahead!

Thanks for what you're doing!

b6

On Tue, Mar 16, 2021 at 11:29 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

Hope all is well and you feel better.

I just wanted to inform you our research nurse sent you the kit for b6

Please let me know how you are doing?and if you have any questions

Farinaz

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Thursday, March 4, 2021 2:04:41 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: :Covid-19 Vaccine Adverse Reaction

I just received it. That works great too!

Again thank you so much!

b6

On Thu, Mar 4, 2021, 12:45 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Our research nurse(Amanda) already sent you a televisit link for Tuesday 3pm ET.

Best

Farinaz

From: b6
Sent: Thursday, March 4, 2021 9:33 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: :Covid-19 Vaccine Adverse Reaction

If Friday March 5th is still available I will take it. If not, I can do any of the other 2.

Thank you...thank you...thank you!

b6

On Wed, Mar 3, 2021, 10:25 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Dear b6

I am really sorry to hear about your illness. We started an effort at NIH to look at neurological side effects of COVID19 vaccines. I suggest we set a time and have a televisit to discuss your symptoms.

I have availabilities on

Friday 3/5 4-5pm ET

Tuesday 3/9 3-5pm ET

Thursday 3/11 3-5pm ET

Please let me know which date/time works for you and one of our team member will send you MS teams link.

Best Regards,

Farinaz Safavi MD, PhD

Section of Infections of Nervous System

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Wednesday, March 3, 2021 11:00 PM
To: Safavi, Farinaz (NIH/NINDS) [E]; Nath, Avindra (NIH/NINDS) [E]; Wiebold, Amanda (NIH/NINDS) [E]; Smith, Bryan (NIH/NINDS) [E]
Subject: Potential SPAM:Covid-19 Vaccine Adverse Reaction

To whom this may concern,

Good evening,

My name is b6 I am a b6 that lives in b6 I am a b6 that willing received my Pfizer covid-19 vaccine b6 I have sent messages to the CDC, FDA, Pfizer, and VAERS. No answers to date from any government or pharmaceutical agencies, but I did get an acknowledgment email from VAERS. I have emailed direct person's with each agency as well, with still no answers.

I have also found information, and been in contact with others experiencing this same reaction, one of which is b6 who has been in contact with you also. All of these person's have been ignored by government and pharmaceutical agencies as well. We want to tell our stories in hopes for answers. We have gone from scared, to frustrated, and now to being angry.

I want to tell you my story...

b6 I was inoculated with the Pfizer covid-19 vaccine in my left deltoid. The day I received the vaccine I had an immediate reaction, but I didn't realize it at the time. I thought I was having a hot flash/slight panic attack. My blood pressure spiked, I was hot, felt like I couldn't breathe, and had instant heart palpitations, fast heart rate and respirations. This resulted in me being monitored an extra 30 minutes. I have never been afraid of vaccines, and willingly get the flu shot every year, so this reaction seemed "off."

In the middle of the night of b6 I woke up and thought the bed was vibrating, and I had a sharp pain in my left scapula. I tried to go back to sleep thinking that the heater kicked on and was making the wall vibrate, and that I was sleeping in a wrong position that my scapula area was sore.

I wake up b6 and as I am drinking my coffee, I notice this vibrating sensation was coming from inside me. I can feel it from my scapula down my left arm. It continues all day, so I now think I have a rib out of place and it has pinched a nerve.

I wake up b6 and the vibrations have started down my right arm as well. This continues for a few days, until I can see a chiropractor. I get in b6 get adjusted, and think I have a little relief, but it was only momentarily. That afternoon and evening still no improvement.

b6 I'm in urgent care. I am miserable at this point, because now I have vibrations running up and down my whole spine, up my neck, and still down both arms. The UC physician gives me b6 b6 tells me I'm having muscle spasms.

b6 I proceeded to the ER in the morning. I can't sleep, no appetite, constant vibrations everywhere now, tremors, and my poor family has not had b6 for days now. They do a b6 b6 Tell me to see my PCP. Well, my PCP unfortunately passed away this last year, so now I get to find someone new that knows nothing about me, and I have this weird reaction going on in my body. ER says b6 b6 refers me to see a neurologist, and sends me on my way.

Go to PCP, b6 and she prescribed me b6 Gives the referral to see the neurologist. Go to neurologist, and she says I am fine, but wants to b6 b6 I should interject, that my lower lumbar region at this time, has massive mobile and slightly tender lymph nodes present. Then she puts me on b6

Flash forward to today. I have seen the chiropractor, PCP, urgent care doctor, ER NP, and now the neurologist. No one knows what is wrong. My chiropractor is the only one that is listening to me. She is 100% with me that the covid vaccine has caused this. My other providers are not dismissing that it was the vaccine, but want to rule everything else out first. But... I was a perfectly healthy b6 with no med hx of anything, b6 b6

I had my b6 I don't think it will really show anything, but I just keep trying to get answers, or rule things out at least. I feel these vibrations all the time! It is like an electric current runs through my body. It makes me feel like I am in someone else's body. This is not the b6 I was. It has been b6 that I have had to live like this.

I have seen videos of people with the same reactions I have going on. Some are the same, some are lighter, and some are more severe. I consider myself lucky that I am in the middle of the road category. I can still do most day to day functions, as well as, be present for b6 But some days I can't do anything, because I am mentally, physically, and emotionally exhausted. Spiritually I know God is weathering this storm with me, and that he is the ultimate physician.

I tell you my story, because I am a real person, with a very real adverse reaction to the covid-19 vaccine. I need help!! I would not be pursuing so many people for help if I were not 100% certain of this. I am a b6 b6 There is a face to my name that carries multiple facets. Others have stories just like mine as well. I plead with you to listen and ask for your help. Thank you!

Sincerely,

b6

Farinaz

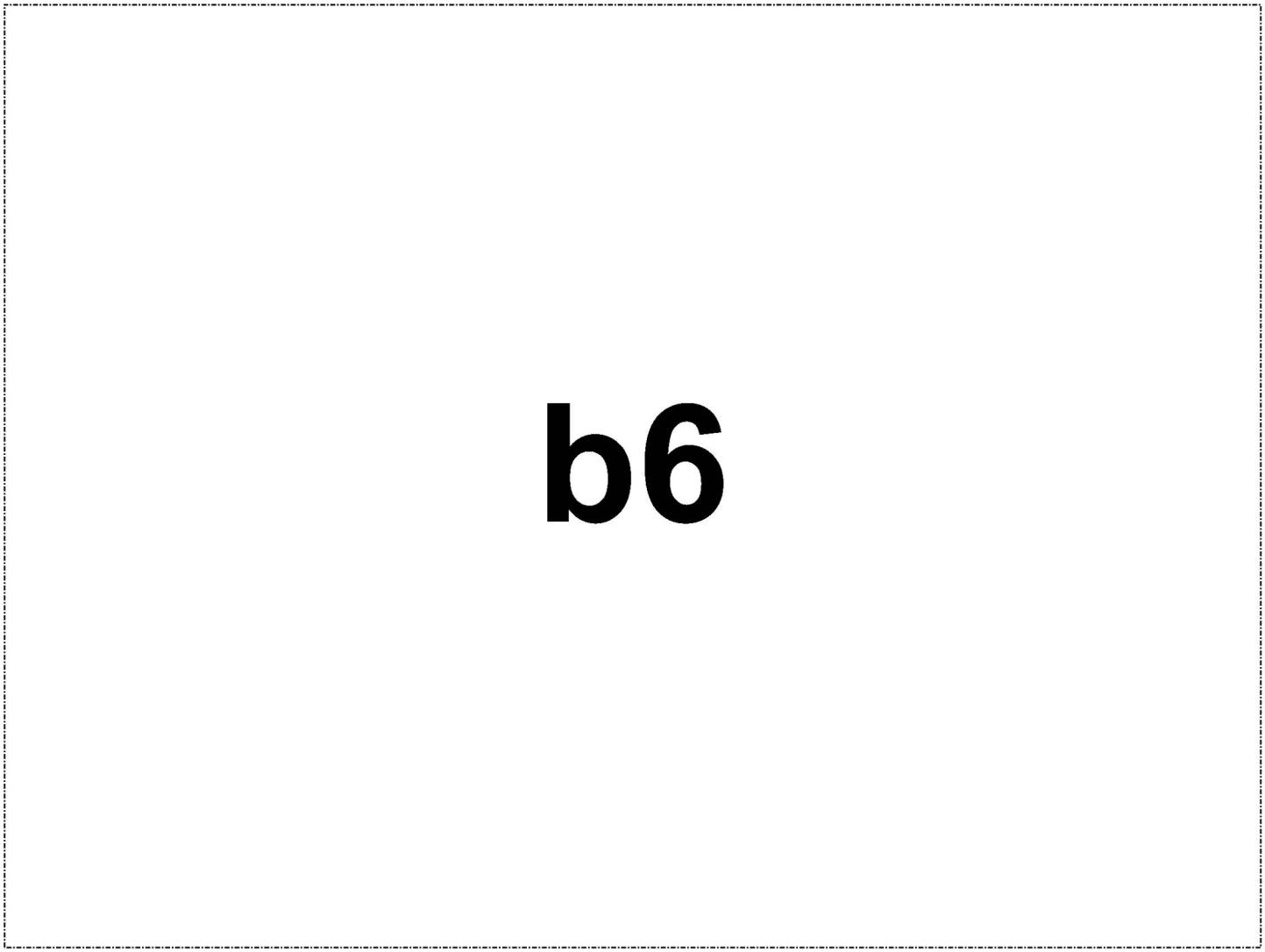
From: b6
Sent: 7/2/2021 4:24:14 PM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
Subject: Re: post vaccine patient

Good morning Dr Safavi!
I will do better at putting the numbers in next week, so it's not a picture. Lol

I am really surprised at what has changed so far. I have already b6

Also, this completely fixed my embarrasing GI issues. And I no longer feel like I have a UTI all the time... many times blood coming up in my urine. Soooooo all good things.
My POTS is still there, but the weakness and tremors are really way better.

Makes me tear up actually.
Thanks again. You are a hero in my eyes.



On Jun 28, 2021, at 1:06 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Dear b6
Hope all is well.
Can you please fill out attached scoring a week after the last one you did at NIH and send it back to me?
Thank you

Farinaz

From: b6
Sent: Monday, May 17, 2021 9:38 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Cc: Nath, Avindra (NIH/NINDS) [E]
Subject: Re: post vaccine patient

Thank you Dr Safavi

> On May 17, 2021, at 7:35 AM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:
>
> Dear b6
> We would be happy to bring you here at NIH and perform some work up and some treatment as Dr.Nath suggested in his previous email.I believe our research nurse, Amanda, will be in touch with you to coordinate next steps.
> Best
> Farinaz
>
> ---
>
> **From:** b6
> **Sent:** Monday, May 17, 2021 9:29 AM
> **To:** Nath, Avindra (NIH/NINDS) [E]
> **Cc:** Safavi, Farinaz (NIH/NINDS) [E]
> **Subject:** Re: post vaccine patient
>
> I am sorry to bother you both, as it appears you are working around the clock helping people. This must be very taxing and exhausting for you, so I very much appreciate your time.
>
> I am b6 post vax and I feel this electrical current so bad in my brain and body that I could light a light bulb. It also painful but the pain is likely something I could learn to live with. I am left with this parkinson-like tremor that is so bad at night for some reason that it's hard to roll over in bed. And other issues.

I have cut out most food in an attempt to get the vibrating head to stop...did end the Diareah. I break out in a rash for any reason, like after b6 b6 And the additional inflammation response from b6 made the strange and scary dissociation/brain fog return for a time.... which really terrifies me. I haven't felt myself since the vaccine and really just feel like glass.
I went from mountaineering the weekend before my shot and teaching my classes the day of, to what feels like my brain and body being put in a prison, struggling to walk for a time.,

I am so so afraid I am stuck this way. I have tried really hard to do everything I can to "recover". I still can't even b6 has been working from home and caring for all of us, but will be called back into work in person b6

I have no idea how to get help for this. Or what else I can do :(

b6

On May 13, 2021, at 12:19 PM, b6 b6 wrote:

We also have b6 results from b6 that we can send. b6 b6

I can upload if Amanda sends a link again.

b6

On May 12, 2021, at 9:08 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Dear b6
We have further discussed b6 symptoms. We are wondering if we should bring her to NIH for further testing and consider treatment with b6
Would that be possible?
Avi

From: b6 b6
Date: Wednesday, May 5, 2021 at 12:08 PM
To: Nath, Avindra (NIH/NINDS) [E]
b6
Subject: b6

Dr. Nath,

b6

b6 The attached pre-print shows evidence of novel antineuronal antibodies from COVID. This patient responded favorably to IVIG.

b6 remains symptomatic, now b6 Most of her testing has b6
b6 Her care teams are attempting to treat symptoms, with no response.

Your thoughts on this? Any updates from b6
b6

Thanks,
b6

https://www.biologicalpsychiatryjournal.com/action/showPdf?pii=S0006-3223%2821%2901215-4

<WHO scale.docx>

From: Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540-b6]
Sent: 1/15/2021 4:46:38 PM
To: b6
Subject: RE: NIH Study

Then I will request b6

Thank you,
Amanda

From: b6
Sent: Friday, January 15, 2021 11:41 AM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: NIH Study

We don't have access to b6 I will send the lab results and visit summaries in the next couple days.

b6

> On Jan 15, 2021, at 9:39 AM, Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:
>
> They look excellent on my end. Is there anything for me to request or are you sending me all the medical records by secure email? Is there any b6 for me to get?
>
> Thanks,
> Amanda
>
> ---
>
> **From:** b6
> **Sent:** Friday, January 15, 2021 11:33 AM
> **To:** Wiebold, Amanda (NIH/NINDS) [E] b6
> **Subject:** Re: NIH Study
>
> Amanda,
> I have attached the signed consent and records request forms.
>
> Best
> b6
>
> > On Jan 15, 2021, at 7:32 AM, Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:
> >
> > Good morning,

I will call the number below at 10:00 AM EST. I will send the secure email link shortly.

Thank you,
Amanda

From: b6
Sent: Friday, January 15, 2021 9:30 AM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: NIH Study

Amanda,

Thanks you for your email. She is available to take your call anytime 10:00-3:00 today, your time.

A secure email for medical records would be easier for us.

b6

On Jan 14, 2021, at 7:51 PM, Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

b6

I am the research nurse that works with Dr. Nath. I would be happy to go over the consent with b6 Let me know when a good time to talk on the phone would be.

I am attaching two forms.

1. The consent form. Please review prior to our telephone call. **Do not sign** it until after we talk on the phone. This will give us permission to receive specimens.
2. Medical Records Release form. Please fill out the sections highlighted in yellow and return to me. This gives us permission to request and to review your medical records.

If you have any medical records you can fax them to us directly or I can provide you with secure email access. If you have any imaging you can upload them directly following the instructions here https://www.cc.nih.gov/dcri/imaginglibrary.html.

Let me know if you have any questions.

Thanks,

Amanda Wiebold, BSN, RN, CNRN
Research Nurse Specialist
NINDS Section of Infections of the Nervous System
10 Center Drive, Building 10/7C107, MSC 1430
Bethesda, Maryland 20892
Office: b6
Cell: b6
Fax: 301-402-1137
Email: b6

b6

<15-N-0125.2.Consent.200422.pdf>
<NIH-1208 Authorization for the Release of Medical Information modified.pdf>

From: Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540-b6]
Sent: 1/15/2021 2:51:37 AM
To: b6
Subject: NIH Study
Attachments: 15-N-0125.2.Consent.200422.pdf; NIH-1208 Authorization for the Release of Medical Information modified.pdf

b6

I am the research nurse that works with Dr. Nath. I would be happy to go over the consent with b6 Let me know when a good time to talk on the phone would be.

I am attaching two forms.

1. The consent form. Please review prior to our telephone call. **Do not sign** it until after we talk on the phone. This will give us permission to receive specimens.
2. Medical Records Release form. Please fill out the sections highlighted in yellow and return to me. This gives us permission to request and to review your medical records.

If you have any medical records you can fax them to us directly or I can provide you with secure email access. If you have any imaging you can upload them directly following the instructions here https://www.cc.nih.gov/dcri/imaginglibrary.html.

Let me know if you have any questions.

Thanks,

Amanda Wiebold, BSN, RN, CNRN
Research Nurse Specialist
NINDS Section of Infections of the Nervous System
10 Center Drive, Building 10/7C107, MSC 1430
Bethesda, Maryland 20892
Office: b6
Cell: b6
Fax: 301-402-1137
Email: b6

PRINCIPAL INVESTIGATOR: Avindra Nath, MD

STUDY TITLE: Natural History Study of Inflammatory and Infectious Diseases of the Nervous System

STUDY SITE: NIH Clinical Center

Cohort: Biological Samples Only Consent

Consent Version: 03/17/2020

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Avindra Nath, MD, b6

Study Coordinator: Amanda Wiebold, RN,

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers. Taking part in research at the NIH is your choice.

If the individual being enrolled is a minor then the term "you" refers to "you and/or your child" throughout the remainder of this document.

If the individual being asked to participate in this research study is not able to give consent to be in this study, you are being asked to give permission for this person as their decision-maker. The term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research, throughout the remainder of this document.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn more about how inflammation and infections hurt the brain and nervous system so we can develop better tests and treatments for them.

BACKGROUND

Inflammation is the way your body reacts to infection or injury. Signs of inflammation can include swelling, pain, redness or heat. Infections and/or inflammation in the brain can cause major health problems. Brain infections can be hard to find sometimes because we do not always have good tests for them. Sometimes inflammation in the brain can happen and doctors do not know what caused it. We would like to learn more about how diseases work and affect the brain, so we can figure out better ways to test for them and treat them. We hope that with better and earlier testing and treatment, we can help people avoid serious health problems and death.

This consent form describes the participation of those who are sending biological samples (such as blood or spinal fluid) collected during care procedures to NIH for analysis.

STUDY POPULATION

Up to 1000 people will take part in this study.

•

PROCEDURES/STUDY OVERVIEW

Your own clinician outside of NIH will collect blood, tissue, and/or other samples from you, such as cerebrospinal fluid (CSF) as part of the care for your condition. These samples will be sent to the NIH. We may ask you to send us additional blood, urine, and/or saliva for research. We will analyze your samples using research tests to try to give you and your own clinicians more information about your illness. Your samples may be processed in new ways that cannot currently be done by your own clinicians.

Induced Pluripotent Stem Cells (iPS)

We may use your skin or blood cells to create adult stem cells, also called iPS (induced pluripotent stem) cells. Stem cells can be turned into different cell types. Studying different cell types from the iPS cells may help us better understand the conditions we are studying. The iPS cells will not be used for cloning. iPS cells cannot currently be used to grow artificial organs or organisms, but this may change in the future.

Genetic Testing

Your blood may be used for genetic research purposes. The genetic material, DNA, will be taken from the sample. Different types of genetic testing may be done, depending on your condition:

1. It may be analyzed to identify the genes that might be causing your condition. This will help us understand how changes in the genes may cause symptoms. Genetic testing can be helpful in establishing a diagnosis. It may eventually lead to improved treatment or prevention.

2. To try to identify genetic changes that may be associated with your condition we may sequence the part of the DNA that provides instructions for making proteins, called the "exome." The exome makes up about 1% of your DNA.

3. We may analyze the DNA and do "whole genome" sequencing. Whole genome sequencing provides information on most of your DNA. Sequencing takes months to complete. It may take even longer for us to analyze the results of the sequencing and to understand which genes might be involved in your condition.

After the genetic sequencing and analysis are complete, you may meet again with the study team and the genetic counselor to discuss the results. Results about known or likely disease-causing gene variations will be given to you as part of genetic counseling.

The genetic testing for this study will not detect all gene changes that are associated with known diseases. However, we will tell you if we find gene changes in your DNA that are known to have major and direct medical significance and are associated with illnesses or conditions that could benefit from early treatment. We call these "reportable gene changes." We suggest you share this information with your own doctors and that you have a clinical laboratory confirm the "reportable gene change" before you take any action on this information.

We will find individual DNA variations in everyone. We will not inform you of all gene variations, as not all of them have health implications. For example, we will not tell you about gene changes that only predispose to a particular disease--like a gene change that influences the risk for heart disease, but where the development of heart disease depends on other factors (such as diet and smoking). We will also not tell you if you are a carrier of a recessive mutation, which means that you have one copy of a recessive mutation and one copy of the normal gene, if being a carrier causes no known health problems for you.

The results from this research study will be preliminary. Further research may be necessary before they are fully understood. We do not plan to provide you with research results. However, if we obtain information that may be important for your health, we will share it with you. By participating in this study, you do not waive any rights that you may have regarding access to and disclosure of your records.

Banking and Sharing

Your blood, saliva, urine, tissue sample, spinal fluid or blood cells samples and MRI and other clinical data will be stored securely on the NIH campus. Your data and samples may be sent to a repository for storage and may be released for research purposes. Your name and identifying information will not be on the samples and data. A code will be assigned. The key to the code will be kept at NIH in a separate, secure area.

If you withdraw from this research study before it is complete, you may ask that your remaining samples be destroyed. Results obtained before you withdraw will be kept. Your privacy will be protected as much as possible.

Your blood, saliva, urine, tissue sample, spinal fluid or blood cells samples and MRI and other clinical data may be used for other research projects, including those not related to your current condition. If you do not want your samples and data used for other projects, you should not participate in this study.

RISKS, INCONVENIENCES AND DISCOMFORTS

There are minimal risks to you from sharing your samples collected by your outside clinician with us.

Genetic Testing

Genetic testing can provide information about how illness is passed on within a family. This knowledge may affect your emotional wellbeing. You might feel differently about your life if you learned that you or your children were at increased risk of a disease, especially if there were no treatment. Your children, brothers or sisters may find out that they are at risk for health problems because of your genetic information. This might affect your relationships. Other family members may also be affected by uncovering risks they did not want to know about. This information can cause stress, anxiety, or depression.

Some genetic testing shows if people are directly related. Some genetic tests can show that people were adopted or that their biological parent is someone other than their legal parent. If these facts were not known previously, they could be troubling. Genetic counseling is available at NIH to help you understand the implications of your genetic testing.

Because of the emotional risk, some people do not want to know the results of genetic testing. It is our policy to not disclose the results of research genetic testing unless it may have direct medical implications for you or your family.

Results of the research genetic testing in this study are often difficult to interpret because the testing is being done for research purposes only and the laboratories are not clinically certified.

You may be referred to a CLIA certified laboratory, possibly outside of NIH, for additional testing or confirmation of the research results. NIH will not cover the cost of the additional testing. You or your insurer will be responsible for the cost.

The results from this research study will be preliminary. Further research may be necessary before they are fully understood. We do not plan to provide you with research results. However, if we obtain information that may be important for your health, we will share it with you. By participating in this study, you do not waive any rights that you may have regarding access to and disclosure of your records.

Your genetic information will be kept confidential to the extent possible. The results of your genetic testing will be kept in a locked and secured manner at the NIH.

Banking and Sharing

We will remove any information that could identify you from data and samples that are sent to repositories or shared. Data and samples will be sent with a code. This linking code will be kept at NIH. However, there is a very small chance that the data or samples could be identified as yours.

Research using data or samples from this study may lead to new tests, drugs, or devices with commercial value. You will not receive any payment for any product developed from research using your data or samples.

ANTICIPATED BENEFITS

There are no expected direct benefits for you in this study. This study will likely increase our general knowledge of how infections and immune conditions affect the brain and will probably help us to diagnose brain infections and immune disorders earlier and manage patients better. The study results may help to develop new treatments in the future.

RIGHT OF WITHDRAWAL AND CONDITIONS FOR EARLY WITHDRAWAL

You may withdraw from the study at any time and for any reason without loss of benefits or privileges to which you are otherwise entitled. If you withdraw from this research project before it is complete, any remaining samples you have contributed will be discarded. Results obtained before you withdraw will be kept and your privacy will be protected.

CONFLICT OF INTEREST

The National Institutes of Health reviews NIH staff researchers at least yearly for conflicts of interest. The following link contains details on this process http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf. You may ask your research team for additional information or a copy of the Protocol Review Guide.

RESULTS FROM THIS STUDY

We will share the results of the tests performed in this study with you. With your written permission, we will discuss and/or send test results and a letter to your doctors.

ALTERNATIVES TO PARTICIPATION

This study does not provide treatment and you do not have to stop any treatment in order to participate. You may choose not to participate in this study, but to receive diagnostic and treatment care from your own physicians. The alternative is not to participate.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will not receive compensation for participation in this study.

Will you receive reimbursement or direct payment by NIH as part of your participation?

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

This study does not offer reimbursement for, or payment of, travel, lodging or meals.

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those

disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator Avindra Nath, MD, b6 You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR	Print Name of LAR	Date

Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study.

Signature of Parent/Guardian	Print Name of Parent/Guardian	Date

Signature of Parent/Guardian *(as applicable)*	Print Name of Parent/Guardian	Date

Assent: *(Use this section only when this process is approved by an IRB for older minors. Do not use if an IRB requires a separate assent form for this population.)*

I have had this study explained to me in a way that I understand, I have been given the opportunity to discuss it, and I have had the chance to ask questions. I agree to take part in this study.

Assent of Minor: *(as applicable)*

Signature of Minor	Print Name of Minor	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process and this English consent form has been approved by the IRB for use as the basis of translation.

Witness:

Signature of Witness*	Print Name of Witness	Date

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.

REQUEST FOR MEDICAL INFORMATION FROM SOURCE OUTSIDE THE NATIONAL INSTITUTES OF HEALTH

INSTRUCTIONS: Complete this form in its entirety and forward directly to the requesting facility.

CC PATIENT IDENTIFICATION

(Patient Name) (Patient Number) (Date of Birth)

SOURCE OF INFORMATION REQUESTED

(Name of Health Care Organization or Physician) (Phone Number) (Fax Number)

(Street Address) (City) (State) (Zip Code)

INFORMATION REQUESTED

The purpose or need for disclosure: Review of clinical care and consideration for research study

NIH Requestor/Point of Contact: Amanda Wiebold b6

Identify the specific items and related dates pertaining to the information to be released.

1. Medical Reports:

   Laboratory results, clinic notes, and brain MRI or head CT reports

   Send to: National Institutes of Health Clinical Center
   National Institute of Neurological Disorders and Stroke
   Building 10, Room 7C103
   10 CENTER DRIVE MSC 1430
   BETHESDA, MD 20892-1430
   ATTENTION: Amanda Wiebold/ Dr. Bryan Smith

   OR
   Fax to: (301) 402-1137
   Attn: Amanda Wiebold or
   Dr. Bryan Smith

2. MRI scans on CD

   Send to: National Institutes of Health Clinical Center
   National Institute of Neurological Disorders and Stroke
   Building 10, Room 7C103
   10 CENTER DRIVE MSC 1430
   BETHESDA, MD 20892-1430
   ATTENTION: Amanda Wiebold/ Dr. Bryan Smith

3. Tissue/Pathology Slides

   Send to: National Institutes of Health Clinical Center
   Laboratory of Pathology
   Building 10, Room 2B50
   10 CENTER DRIVE MSC 1500 BETHESDA,
   MD 20892-1500

AUTHORIZATION

I hereby authorize the release of the above-requested medical information.

(Signature of Patient/Legal Guardian) (Printed Name of Patient) (Date Signed)

(Street Address) (City) (State) (Zip Code)

From: b6
Sent: 1/15/2021 4:33:01 PM
To: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6
Subject: Re: NIH Study
Attachments: Scan01152021.pdf; Scan01152021-2.pdf

Amanda,
I have attached the signed consent and records request forms.

Best
b6

On Jan 15, 2021, at 7:32 AM, Wiebold, Amanda (NIH/NINDS) [E] b6 wrote:

Good morning,

I will call the number below at 10:00 AM EST. I will send the secure email link shortly.

Thank you,
Amanda

From: b6
Sent: Friday, January 15, 2021 9:30 AM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: NIH Study

Amanda,

Thanks you for your email. She is available to take your call anytime 10:00-3:00 today, your time.

A secure email for medical records would be easier for us.

b6

On Jan 14, 2021, at 7:51 PM, Wiebold, Amanda (NIH/NINDS) [E]
b6 wrote:

b6

I am the research nurse that works with Dr. Nath. I would be happy to go over the consent with b6 Let me know when a good time to talk on the phone would be.

I am attaching two forms.

1. The consent form. Please review prior to our telephone call. **Do not sign** it until after we talk on the phone. This will give us permission to receive specimens.
2. Medical Records Release form. Please fill out the sections highlighted in yellow and return to me. This gives us permission to request and to review your medical records.

If you have any medical records you can fax them to us directly or I can provide you with secure email access. If you have any imaging you can upload them directly following the instructions here https://www.cc.nih.gov/dcri/imaginglibrary.html.

Let me know if you have any questions.

Thanks,

Amanda Wiebold, BSN, RN, CNRN
Research Nurse Specialist
NINDS Section of Infections of the Nervous System
10 Center Drive, Building 10/7C107, MSC 1430
Bethesda, Maryland 20892
Office: b6
Cell: b6
Fax: 301-402-1137
Email: b6

<15-N-0125.2.Consent.200422.pdf>
<NIH-1208 Authorization for the Release of Medical Information modified.pdf>

REQUEST FOR MEDICAL INFORMATION FROM SOURCE OUTSIDE THE NATIONAL INSTITUTES OF HEALTH

INSTRUCTIONS: Complete this form in its entirety and forward directly to the requesting facility.

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b6 (Patient Name) _____ (Patient Number) b6 (Date of Birth)

SOURCE OF INFORMATION REQUESTED

b6 (Name of Health Care Organization or Physician) b6 (Phone Number) b6 (Fax Number)

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   10 CENTER DRIVE MSC 1430
   BETHESDA, MD 20892-1430
   ATTENTION: Amanda Wiebold/ Dr. Bryan Smith

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   Send to: National Institutes of Health Clinical Center
   Laboratory of Pathology
   Building 10, Room 2B50
   10 CENTER DRIVE MSC 1500 BETHESDA,
   MD 20892-1500

AUTHORIZATION

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b6 (Signature of Patient/Legal Guardian) b6 (Printed Name of Patient) b6 (Date Signed)

b6 (Street Address) b6 b6 (State) b6 (Zip Code)

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   Laboratory of Pathology
   Building 10, Room 2B50
   10 CENTER DRIVE MSC 1500 BETHESDA,
   MD 20892-1500

AUTHORIZATION

I hereby authorize the release of the above-requested medical information.

b6 b6 (Printed Name of Patient) b6 (Date Signed)

b6 (Street Address) b6 b6 (State) b6 (Zip Code)

PRINCIPAL INVESTIGATOR: Avindra Nath, MD

STUDY TITLE: Natural History Study of Inflammatory and Infectious Diseases of the Nervous System

STUDY SITE: NIH Clinical Center

Cohort: Biological Samples Only Consent

Consent Version: 03/17/2020

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Avindra Nath, MD, b6

Study Coordinator: Amanda Wiebold, RN,

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers. Taking part in research at the NIH is your choice.

If the individual being enrolled is a minor then the term "you" refers to "you and/or your child" throughout the remainder of this document.

If the individual being asked to participate in this research study is not able to give consent to be in this study, you are being asked to give permission for this person as their decision-maker. The term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research, throughout the remainder of this document.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn more about how inflammation and infections hurt the brain and nervous system so we can develop better tests and treatments for them.

BACKGROUND

Inflammation is the way your body reacts to infection or injury. Signs of inflammation can include swelling, pain, redness or heat. Infections and/or inflammation in the brain can cause major health problems. Brain infections can be hard to find sometimes because we do not always have good tests for them. Sometimes inflammation in the brain can happen and doctors do not know what caused it. We would like to learn more about how diseases work and affect the brain, so we can figure out better ways to test for them and treat them. We hope that with better and earlier testing and treatment, we can help people avoid serious health problems and death.

This consent form describes the participation of those who are sending biological samples (such as blood or spinal fluid) collected during care procedures to NIH for analysis.

STUDY POPULATION

Up to 1000 people will take part in this study.

•

PROCEDURES/STUDY OVERVIEW

Your own clinician outside of NIH will collect blood, tissue, and/or other samples from you, such as cerebrospinal fluid (CSF) as part of the care for your condition. These samples will be sent to the NIH. We may ask you to send us additional blood, urine, and/or saliva for research. We will analyze your samples using research tests to try to give you and your own clinicians more information about your illness. Your samples may be processed in new ways that cannot currently be done by your own clinicians.

Induced Pluripotent Stem Cells (iPS)

We may use your skin or blood cells to create adult stem cells, also called iPS (induced pluripotent stem) cells. Stem cells can be turned into different cell types. Studying different cell types from the iPS cells may help us better understand the conditions we are studying. The iPS cells will not be used for cloning. iPS cells cannot currently be used to grow artificial organs or organisms, but this may change in the future.

Genetic Testing

Your blood may be used for genetic research purposes. The genetic material, DNA, will be taken from the sample. Different types of genetic testing may be done, depending on your condition:

1. It may be analyzed to identify the genes that might be causing your condition. This will help us understand how changes in the genes may cause symptoms. Genetic testing can be helpful in establishing a diagnosis. It may eventually lead to improved treatment or prevention.

2. To try to identify genetic changes that may be associated with your condition we may sequence the part of the DNA that provides instructions for making proteins, called the "exome." The exome makes up about 1% of your DNA.

3. We may analyze the DNA and do "whole genome" sequencing. Whole genome sequencing provides information on most of your DNA. Sequencing takes months to complete. It may take even longer for us to analyze the results of the sequencing and to understand which genes might be involved in your condition.

After the genetic sequencing and analysis are complete, you may meet again with the study team and the genetic counselor to discuss the results. Results about known or likely disease-causing gene variations will be given to you as part of genetic counseling.

The genetic testing for this study will not detect all gene changes that are associated with known diseases. However, we will tell you if we find gene changes in your DNA that are known to have major and direct medical significance and are associated with illnesses or conditions that could benefit from early treatment. We call these "reportable gene changes." We suggest you share this information with your own doctors and that you have a clinical laboratory confirm the "reportable gene change" before you take any action on this information.

We will find individual DNA variations in everyone. We will not inform you of all gene variations, as not all of them have health implications. For example, we will not tell you about gene changes that only predispose to a particular disease--like a gene change that influences the risk for heart disease, but where the development of heart disease depends on other factors (such as diet and smoking). We will also not tell you if you are a carrier of a recessive mutation, which means that you have one copy of a recessive mutation and one copy of the normal gene, if being a carrier causes no known health problems for you.

The results from this research study will be preliminary. Further research may be necessary before they are fully understood. We do not plan to provide you with research results. However, if we obtain information that may be important for your health, we will share it with you. By participating in this study, you do not waive any rights that you may have regarding access to and disclosure of your records.

Banking and Sharing

Your blood, saliva, urine, tissue sample, spinal fluid or blood cells samples and MRI and other clinical data will be stored securely on the NIH campus. Your data and samples may be sent to a repository for storage and may be released for research purposes. Your name and identifying information will not be on the samples and data. A code will be assigned. The key to the code will be kept at NIH in a separate, secure area.

If you withdraw from this research study before it is complete, you may ask that your remaining samples be destroyed. Results obtained before you withdraw will be kept. Your privacy will be protected as much as possible.

Your blood, saliva, urine, tissue sample, spinal fluid or blood cells samples and MRI and other clinical data may be used for other research projects, including those not related to your current condition. If you do not want your samples and data used for other projects, you should not participate in this study.

RISKS, INCONVENIENCES AND DISCOMFORTS

There are minimal risks to you from sharing your samples collected by your outside clinician with us.

Genetic Testing

Genetic testing can provide information about how illness is passed on within a family. This knowledge may affect your emotional wellbeing. You might feel differently about your life if you learned that you or your children were at increased risk of a disease, especially if there were no treatment. Your children, brothers or sisters may find out that they are at risk for health problems because of your genetic information. This might affect your relationships. Other family members may also be affected by uncovering risks they did not want to know about. This information can cause stress, anxiety, or depression.

Some genetic testing shows if people are directly related. Some genetic tests can show that people were adopted or that their biological parent is someone other than their legal parent. If these facts were not known previously, they could be troubling. Genetic counseling is available at NIH to help you understand the implications of your genetic testing.

Because of the emotional risk, some people do not want to know the results of genetic testing. It is our policy to not disclose the results of research genetic testing unless it may have direct medical implications for you or your family.

Results of the research genetic testing in this study are often difficult to interpret because the testing is being done for research purposes only and the laboratories are not clinically certified.

You may be referred to a CLIA certified laboratory, possibly outside of NIH, for additional testing or confirmation of the research results. NIH will not cover the cost of the additional testing. You or your insurer will be responsible for the cost.

The results from this research study will be preliminary. Further research may be necessary before they are fully understood. We do not plan to provide you with research results. However, if we obtain information that may be important for your health, we will share it with you. By participating in this study, you do not waive any rights that you may have regarding access to and disclosure of your records.

Your genetic information will be kept confidential to the extent possible. The results of your genetic testing will be kept in a locked and secured manner at the NIH.

Banking and Sharing

We will remove any information that could identify you from data and samples that are sent to repositories or shared. Data and samples will be sent with a code. This linking code will be kept at NIH. However, there is a very small chance that the data or samples could be identified as yours.

Research using data or samples from this study may lead to new tests, drugs, or devices with commercial value. You will not receive any payment for any product developed from research using your data or samples.

ANTICIPATED BENEFITS

There are no expected direct benefits for you in this study. This study will likely increase our general knowledge of how infections and immune conditions affect the brain and will probably help us to diagnose brain infections and immune disorders earlier and manage patients better. The study results may help to develop new treatments in the future.

RIGHT OF WITHDRAWAL AND CONDITIONS FOR EARLY WITHDRAWAL

You may withdraw from the study at any time and for any reason without loss of benefits or privileges to which you are otherwise entitled. If you withdraw from this research project before it is complete, any remaining samples you have contributed will be discarded. Results obtained before you withdraw will be kept and your privacy will be protected.

CONFLICT OF INTEREST

The National Institutes of Health reviews NIH staff researchers at least yearly for conflicts of interest. The following link contains details on this process http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf. You may ask your research team for additional information or a copy of the Protocol Review Guide.

RESULTS FROM THIS STUDY

We will share the results of the tests performed in this study with you. With your written permission, we will discuss and/or send test results and a letter to your doctors.

ALTERNATIVES TO PARTICIPATION

This study does not provide treatment and you do not have to stop any treatment in order to participate. You may choose not to participate in this study, but to receive diagnostic and treatment care from your own physicians. The alternative is not to participate.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will not receive compensation for participation in this study.

Will you receive reimbursement or direct payment by NIH as part of your participation?

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

This study does not offer reimbursement for, or payment of, travel, lodging or meals.

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those

disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator Avindra Nath, MD, b6 You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

b6	b6	b6
Signature of Research Participant	Print Name of Research Participant	Date

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR	Print Name of LAR	Date

Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study.

Signature of Parent/Guardian	Print Name of Parent/Guardian	Date
Signature of Parent/Guardian *(as applicable)*	Print Name of Parent/Guardian	Date

Assent: *(Use this section only when this process is approved by an IRB for older minors. Do not use if an IRB requires a separate assent form for this population.)*

I have had this study explained to me in a way that I understand, I have been given the opportunity to discuss it, and I have had the chance to ask questions. I agree to take part in this study.

Assent of Minor: *(as applicable)*

Signature of Minor	Print Name of Minor	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process and this English consent form has been approved by the IRB for use as the basis of translation.

Witness:

Signature of Witness*	Print Name of Witness	Date

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.

From: b6
Sent: 9/19/2021 9:55:45 PM
To: Mina, Yair (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=991b96ac7afa4b5f9ec560d237ce2e76 b6
CC: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6 b6 Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540 b6 b6
Subject: Re: b6

Patient Name: b6

Email: b6
Cell Phone: b6

I would be happy to present the patient at that time and get all of your input as to the best course of management. He has had b6 b6

Thank you so much !

On Sun, Sep 19, 2021 at 3:33 PM Mina, Yair (NIH/NINDS) [E] b6 wrote:

Hi b6

Our next meeting is on Monday 10/4 **at 1pm**

Please let me know if you would be able to present the case there (a short 15-20 minutes discussion).

Regardless, you can have the patient contact Amanda so we can start the process of records release and review.

Her contact info is below.

We can also review any imaging if it is uploaded using this link

https://www.cc.nih.gov/dcri/imaginglibrary.html

Let us know

Thanks

b6

Amanda Wiebold, BSN, RN, CNRN
Research Nurse Specialist
NINDS Section of Infections of the Nervous System
10 Center Drive, Building 10/7C107, MSC 1430
Bethesda, Maryland 20892
Office: b6
Cell: b6
Fax: 301-480-5594
Email: b6

From: "Nath, Avindra (NIH/NINDS) [E]" b6

Date: Saturday, September 18, 2021 at 16:37:45
To: b6
Cc: b6 "Mina, Yair (NIH/NINDS) [E]" b6 "Wiebold, Amanda (NIH/NINDS) [E]" b6
Subject: Re: b6

Wonderful. We have a Neuro-ID/immunology case presentations every Monday at 12 noon-1 pm. One of us would need to present him to our group. A decision would then be made by the group to see if he would meet the criteria for our protocol and what the plan would be for his further workup. I have copied Yair Mina, our clinical fellow who directs the meetings. Would it be possible for you to do a brief presentation? I have also copied our research nurse who can consent the patient. Our protocol requires that the patient or their legal guardian directly contact us for that purpose.

Agree, he has some very unique findings and would be good to get to the bottom of it.

Best.

Avi

Avindra Nath MD

Chief, Section of Infections of the Nervous System

Clinical Director,

National Institute of Neurological Disorders and Stroke

National Institutes of Health, Bethesda, MD

b6 (Office)

(cell)

b6

From: b6
Date: Saturday, September 18, 2021 at 9:10 AM
To: Nath, Avindra (NIH/NINDS) [E] b6
Cc: b6
Subject: Re: b6

I will send off b6

How do I facilitate him going to see you at the NIH for a clinical appointment and testing? Should I have him contact anyone in particular and should I have him block off a number of days for testing etc?

I am so grateful for your help. He is a very special patient and I am concerned and perplexed.

Best,

b6

On Fri, Sep 17, 2021 at 10:11 PM Nath, Avindra (NIH/NINDS) [E] b6 wrote:

> That is fine. Still good to send b6
>
> Avi

From: b6
Date: Friday, September 17, 2021 at 6:04 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Cc: b6
Subject: Re: b6

Thank you so much!

b6

Should I send him to see you? This is all so new - and only since the J&J vaccine. He is a healthy athletic b6
b6

On Fri, Sep 17, 2021 at 5:26 PM Nath, Avindra (NIH/NINDS) [E] b6 wrote:

> Looks like b6
>
> b6
>
> Hope this helps.
>
> Avi

Avindra Nath MD

Chief Section of Infections of the Nervous System

Clinical Director, NINDS, NIH

Bldg 10; Rm 7C-103

10 Center Drive

Bethesda, MD 20892

b6

From: b6
Date: Friday, September 17, 2021 at 3:37 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Cc: b6
Subject: b6

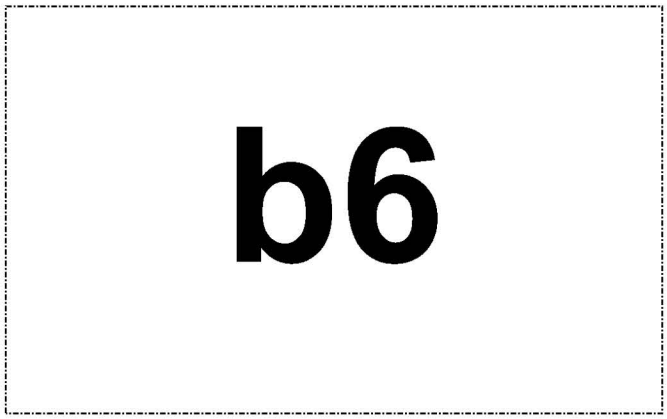
His b6 is cc'd as well.

Any guidance is most appreciated!

--

b6

--


b6

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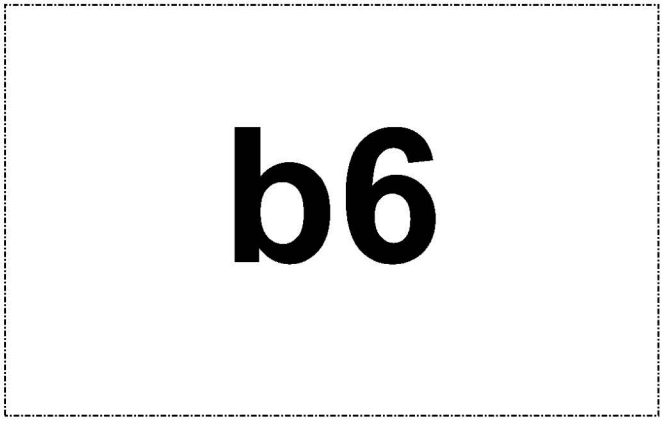
b6

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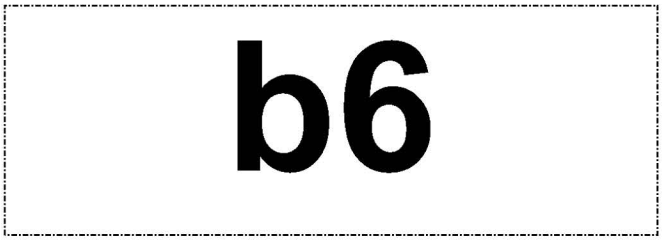

b6

From: b6
Sent: 7/12/2021 5:24:52 PM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
Subject: Re: Covid 19 Pfizer vaccine myelitis?? With stroke

Ok.

Sent from my iPhone

b6

On Jul 12, 2021, at 10:59 AM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi,
I sent you a link for Wed 4pm EST.
Thanks

Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD

From: b6
Sent: Sunday, July 11, 2021 11:16 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Covid 19 Pfizer vaccine myelitis?? With stroke

Sure
Let me know what time and mention EST or CST.

Also just wondering if you had a chance to discuss with b6

b6

On Sun, Jul 11, 2021 at 9:16 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Dear b6

I was under impression that my 2pm meeting is for one hour but actually it is a two hour meeting. Can we schedule our televisit for Wed afternoon? I am flexible after 2pm EST

Please let me know.

Thanks

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

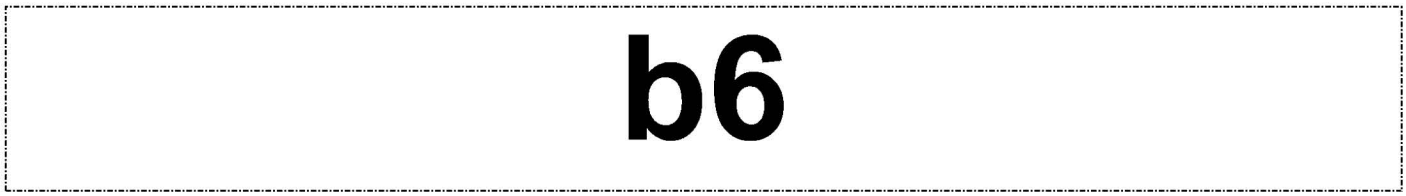
NINDS, NIH, Bethesda, MD

From: b6
Sent: Friday, July 9, 2021 10:57 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Covid 19 Pfizer vaccine myelitis?? With stroke

Ok 3pm ESt.

My number is b6 in case televise system is not working well.

Sent from my iPhone



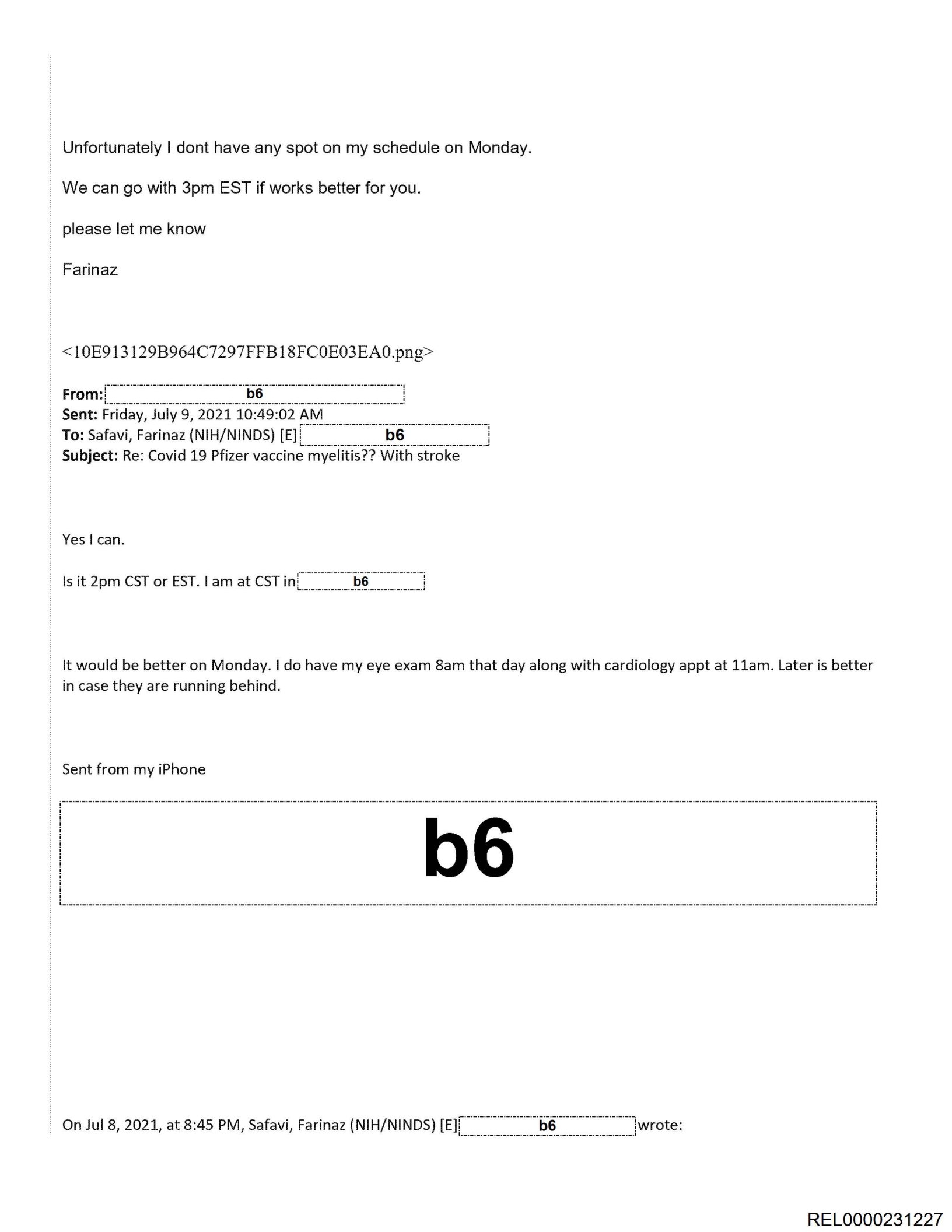
On Jul 9, 2021, at 9:52 AM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Unfortunately I dont have any spot on my schedule on Monday.

We can go with 3pm EST if works better for you.

please let me know

Farinaz



From: b6
Sent: Friday, July 9, 2021 10:49:02 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: Covid 19 Pfizer vaccine myelitis?? With stroke

Yes I can.

Is it 2pm CST or EST. I am at CST in b6

It would be better on Monday. I do have my eye exam 8am that day along with cardiology appt at 11am. Later is better in case they are running behind.

Sent from my iPhone

b6

On Jul 8, 2021, at 8:45 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Dear b6

I am sorry for your illness.We can schedule a televisit to speak about your disease. Does next Tuesday afternoon at 2pmnwork for you?

Thank you

Farinaz

<10E913129B964C7297FFB18FC0E03EA0.png>

From: b6
Sent: Thursday, July 8, 2021 11:52:16 AM
To: Nath, Avindra (NIH/NINDS) [E]
Cc: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Covid 19 Pfizer vaccine myelitis?? With stroke

b6

Thanks.

I can be reached at b6 cell

Or my husband number b6

I went ahead and b6 and starting to feel Better in terms of neurological symptoms. R. Sided paresthesia gone after 3 hrs. My brain feels "clearer" weird?. Usually last time, b6 my motor and balance symptoms were minimal. However dyspnea with mild exertion and heart arrhythmia were major issues with b6 b6

Sent from my iPhone

b6

On Jul 7, 2021, at 8:50 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Dear b6

Sorry to hear of all your symptoms and for the difficulty in getting an appointment at b6 I have copied Dr. Safavi who is a clinical fellow working with me. She has kindly agreed to talk to you to get a better understanding of your illness and then see what we might be able to do to help.

Best wishes.

Avi

From: b6
Date: Wednesday, July 7, 2021 at 5:47 PM
To: b6
Cc: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Re: Covid 19 Pfizer vaccine myelitis?? With stroke

Hi

I am following up with new information for urgent appt to get treatment :

1)

2) b6

3)

4) as I b6 my L.hip sacroilitis pain started coming back with L.LE and LUE, L.eye and check feels tight and walking not as smooth in terms of gait and balance.

5) one rash on R. Hand with blister noted on index finger b6

Sent from my iPhone

b6

b6

On Jun 14, 2021, at 10:18 AM, b6 wrote:

Hi

I am b6 I am reaching out as b6 b6 with assistance of Infectious Disease. No one could figure out here since b6 I had to read myself and collaborate with ID and neurology. They are trying their best since this episode of b6 **My impression was combination of reactivation of dormant germ as well as autoimmune mimicry molecule neuropathy/vasculitis since** stabbing burning migratory paresthesia was Post vaccine only while erythema multiforme like Bullae (2) I had one time before vaccine b6 post diarrhea but after vaccine every month or so with weakness/fatigue all over. However in b6 it was intense and I was non functional with hand and feet stiffness and pain of PiP joints unable to make a fist properly. Had to take b6 to be functional.

For symptoms and summary of case, please read attached email I sent to Dr Avindra Nath**. Main issue is ongoing stabbing burning migratory paresthesia left greater than right with additional L. Sided "cold sensation" and spasticity on left LUE and LLE and endurance 30 min walking (before fatigue & HA sets in) after the** b6 **event.** Since he has b6 and I was having problems reaching directly to your team, on my request he has been kind to provide me your contacts for sooner than later assistance before further deterioration And prevent another major event like paralysis.

As an update, working diagnosis is b6

b6

Second working diagnosis is b6
My ID has setup b6
b6 My symptoms are waxing and waning still but more prominent on left head to feet. Now additional intermittent "itchiness" has developed with typical rash papular where I scratch. It is not erythema multiforme like.

I will appreciate if a quick either hospital admission or outpatient appointment is setup for management of this. I will appreciate if we can have telephone conversation sooner than later. I can be reached at b6 Cell.

Hoping for an early reply.

Sent from my iPhone

b6

b6

Begin forwarded message:

From: "Nath, Avindra (NIH/NINDS) [E]" b6
Date: May 31, 2021 at 10:31:43 PM CDT
To: b6
Subject: Re: Covid 19 Pfizer vaccine myelitis??

Dear b6

Sorry to hear of your illness. We have seen several patients with neurological complications following the COVID vaccine. Some have responded to treatment b6 Wonder if you might consider such intervention

Avi

From: b6
Date: Monday, May 31, 2021 at 10:44 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Covid 19 Pfizer vaccine myelitis??

Hi

I wonder if you remember me. I had discussed with you about b6
b6

Guess what! I may need a personal favor about me. I am b6
b6

Recently on b6, I developed suddenly L.sided "heaviness" with mild weakness with spasticity (endurance) from head to toe with neck stiffness and some immediate memory of "names". I already had ongoing waxing-waning stabbing-burning patches that were migratory on my bilateral UE and LE since 4th day of my Pfizer #1 vaccine on b6 b6 However this time 2 days before that my above paresthesia had increased to trunk, neck, face and head on left side.

History is that right at 24hrs after #1 vaccine I suddenly developed total weakness all over and somnolence, unable to continue to type or walk with foggy brain. I took b6 and slept for 2hrs in my office and felt fine. But at day 4, developed migratory and fleeting stabbing-burning paresthesia patches on my UE and LE but no motor function issue. Looking back I do have issues in memory of names (recalling a name) but could be age. Other complication is that I get these weird initially bulae 1-2 on my LLE which became bil UE in b6 and then b6 I had it on my upper Thorax near neck.

I improved with b6 but not resolved totally in 48hrs.

However the bulae 1-2 occurred before the vaccine but I was b6 First occurred since b6 post severe gastroenteritis (woken from sleep) with nausea b6 or so. So I got tested since I still had issues and found b6 or so. I kept having 1-2 blisters/bulae that I would find during shower since warm water would make it sting and forced me to see. I also had episode of b6

So in short, I felt I have reactivation of done "dormant infection" causing recurrent blister and an autoimmune mimicry molecule attacking my nervous system.

Here are some timelines>>>

-migratory paresthesias started only after vaccine day 4 b6 after extreme weakness 24hrs.

-However blisters/bulae first time occurred b6 after severe diarrhea and after that intermittently occurred from b6 w/o diarrhea issues.

- b6

-Severe Diarrhea with nausea needing hospitalizations First occurred b6 (moved to new city and drank tap water or ate fruit??) almost every month until b6 when I b6 I didnot have any episode for 1 year until b6 when workup confirmed b6 No diarrhea after that.

Hope to hear soon as to which direction to go for further workup. I really had to steer this myself with ID and neurology. I have been reading extensively since b6 I am in the process of b6
b6 Hopefully I can sort my personal adverse event

from Pfizer (I anticipated due to b6 as we continue thinking out of box. Working diagnosis is b6

b6

Hope to hear from you soon and help me link to right time to figure this before it worsens or I get paralyzed.

Sent from my iPhone

b6

b6

From: b6
Sent: 4/19/2021 8:10:33 PM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
Subject: Re: COVID Vaccine Side Effect Potential

Perfect, thank you. I will do so, sorry I didn't have it to bring.

Sent from my iPhone

On Apr 19, 2021, at 4:07 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Great.Since we need the actual CD,it might be better you pick it up when you can and directly send it to us.
We will coordinate with you when you have it.
Thank you

Farinaz

From: b6
Sent: Monday, April 19, 2021 4:01:57 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: COVID Vaccine Side Effect Potential

Yes, definitely. I will request right now - should I have them sent to your attention?

Sent from my iPhone

On Apr 19, 2021, at 3:01 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

I dont think so we need b6 to upload it in our system.Can you request it from medical records and mail it to us later if you can not get it now with the short notice.
Farinaz

Farinaz

From: b6
Sent: Monday, April 19, 2021 2:56:44 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: COVID Vaccine Side Effect Potential

Hi Dr. Safavi,

I don't have a CD with b6 but I do have access to the records from b6 I signed the form and sent through to share data. Is there a way I can have b6 forward to you?

Thanks
b6

Sent from my iPhone

On Apr 19, 2021, at 2:46 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6
I just wanted to make sure you bring your b6 CD with you when you come to NIH If Amanda has not told you yet.
tahnk you
Best

Farinaz

From: b6
Sent: Tuesday, April 6, 2021 9:58:17 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Cc: b6
Subject: Re: COVID Vaccine Side Effect Potential

Great, I sent it to my work email as well - Teams is connected to that email, so I will join from there - in case you need it b6 See you at 3pm.

Thanks,
b6

On Tue, Apr 6, 2021 at 9:33 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

> Fantastic!Will send you Microsoft Teams link shortly.
>
> Farinaz Safavi MD, PhD
>
> Division of Neuroimmunology and Neurovirology
>
> NINDS, NIH, Bethesda, MD

From: b6
Sent: Tuesday, April 6, 2021 9:31 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Cc: b6
Subject: Re: COVID Vaccine Side Effect Potential

I am pretty open this afternoon as well, let's do 3pm if that works.

Thanks,

b6

On Tue, Apr 6, 2021 at 9:25 AM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6

Thank you very much for contacting me. We have started a research effort at NIH to look into neurological complications of COVID vaccine. It would be great if we can meet through the televisit and discuss your symptoms. I have an availability today after 3pm ET. What time works for you?

Please let me know

Farinaz Safavi MD, PhD

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Tuesday, April 6, 2021 9:16 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: COVID Vaccine Side Effect Potential

Hi Dr. Safavi,

My neurologist b6 at b6 b6 recommended reaching out to you regarding my recent potential reaction to the COVID vaccine. He noted you may be interested in speaking to me directly and taking some additional blood work etc. I am happy to help and provide you access to any of my information if it would help with your research.

Please feel free to reach out. You can reach me at this email b6 or call me at b6 b6

Kind Regards, b6

From: b6
Sent: 4/19/2021 8:44:49 PM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
Subject: Re: Vaccine adverse event

Hi Dr. Safazi, I have reached out to my neurologist, b6 and am waiting to hear back from him so you two can be in contact.

Also, I wanted you to know that I would be willing to travel to Bethesda if need be. I am desperate to get better and coming up there would be no big deal for any further diagnostic studies or possible treatments, especially if there are any issues doing it here in b6

Thanks so much for all your help.

b6

From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: April 19, 2021 12:30 PM
To: b6
Subject: RE: Vaccine adverse event

I will send you a MS teams link now.
Thanks

Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD

From: b6
Sent: Monday, April 19, 2021 3:29 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Vaccine adverse event

Yes, I am free the rest of this afternoon and also anytime after 3 tomorrow or 1 Wednesday.
b6

Sent from my iPhone

> On Apr 19, 2021, at 3:10 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:
>
> Hi b6
> Can we shortly speak about your condition?
> When do you have time?

Farinaz

From: b6
Sent: Monday, April 19, 2021 3:06 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Vaccine adverse event

Hi Dr. Safazi,

I signed a release form and gave it to Amanda, this will allow b6 to send you the b6 I was also wondering how long the b6 usually take to get results?

I saw Rheumatology last week. My b6 although I am so far not meeting full criteria for b6 diagnosis. b6 He sent b6 to further evaluate for b6 b6 He noted b6 I am b6 which has helped a bit with fatigue and the leg pain, but also seems to exacerbate pain. I'm currently b6 I am staying here until we get the rest of the results and can figure out a treatment plan. I will keep you updated and share records as they come in.

Thanks for your help,

b6

<AA5709D6DEDF499487845A6EF648A70E.png>
From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: April 15, 2021 3:25 PM
To: b6
Subject: Re: Vaccine adverse event

Dear b6
My apologies for delayed respond and sorry to hear that your symptoms have not improved.
I think getting a full Rheum work up is important to make sure we are not missing any other inflammatory diseases that has been unmasked by vaccination.
If Rheum agrees that your symptoms can not be explained by any other diseases then we can attribute to an immune mefiated disease happens post vaccination.
We currently think if no other disease explain the symptoms,it can be due to antibody mediated process to subunits of spike protein. However, this is just hypothetical thought.In that case glucocorticoid may help.

Can you by any chance send us your b6 we may be able to do some further staining.

Please let me know,If I can be any help.
I would be more than happy to speak with your physicians and share our thoughts.

Best

Farinaz
<AA5709D6DEDF499487845A6EF648A70E.png>
From: b6
Sent: Monday, April 12, 2021 4:34:22 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: Vaccine adverse event

Hi Dr Safazi,

I was meaning to email you today, unfortunately my b6 I will upload my report.

I had been doing a bit better and had gone back to work. I had a bad stomach virus about 2 weeks ago and seemed to recover fine. Over the past week I started having severe fatigue. It got to the point on Thursday that I couldn't function at work. My husband had to come get me because I was so weak, they took me to his car in a wheelchair.

I am having joint pain in my feet, left knee, hips and back. My legs feel tired and sore all the time as do my upper back and shoulders. I am trying to see rheumatology this week. If I walk around the house or get up for more than a few hours, I hit the wall of fatigue and have to go to bed.

I think i mentioned that I had b6

b6

I suspect b6 but will need labs done first. I am b6 and quite concerned. I do have neuropathy but it is intermittent. I never had neuropathy before the vaccine.

Any thoughts from you would be much appreciated. I'm definite quite concerned about my relapse. My b6 isn't really bothering me much, but the profound fatigue and body pain is worse in many ways.

Take care,

b6

Sent from my iPhone

> On Apr 11, 2021, at 10:59 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:
>
> Dear b6
> Hope all is well and your symptoms have recovered completely.I remeber you told me about b6 and wondering what was the results for b6
> Really appreciate if you let me know.
> Thank you
>
> Farinaz

<F60D8295E91F48448F4B42FAE3845839.png>
From: b6
Sent: Friday, March 26, 2021 10:44:25 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: Vaccine adverse event

Hi Farinaz,

Thank you for the recommendation. I have already heard from your assistant. I appreciate the recommendations!

Take care,

b6

Sent from my iPhone

On Mar 26, 2021, at 10:42 AM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Hi b6
It was nice talking to you yesterday. Following our discussion, I was thinking I may check b6 to make sure we do not miss anything but of course I leave it to you and your providers.

b6

Our research nurse is already aware and get back to you(if she has not already) for paperwork.
Please let me know if I can be any help.
Best
Farinaz

Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD

From: b6
Sent: Thursday, March 25, 2021 2:11 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Vaccine adverse event

Okay wil try

Sent from my iPhone

On Mar 25, 2021, at 2:04 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

It seems that you can connect to teams.How about you leave and join again?

Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD

From: b6
Sent: Wednesday, March 24, 2021 1:37 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Vaccine adverse event

Sounds great, thanks! I look forward to it

Sent from my iPhone

On Mar 24, 2021, at 1:35 PM, Safavi, Farinaz (NIH/NINDS) [E]
b6 wrote:

Lets meet at 2pm.I have another patient at 3pm.
I can send you the link

Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD

From: b6
Sent: Wednesday, March 24, 2021 1:32 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: Vaccine adverse event

Hi there, if a later time is available (2:30 onwards) that would be great. If not, I

will make 1:30 work. Please let me know.

Thank you so much, I look forward to speaking with you.

Thank you,

b6

Sent from my iPhone

On Mar 24, 2021, at 1:10 PM, Safavi, Farinaz (NIH/NINDS) [E] b6 > wrote:

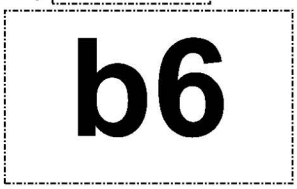
Dear b6
I am really sorry to hear about your symptoms and illness.I would be happy to speak with you and go through your course of disease and see how we can help.
Can we talk tomorrow at 1:30pm ET?
Please let me know.
Farinaz

Farinaz Safavi MD, PhD
Division of Neuroimmunology and Neurovirology
NINDS, NIH, Bethesda, MD

From: b6
Sent: Tuesday, March 23, 2021 10:20 PM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Vaccine adverse event

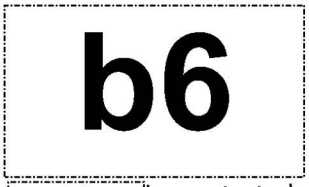
> Hi Dr Safazi
>
> I got your info from a colleague who also has had issues since the covid vaccine.
>
> I am a b6 b6 in b6 I received the Pfizer vaccine on b6 and b6 Immediately after each vaccine I had flushing, tachycardia, mildly elevated BP, and dizziness. It lasted about an hour the first time. The second time I anticipated the reaction and thought maybe the first time was due to anxiety. I had the fishing again and laid down to let the tachycardia settle. It lasted 20 min. I got up and left and then it started again much more severely while I was driving home.
>
> I felt achy and had brain fog for a few days after the 2nd shot. A few days later b6 b6 I am not sure if I myself contracted it. Over the next 2 weeks I felt severely fatigued, brain fog, nausea, diarrhea. I then started having severe flushing and tachycardia episodes along with diarrhea. I had two severe episodes at work and was taken by ambulance to b6

My b6



>

> I have seen cards and been diagnosed with

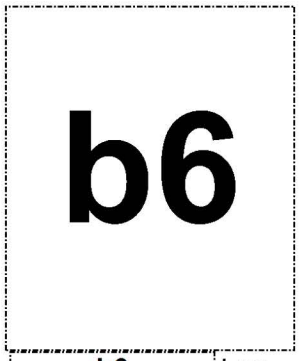


b6 I was started on b6

b6 I ended up taking b6 b6 which helped reduced the flushing and tachycardia at rest.

>

> I continue to have intermittent neuropathy in my feet. b6 I am awaiting results of



b6 I am having b6 tomorrow due to some facial numbness I have had.

>

> I had to take b6 b6 due to the severity of my symptoms. b6 b6 b6 but I still struggle with b6 b6

neuropathy, fatigue, diarrhea, and other vague symptoms.
>
> I am hoping you can help me or shed light on this reaction. I am desperate to get my life back.
>
> Thank you for taking the time to read my email.
>
> Sincerely,
>

>
>
> Sent from my iPhone

From: b6
Sent: 8/31/2022 1:14:35 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6-b6
CC: Marques, Adriana (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=014a21e4bacf454a8399589cbab58d3c-b6
Subject: Re: [EXTERNAL] NCT02435810, 150125, Inflammatory and Infectious Diseases of the Nervous System

Hello Dr Avi, Dr Marque
Thank you very much for your very kind response and recommendations to see Dr Marque. She looks to be a top expert in her field and I am hopeful she can help to solve some of these life changing health challenges the infections have caused.
I look forward to her response and further directions?
Sincerely
b6

Sent from my iPhone

On Aug 30, 2022, at 10:49 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Dear b6
Sorry to hear of your illness. I have copied Dr. Marque who is an expert in tick borne illnesses to see if she might be able to help.
Tick borne illnessess are out of my area of expertise.
Best.
Avi

From: b6
Date: Tuesday, August 30, 2022 at 7:59 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: [EXTERNAL] NCT02435810, 150125, Inflammatory and Infectious Diseases of the Nervous System

Hello
My name is b6 I am b6 living in the b6 area.
I had seen the study underway on Inflammatory and Infectious disease of the nervous system.
I have struggled with my health on and off for a number of years. Approximately 10 years ago I came down with a mystery illness that flattened me. So many strange symptoms all over and neurological issues. After a number of years I was diagnosed with b6
b6 I went under treatment for a number of years.
We had been living in the b6 went through a recovery program with b6
I had been very active volunteering with b6
b6 Training my Golden Retriever to be a volunteer therapy dog (walk 2 plus miles day) Pilates and watching my grand children.
I was bitten again by a tick about a year or two ago and started experiencing many strange symptoms again. b6 In b6 of 2022 I had a severe reaction to a J&J Vaccine Booster terrible vertigo, shortness of breath, heart pvc, fatigue, b6 balance issues, neurological over reaction to everything in your everyday life. I had seen many specialists had many tests. In March tested positive for b6

b6 with many long haul symptoms now also b6
I now am left with a severely over reactive nervous system, vertigo, balance, shaking, chills, over reactive lights, stores, people, extremely fatigued, severe headaches all over and base of neck, low grade fever on and off. Severe inflammation in body and brain. Also b6 b6
I have b6 extensive testing at b6 last year was normal. I'm b6 No other major illnesses or conditions.
I have unfortunately had to give up most of the things I love doing because I'm so ill.
I believe these number of b6 and long Covid may make me a possible candidate for your study due to the enormous neurological problems they have caused.
Sincerely,
b6

I

Sent from my iPhone

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

From: b6
Sent: 5/6/2021 2:29:42 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6-b6
Subject: Re: Novel anti-neuronal antibodies

Dr. Nath,

Sorry to bombard you with information. I came across a review article that may shed some light on the pathophysiology of COVID, it's connection to "long hauling" and potentially to vaccine reactions. I have speculated that the common thing with each was the spike protein. Science is discovering that the free spike protein is pathogenic by itself. Please review the attached article. Potential treatments could include a class of drugs already FDA approved, the angiotensin receptor blockers (ARBs) several clinical trials are listed, proposing ARBs as treatments for acute Covid.

Respectfully,

b6

On May 5, 2021, at 8:43 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Sorry, for not getting back to you. Let me look into it further and then get back to you.
Avi

From: b6
Date: Wednesday, May 5, 2021 at 12:08 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Novel anti-neuronal antibodies

Dr. Nath,

b6
b6 The attached pre-print shows evidence of novel antineuronal antibodies from COVID. This patient responded favorably to IVIG.

b6 remains symptomatic, now b6 Most of her testing has b6
b6 Her care teams are attempting to treat symptoms, with no response.

Your thoughts on this? Any updates from b6

Thanks,
b6

https://www.biologicalpsychiatryjournal.com/action/showPdf?pii=S0006-3223%2821%2901215-4

From: b6
Sent: 5/6/2021 2:30:20 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6-b6
Subject: Re: b6
Attachments: ACE2-Spike .pdf

Failed to attach.

On May 5, 2021, at 8:43 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Sorry, for not getting back to you. Let me look into it further and then get back to you.
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Thanks,
b6

https://www.biologicalpsychiatryjournal.com/action/showPdf?pii=S0006-3223%2821%2901215-4

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https://doi.org/10.1186/s41231-020-00067-w

Translational Medicine Communications

REVIEW Open Access

Identifying pathophysiological bases of disease in COVID-19

Carla J. Goldin[1,2], Ramiro Vázquez[3,4], Fernando P. Polack[1] and Damian Alvarez-Paggi[1,2*]

Abstract

COVID-19 is an infectious disease caused by the SARS-CoV-2 virus that can affect lung physiology encompassing a wide spectrum of severities, ranging from asymptomatic and mild symptoms to severe and fatal cases; the latter including massive neutrophil infiltration, stroke and multiple organ failure. Despite many recents findings, a clear mechanistic description underlying symptomatology is lacking.

In this article, we thoroughly review the available data involving risk factors, age, gender, comorbidities, symptoms of disease, cellular and molecular mechanisms and the details behind host/pathogen interaction that hints at the existence of different pathophysiological mechanisms of disease. There is clear evidence that, by targeting the angiotensin-converting enzyme II (ACE2) –its natural receptor–, SARS-CoV-2 would mainly affect the renin-angiotensin-aldosterone system (RAAS), whose imbalance triggers diverse symptomatology-associated pathological processes. Downstream actors of the RAAS cascade are identified, and their interaction with risk factors and comorbidities are presented, rationalizing why a specific subgroup of individuals that present already lower ACE2 levels is particularly more susceptible to severe forms of disease. Finally, the notion of endotype discovery in the context of COVID-19 is introduced.

We hypothesize that COVID-19, and its associated spectrum of severities, is an umbrella term covering different pathophysiological mechanisms (endotypes). This approach should dramatically accelerate our understanding and treatment of disease(s), enabling further discovery of pathophysiological mechanisms and leading to the identification of specific groups of patients that may benefit from personalized treatments.

Keywords: SARS-CoV-2, COVID-19, Pathophysiology, RAAS, Risk factors, Comorbidities, Endotypes

Introduction

The recently described SARS-CoV-2 virus is the latest addition into the group of pathogenic human coronaviruses (HCoV). The *Coronavirinae* subfamily encompasses four different genera: *alpha, beta, gamma* and *deltacoronavirus*. The genetic and serologic groups *alfa-* and *betacoronavirus* includes pathogens that mainly infect mammals (except pigs) [1]. The normally circulating 229E and NL63 are *alphacoronaviruses* whereas OC43 and HKU1 are *betacoronaviruses*. During the last twenty years, three additional HCoVs from zoonotic origin have surfaced: SARS-CoV, MERS-CoV and SARS-CoV-2,all belonging to the *betacoronavirus* genus. While the usual HCoV are normally associated with common cold symptoms, these last pathogens may elicit infections that range from asymptomatic carrier to severe pneumonia, leading to acute respiratory distress syndrome (ARDS). A common feature of SARS-CoV and SARS-CoV-2 is that viral attachment occurs via interaction of the viral spike (***S***) protein —which is primed by the Transmembrane Serine Protease 2 (TMPRSS2)— to the host angiotensin-converting enzyme 2 (ACE2), allowing viral entry [2, 3]. Interestingly, this feature is shared with the NL63 HCoV, while the other HCoVs employ different receptors such as dipeptidyl peptidase 4 and aminopeptidase N [4]. The ***S***/ACE2 interaction gives place to a cross-talk point between viral infection and the renin-angiotensin-aldosterone

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system (RAAS), and there is mounting evidence that this interplay may crucially affect disease severity (see below).

SARS-CoV-2 causes COVID-19, a disease that presents a wide range of clinical manifestations, from asymptomatic to severe ARDS and may result fatal due to respiratory insufficiency, stroke, thrombotic complications [5] and, finally, multi organic failure [6]. Although an accurate mechanistic description is lacking, it is proposed that an uncontrolled and excessive release of pro-inflammatory cytokines (called "cytokine storm") may cause some of the symptoms, including shock and tissue damage, and massive neutrophil infiltration [7]. Current consensus is that older people, immunocompromised or patients with significant underlying conditions and co-morbidities such as diabetes and hypertension are more likely to experience severe COVID-19 symptoms [8].

Assessment of the mechanisms underlying SARS-CoV-2-induced disease and severity has focused mainly on the immunopathological features [7, 9, 10], and have resulted in some unexpected findings: the unusual seroconversion processes involving IgM and IgG titers among infected patients [11], the age-dependent cytokine storm-induced reduction and functional exhaustion of $CD4^+$ and $CD8^+$ T cells —both critical to eliminate virus-infected cells and for achieving successful recovery [12]—, and the possible link between severity and genetic variations in chemokine receptors and blood group loci [13], among others. These findings clearly hint at the existence of distinct pathophysiological bases of disease in COVID-19. In addition, other actors have been identified or proposed, such as endocrine and metabolic pathways [14] and the role of infected endothelial cells [15] in disease severity. However, a comprehensive and cohesive evaluation of these factors is lacking. In the following sections, we present a detailed review attempting to identify molecular bases of disease severity based on the specifics of host/pathogen interplay, with an emphasis on the endocrine-immune interactions involved. Finally, we speculate that COVID-19 is actually an umbrella term that includes several pathophysiological mechanisms, known as endotypes, originated in the individual-specific host/pathogen interactions, which simultaneously depend on the functional status of the RAAS.

The entry point of SARS-CoV-2: ACE2 and TMPRSS2

ACE2 is a central component of the RAAS

The coronaviruses SARS-CoV, SARS-CoV-2 and NL63-CoV rely on binding of their ***S*** protein to ACE2 [2, 16] for attachment and cell entry, being able to infect many of the organs where it is expressed [17–19]. Human ACE2 is a transmembrane enzyme that contains different functional domains: a *C*-terminal anchoring region, a *N*-terminal signal peptide region, and an extracellular HEXXH zinc-binding metalloprotease domain [20–22]. ACE2 is a member of the RAAS, that involves a variety of hormones and enzymatic reactions whose primary role consists of regulating the homeostasis of the cardiovascular and renal systems [23, 24], playing also a critical function in inflammatory response [25]. This system consists of two main axes: the classic angiotensin-converting enzyme (ACE)-angiotensin II-AT1 receptor, and the ACE2-angiotensin-(1–7)-Mas receptor axis, that was discovered rather recently (Fig. 1).

Both ACE and ACE2 are found in the cytoplasmic membrane of arterial and venous endothelial cells, and arterial smooth muscle cells [26, 27]. ACE2 is expressed in several organs such as the heart, kidney, lung and testes, among others [17, 19]. In particular, it is present in human nasal epithelium, alveolar and small intestinal cells [28]. ACE and ACE2 have been largely studied as pivotal members of the RAAS. As shown in Fig. 1, they play antagonistic roles by processing the renin-cleaved decapeptide angiotensin both competitively or in an alternate fashion. The main role of ACE2 is countering ACE activity by reducing angiotensin 2 (AngII) —a potent vasopressor and sodium-and-water retaining octapeptide— bioavailability and increasing angiotensin-(1–7) (Ang-(1–7)) formation —a vasodilator and diuretic peptide—, although alternative catalytic pathways exist [29–31]. In this context, an imbalance in ACE2/Ang-(1–7) and ACE/AngII axes may be critical in the development of cardiovascular diseases [32]. Activation of the ACE-mediated classic axis leads to deleterious effects: vasoconstriction, fibrosis, migration, fluid retention, thrombosis and inflammation; on the other hand, the ACE2-centered via exerts protective vasodilation, and antithrombotic, antiarrhythmic and anti-inflammatory actions [33, 34].

S induces downregulation of ACE2 after complex formation

The extracellular domain of ACE2 can be cleaved from the transmembrane domain by at least two different enzymes, ADAM metallopeptidase domain 17(ADAM17) and TMPRSS2, and the resulting soluble protein is released into the bloodstream and ultimately excreted into urine [3, 35]. TMPRSS2 is a type II transmembrane serine protease expressed in the airway epithelial cells and several tissues. It participates not only in SARS-CoV-2 infection, but is also required by other respiratory viruses such as human influenza and metapneumoviruses [36, 37]. TMPRSS2 increases the infective capacity of both NL63 ***S***- and SARS CoV ***S***- pseudotyped HIV as well as authentic SARS-CoV and SARS-CoV-2, even in cells with low levels of ACE2 expression, inducing ACE2 shedding and thereby loss of its physiological

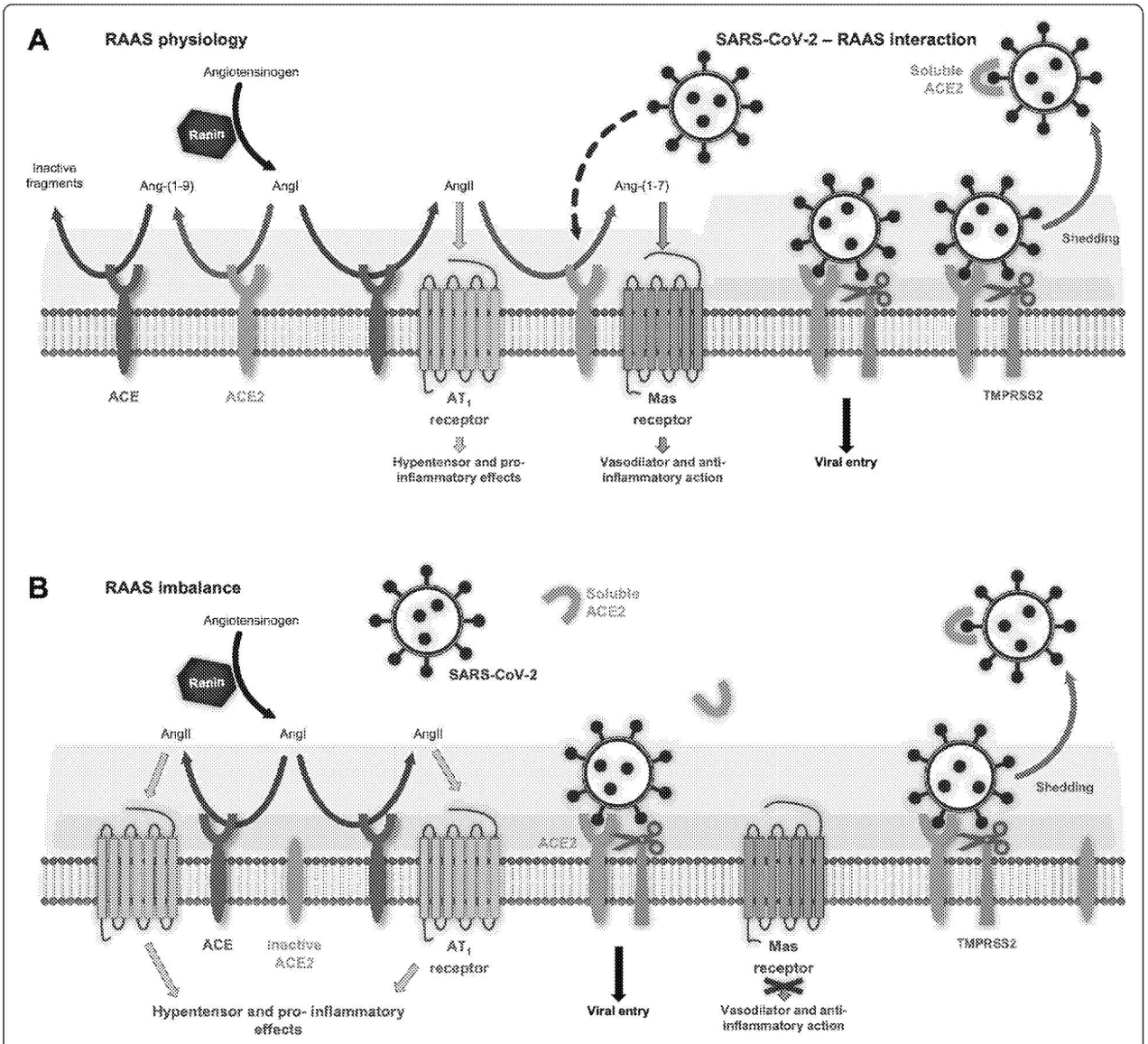

Fig. 1 **a** Key pivotal modulating and antagonistic roles of ACE and ACE2 in the RAAS, and SARS-Cov-2 binding to ACE2 and TMPRSS2. ACE catalyzes the conversion of AngI into AngII, thereby inducing hypertensive and pro-inflammatory effects, while ACE2 mediates the formation of angiotensin-(1–9) from AngI. ACE2 also counters ACE activity by reducing AngII bioavailability and increasing Ang-(1–7) formation, which acts as a vasodilator and exerts antiinflammatory activities through Mas receptors. SARS-CoV-2 interacts and downregulates ACE-2. **b** In this context, an imbalance in ACE2/Ang-(1–7) and ACE/AngII axes would be critical in the development of severe COVID-19 symptomatology

function [2, 37–39] (Fig. 1). The role of TMPRSS2 enabling viral entry would consist of: i) ACE2 cleavage, promoting viral uptake, and ii) ***S*** cleavage in two distinct sites, allowing viral fusion to a host membrane [3, 37, 40]. In the case of SARS-CoV, both mechanisms are independent since ACE2 processing by TMPRSS2 is necessary to increase SARS-CoV ***S***-driven entry but is dispensable for SARS-CoV ***S*** activation [3]. In addition, SARS-CoV ***S*** and, to a lesser extent, NL63-CoV ***S*** can also induce ADAM-17 dependent cleavage of ACE2 in vitro [38, 39].

The interaction energies of different CoV ***S*** proteins with ACE2 have been shown to follow a NL63-CoV < < SARS-CoV < SARS-CoV-2 [41, 42] order due to overlapping but not identical binding interfaces and amino acid variations in the ***S*** protein among the different viruses [42, 43]. Interestingly, although the interaction energy between SARS-CoV-2 receptor binding domain (RBD) and ACE2 is higher than that observed for SARS-CoV RBD, SARS-CoV-2 RBD is less accessible, resulting in similar apparent binding affinities [44]. The interplay between ***S*** and ACE2 complex formation and the

activation of host proteases suggests that although the viral entry mechanisms are similar between NL63-CoV, SARS-CoV and SARS-CoV-2, ACE2 downregulation levels might correlate with the binding affinities involved in complex formation, which may play a key part in COVID-19 symptomatology.

SARS-CoV-2-induced RAAS imbalance results in inflammation and other severe COVID-19 symptoms

The role of unbalanced RAAS as a central player in ARDS and acute lung injury is nowadays well established [45]. ACE-generated AngII triggers inflammatory processes, stimulating proliferation of mononuclear cells and regulating the recruitment of proinflammatory cells (by expressing vascular permeability factors and adhesion molecules, among others) [46], rendering the AngII-degrading ACE2 as an essential actor for homeostasis. ACE2-deficient animals are significantly more susceptible to severe pulmonary damage in the context of SARS coronavirus, Influenza H7N9 virus or bacteria infections, as well as LPS inhalation [47–50]. These facts hint at a counterintuitive role of ACE2 expression levels in determining the severity of SARS-CoV-2 infection: although SARS-CoV-2 entry is dependent on ACE2, it is established that lower levels of this molecule can cause exacerbated inflammation, at least to some extent. In mice, during lung infection the initial reduction of pulmonary ACE2 is crucial for recruiting the inflammatory neutrophils to combat the infection, and the subsequent recovery of pulmonary ACE2 is critical to prohibit exuberant neutrophil accumulation. It was found that ACE2 modulated neutrophil infiltration through IL-17-mediated STAT3 signaling, which also recruits factors from the inflamed microenvironment [48]. Confounding factors that either prevent the ACE2 dynamics from occurring or disrupt it are detrimental to the host, resulting in either compromised host defense capability or heightened inflammatory lung diseases [48]. Evidence shows that SARS-CoV ***S*** protein, which is not infective, exerts proinflammatory effects: intraperitoneally inoculation with recombinant SARS-CoV ***S*** worsens the severity of acid aspiration-induced acute lung injury in wild-type mice [47], increasing AngII levels in the lungs. Furthermore, when AngII receptor type 1 (AT1R) was blocked, acute lung injury in ***S***-treated mice was attenuated [47]. Complement system also plays a role: infection of C3 deficient mice with mouse-adapted SARS-CoV exhibited less respiratory dysfunction and fewer neutrophils, inflammatory monocytes and lower cytokine levels in lungs than wild-type mice [51].

Endothelial cells continuously express ACE2, constituting an optimal infection target for SARS-CoV and SARS-CoV-2 [52, 53]. This allows infection spreading and affects the RAAS ecosystem of each organ, and entails direct injury in the endothelium leading to endotheliitis [53], higher vascular permeability and hemostatic dysfunction [54]. In addition, such constitutive expression would explain the significant thrombotic disorders recently reported in the autopsies of COVID-19 patients [55]. In addition, many of the observed severe symptoms or causes of death are represented over different organs. The major complications observed are ARDS [56–60], acute cardiac injury [56, 58, 60], heart failure [56, 61], shock [56, 58, 60], acute kidney injury [56, 58–60], hypoxic encephalopathy [56], lymphopenia [60] and acute pulmonary embolism [62], which could all be at least partially ascribed to disbalancing of the RAAS.

Recent studies have shown a high incidence of neurological symptoms in COVID-19 cases. Although most of them are minor (like headache, nausea, and a loss of sense of smell and taste), more complicated symptomatology, such as convulsions, stroke and thrombotic complications have been also reported [63–65]. There is a strong possibility that these complications arise, at least in part, from downregulation of ACE2. It is now heavily documented that one of the important effects of ACE2 /Ang-(1–7)/mas receptor axis is on the brain and cerebral blood vessels [66], exerting protection against stroke [67] and there is evidence supporting the overall concept that the aging increases the sucseptivility of the cerebrovasculature to the effects of RAAS disbalance [68].

Taking into account the results obtained in mice models and SARS-CoV, and its similarities with SARS-CoV-2, there is strong evidence that differences in expression levels of ACE2 in the context of SARS-CoV-2 infection may constitute a molecular basis of exacerbated inflammation (Fig. 2). This is further supported by the observation that patients with severe COVID-19 show an increase in neutrophil count and in the neutrophil-to lymphocyte ratio and elevated levels of proinflammatory cytokines [7], consistent with in vivo results of neutrophil infiltration after ACE2 downregulation [48]. Moreover, a correlation between the ratio of pro- and anti-inflammatory cytokine concentrations and symptom severity has been observed [69]. It can be speculated that only a few cases of HCoV-NL63-induced severe cases have been reported due to the lower ***S***/ACE2 complex affinity that results in milder dysregulation of ACE2 levels. However, patients with a subgenotype of HCoV-NL63 were hospitalized with severe lower tract infection in 2018. That subgenotype presented one mutation in its RBD that enhances viral entry into host cells, hinting at ACE2 downregulation underlying the severe symptomatology [70]. Furthermore, another few cases of HCoV-NL63-positive patients (82 yo median age) emerged, showing distress

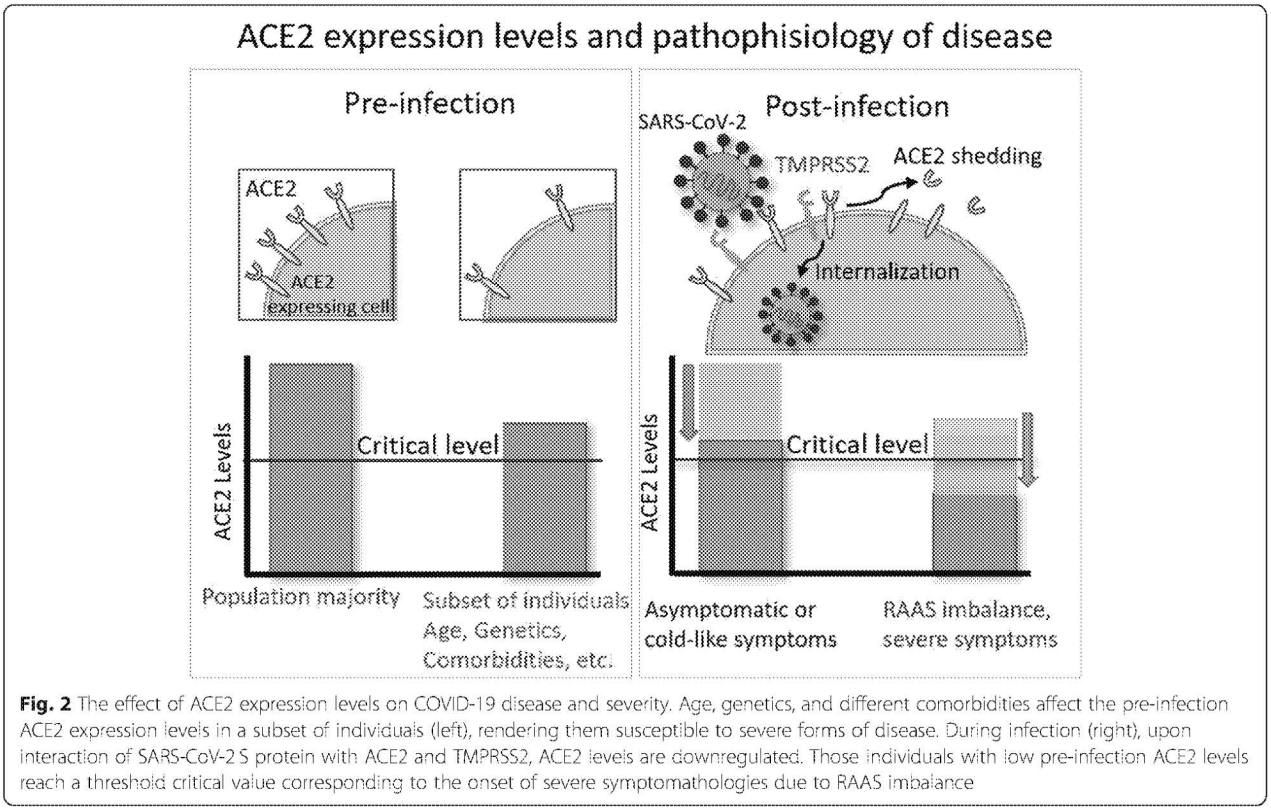

Fig. 2 The effect of ACE2 expression levels on COVID-19 disease and severity. Age, genetics, and different comorbidities affect the pre-infection ACE2 expression levels in a subset of individuals (left), rendering them susceptible to severe forms of disease. During infection (right), upon interaction of SARS-CoV-2 S protein with ACE2 and TMPRSS2, ACE2 levels are downregulated. Those individuals with low pre-infection ACE2 levels reach a threshold critical value corresponding to the onset of severe symptomathologies due to RAAS imbalance

syndrome, with symptoms including pneumonia, multiple organ failure and death, although the subgenotype is unknown [71, 72].

Crucially, the RAAS presents a complex interplay with cyclooxygenase-2 (COX-2 [73, 74]) which is rapidly inducible in several cell types in response to growth factors, cytokines, and pro-inflammatory molecules. It is largely responsible for the onset of inflammation, participating in the synthesis of proinflammatory prostaglandins and triggers production of other proinflammatory chemokines and cytokines, and playing a role in hypertension [75]. Interestingly, while inhibition of COX-2 expression exerts a suppressive effect on lung inflammation [76], it has been shown that both ***S*** and the nucleoprotein (***N***) of SARS-CoV upregulate COX-2 [77] through different molecular mechanisms. Considering the high identity sequence of ***S*** and ***N*** proteins between both viruses (75 and 90%, respectively [78]), SARS-CoV-2 may also elicit upregulation of COX-2, further exacerbating inflammation.

Finally, ACE genotypes may affect the SARS-CoV-2/RAAS interplay. A critical ACE polymorphism consists of the presence (insertion, I) or absence (deletion, D) of a 287-bp *Alu* sequence in intron 16 [79], being the D allele associated with increased activity [80]. Intensive unit care patients bearing the D allele or DD genotype are more susceptible not only to develop ARDS, but also to present a less favourable outcome [81], with a higher risk of mechanical ventilation [82–84]. Interestingly, the D allele was in a higher frequency in those patients who developed the most severe symptoms of SARS-CoV infection [82]. In addition, a recent analysis of the prevalence of ACE (I/D) genotype in different countries showed that as the I/D allele frequency ratio increases, the COVID-19 recovery rate in each country also increases [85].

Pathophysiological contributions of COVID-19 risk factors

Hypertension and diabetes

Despite the large number of SARS-CoV-2 positive patients, understanding COVID-19 pathogenesis remains elusive. Available reports indicate that the most frequent comorbidity in severe COVID-19 is hypertension, followed by diabetes and coronary heart disease [86]. Reports on the clinical characteristics of patients with COVID-19 show that 2.5 to 14.5% of SARS-CoV-2 positive patients present cardiovascular diseases, 12,8 to 56.6% of patients present hypertension and 5.3 to 33.8% patients have diabetes [87].

Ang-(1–7) has multiple beneficial cardiovascular effects: protection against heart failure, natriuretic and antithrombotic, among others [88]. In a mice model of ang II-dependent hypertension, blood pressures were higher

in the ACE2-deficient mice than in wild-type specimens [89]. ACE2 expression in heart is also necessary for structural and functional regulation. After a myocardial infarction, ACE2-deficient mice presented an enhanced susceptibility to a second event, with increased mortality, infarct expansion and adverse ventricular remodeling. Loss of ACE2 also led to increased neutrophil infiltration in the infarct and peri infarct regions, resulting in upregulation of inflammatory cytokines [90].

The kidney is highly sensitive to RAAS perturbation. Several studies demonstrated an increased activity of this system involved in the development and progression of diabetic renal damage [91]. In mice models of either type 1 and type 2 diabetes mellitus, ACE2 expression is elevated in early stages of diabetic nephropathy while decreasing in the late phase of the disease, suggesting that ACE2 may participate in a compensatory mechanism in the diabetic kidney prior to illness onset [92]. Moreover, in a murine model of diabetic nephropathy, recombinant ACE2 administration improves kidney function and structure [93]. In agreement with these results, it was shown that ACE2 expression is decreased in the tubules in human diabetic nephropathy [94]. The imbalance of the RAAS system in favor of AngII in the context of diabetes results in a more severe kidney damage in males than in females, which is even increased if ACE2 is downregulated [95, 96].

Age

Age is a major factor affecting the severity of COVID-19 disease, correlating with both susceptibility to infection and manifestation of clinical symptoms. Therefore, incidence of clinical cases in countries with younger populations is expected to be lower than older population countries, despite the prevalence of other comorbidities [97]. It has been proposed that AT1R-mediated signaling is involved in the aging process per se by promoting several age-related pathologies, such as cardiovascular diseases, diabetes, chronic kidney failure, dementia, osteoporosis and even cancer [98, 99]. Increased AngII bioavailability due to reduced catabolism may result in overactivation of these receptors. In line with this, several authors have observed that ACE2 expression levels are reduced with age [26, 100, 101].

ACE and ACE2 exert catalytic effects on several proteins beyond the RAAS. This apparent promiscuity confers these enzymes enough plasticity to reach the same physiological effects through alternative pathways, thereby producing quicker, more intense and coordinated responses. Thus, age-related alteration in the ACE/ACE2 activity does not only affect the physiology of the RAAS, but also another particular system in which both proteins have a prominent role: the kininogen-kinin-kallikrein (KKK). As shown in Fig. 3a, ACE has been demonstrated to be one of the primary proteases responsible for the hydrolysis of the kinin bradykinin and, to a lesser extent, its derivative des-Arg^9-bradykinin. It is worth remarking that ACE is considered first a kininase, being known as kininase II [102], and then an angiotensinase, due to its »80-fold higher affinity for bradykinin with respect to AngI (4). In fact, the cough presented by some patients treated with ACE inhibitors has been attributed to the blockade of the bradykinin metabolism [103]. ACE2, on the other hand, degrades des-Arg^9-bradykinin but no other forms of bradykinin (4). There are two types of kinin receptors: BR1, selectively sensitive to kinins lacking the C-terminal Arg residue like des-Arg^9-bradykinin; and BR2, optimally stimulated by the full sequence of bradykinin. While BR2 is constitutive and widely expressed in different tissues and mediates vasodilator and anti-inflammatory effects, the gene encoding BR1 is regulated by a promoter region with binding sites for transcription factors such as the activator protein-1 and the nuclear factor kappa B (NFkB), which are up-regulated during inflammation [104]. By acting on BR1 receptors, des-Arg^9-bradykinin induces vasocontraction and pro-inflammatory actions [104]. Thus, SARS-CoV-2 infection would favor the overactivation of the BR1 with deleterious effects in the affected tissue (Fig. 3b). In agreement with this, recent works point out to des-Arg^9-bradykinin as a key mediator of lung injury caused by LPS [104, 105]. By employing ACE2-deficient mice, Sodhi and collaborators found that this enzyme is crucial in counteracting such mechanism giving its ability to inactivate des-Arg^9-bradykinin, and thus the BR1 signaling [105]. Moreover, these authors reported that LPS-mediated inflammation downregulated ACE2 bioavailability by a NFkB-involved mechanism. Of note, AngII induces NFkB expression through AT1R [45].

Aging does not only affect the KKK system through the ACE/ACE2 balance, but also directly altering the pharmacology of BR1 and BR2. It has been observed that although the serum levels of kinins increase with age, the responsiveness of target cells is limited or altered [106]. In this respect, bradykinin-induced vasorelaxation is actually affected by the BR1/BR2 ratio in the vasculature [107]. In older subjects, the density of BR2 is reduced whereas that of pro-inflammatory BR1 seems to be elevated, thereby changing the balance towards a vasoconstrictor response [108] that could result more deleterious in the context of SARS-CoV-2 infection. Most tellingly, both aging and kinins up-regulate the expression of pro-inflammatory COX-2 in several tissues [109–111].

In summary, the aging-related re-adaptation of the RAAS, KKK and COX-2 pathways may put older people in a new equilibrium situation much more sensitive to

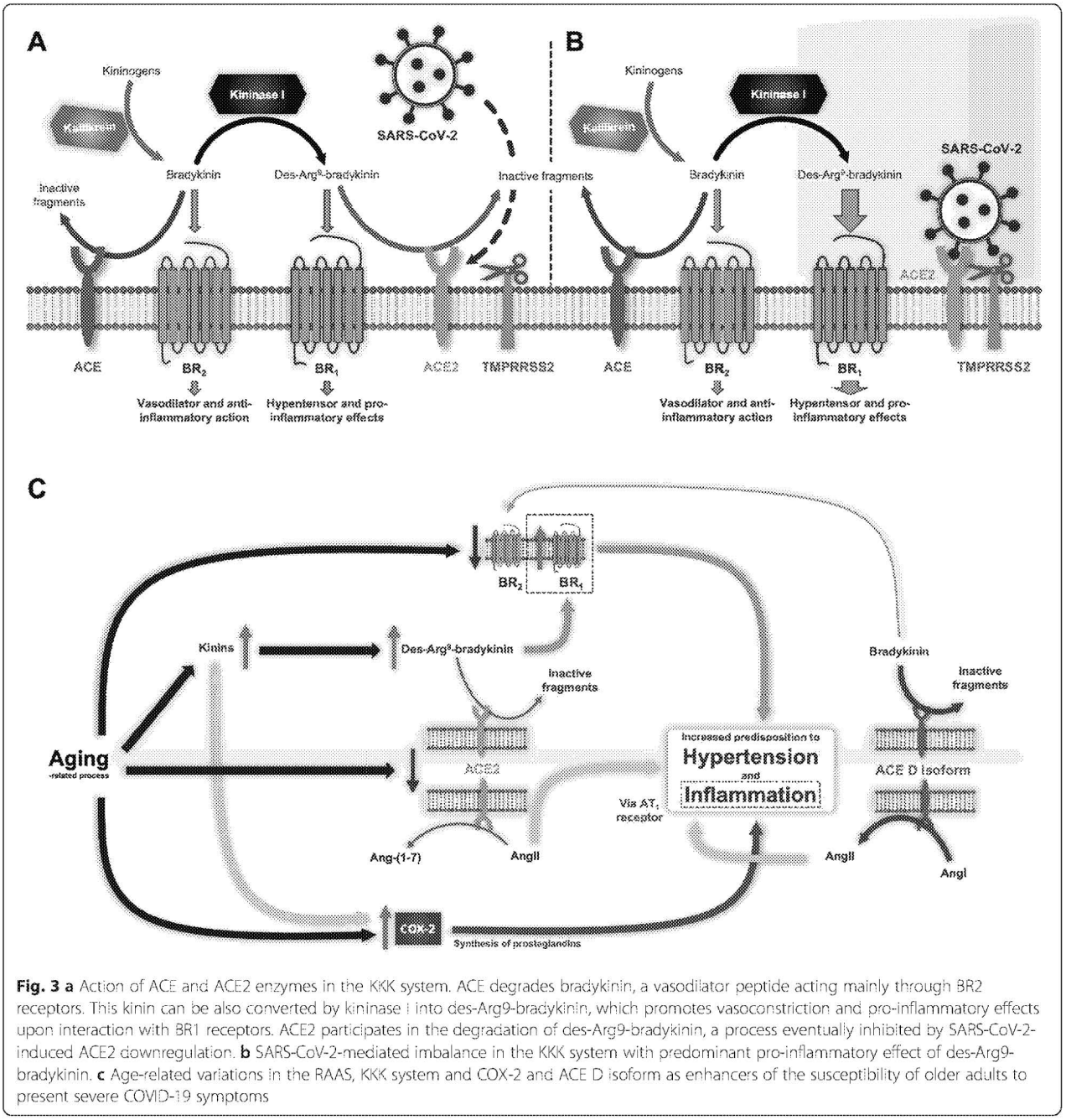

Fig. 3 **a** Action of ACE and ACE2 enzymes in the KKK system. ACE degrades bradykinin, a vasodilator peptide acting mainly through BR2 receptors. This kinin can be also converted by kininase I into des-Arg9-bradykinin, which promotes vasoconstriction and pro-inflammatory effects upon interaction with BR1 receptors. ACE2 participates in the degradation of des-Arg9-bradykinin, a process eventually inhibited by SARS-CoV-2-induced ACE2 downregulation. **b** SARS-CoV-2-mediated imbalance in the KKK system with predominant pro-inflammatory effect of des-Arg9-bradykinin. **c** Age-related variations in the RAAS, KKK system and COX-2 and ACE D isoform as enhancers of the susceptibility of older adults to present severe COVID-19 symptoms

minor fluctuations and with a limited margin of response, rendering them more susceptible to inflammatory processes. These mechanisms and the ACE isoform D are summarized in Fig. 3c as crucial factors increasing COVID-19 severity.

Conclusions: towards endotypification of COVID-19

We are experiencing the first global pandemic since the dawn of precision medicine: an approach that leaves out a "one-drug-fits-all" model, in favor of customization of healthcare. In this context, identifying different endotypes —subtypes of a condition with different underlying pathophysiological mechanisms— should become central for clinical research because it helps to rationalize experimental results and enhances reproducibility: heterogeneous groups of patients consisting of varying unidentified endotypes are prone to obfuscate statistical analysis of clinical trials for potential vaccine candidates and therapeutic treatments and hinder the identification of different factors that modulate disease severity, among

others. Endotype discovery has been particularly successful in the treatment of other respiratory illnesses, such as asthma [112] and bronchiolitis [113, 114] usually combining trajectory analysis of meaningful variables along time, cytokine profiles and multi-omics analysis. We speculate there is mounting evidence showing that COVID-19, with its associated degrees of severity and heterogeneous symptomatology, is actually an umbrella term that may include several endotypes (Fig. 4). The available data about age, gender, genotypes, polymorphisms, comorbidities and symptoms of disease points to the existence of different endotypes, with a probable central role of the RAAS involved in severe cases. Most SARS-CoV-2 cases are asymptomatic, with reports ranging between 50 to 70% of total cases [103]. The remaining occurrences are further split between mild, presenting cold-like symptoms, and severe cases. Considering the current lack of absolute numbers regarding total infections, it is likely that the percentages of severe cases are overestimated, and these may be further subdivided between i) those with other underlying factors, ii) others that are aggravated by comorbidities, and iii) those that are specifically affected by imbalance of the RAAS throughout the infection process. We hypothesize that there is a strong possibility that this particular subset of individuals are thrown off-balance by SARS-CoV-2 infection, constituting a distinctive endotype. For these patients, personalized treatments should address critical open questions such as how to manage ACE inhibitors [115] that are used in clinical practice for treating hypertension and other cardiovascular diseases: Although ACE inhibitors do not interfere directly with ACE2 activity [17], discrepancies exist regarding their effects on ACE2 expression levels in different tissues [116–118] raising the question of whether these drugs would be harmful for COVID-19 patients. Despite this, current consensus is to continue treatment until conclusive data emerge [119–121].

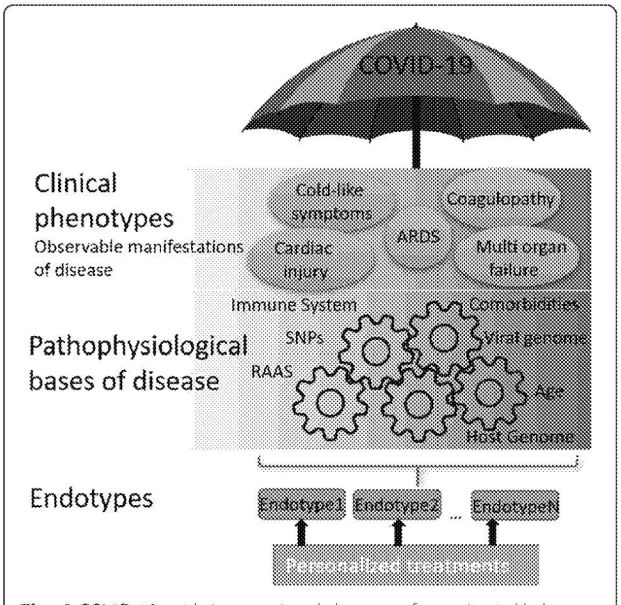

Fig. 4 COVID-19, with its associated degrees of severity, is likely an umbrella term encompassing multiple pathophysiological bases of disease. Endotype discovery should dramatically accelerate our understanding and treatment of disease(s), enable further discovery of pathophysiological mechanisms and lead to identification of specific groups of patients that may benefit from personalized treatments

A constellation of factors may underlie the particular susceptibility of a RAAS-imbalanced endotype. Single nucleotide polymorphism (SNP) present in ACE2 can be classified as harmful or protective, depending on their effect on the binding affinity of the S/ACE2 complex [122], rendering them as possible factor underlying severity across different populations [123]. Aging may predispose to an exacerbated inflammatory response by downregulation of ACE2 and upregulation of COX-2, and gender, genotypes, SNPs and hypertension may play similar roles. Differences in the prevalence of comorbidities among sex -males are more likely to present comorbidities than females- may also partially explain the increased incidence (44 to 76% in males vs 24 to 56% in females) and mortality (55 to 64% in males vs 36 to 45% in females) observed in COVID-19 male patients [124]. These factors are expected to intersect at the regulation of ACE2: low expression levels render individuals particularly vulnerable to SARS-CoV-2, that in turn further downregulates ACE2 levels through shedding, critically affecting RAAS, bradykinin and COX-2 function. In particular, COX-2 may directly be affected by the interaction with ***N*** and ***S*** proteins. This is expected to onset proinflammatory mechanisms that are likely to establish a positive feedback with the ongoing viral infection, thus resulting in pneumonia and the observed cytokine storm, prothrombotic activity, and many of the severe symptoms detected in COVID-19. Although lower levels of ACE2 expression may seem protective as it would hinder viral entry, they appear to play a key role in the onset of severe symptomatology.

Other identified or proposed key factors that must be considered to identify different underlying endotypes include antibody-dependent enhancement [125], the role of previous infections with other coronaviruses, immunological profiles and genetic variations [9, 11–13]. A critical discussion of risk factors, comorbidities, pathophysiological basis of disease and their translational applications within the appropriate theoretical framework is prone to enable better understanding of the molecular basis of disease and, therefore, the design of successful strategies for personalized treatments.

Abbreviations

ACE: Angiotensin-converting enzyme; ACE2: Angiotensin-converting enzyme II; ADAM17: ADAM metallopeptidase domain 17; Ang-(1–7): Angiotensin-(1–7); AngI: Angiotensin 1; AngII: Angiotensin 2; ARDS: Acute respiratory distress syndrome; AT1R: AngII receptor type 1; COX-2: Cyclooxygenase-2; HCoV: Human coronaviruses; KKK: Kallikrein-kininogen-kinin system; N: Viral nucleoprotein protein; NFKB: Nuclear factor kappa-light-chain-enhancer of activated B cells; RAAS: Renin-angiotensin-aldosterone system; RBD: Receptor binding protein; S: Viral spike protein; TMPRSS2: Transmembrane Serine Protease 2

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Authors' contributions

CJG, RV and DA-P wrote the manuscript and prepared the figures. The authors read and approved the final manuscript.

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Availability of data and materials

Because this is a review article, no individual data in any form is included inside the manuscript.

Ethics approval and consent to participate

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Competing interests

The authors declare that they have no competing interests.

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From: b6
Sent: 5/13/2021 3:31:51 AM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6-b6
CC: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246-b6
Subject: Re: post vaccine patient

Dr. Nath,

Yes, she would love to be further evaluated and considered for treatment.

Thank you,

b6

On May 12, 2021, at 9:08 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Dear b6
We have further discussed b6 symptoms. We are wondering if we should bring her to NIH for further testing and consider treatment with b6 Would that be possible?
Avi

From: b6
Date: Wednesday, May 5, 2021 at 12:08 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Novel anti-neuronal antibodies

Dr. Nath,

b6
b6 The attached pre-print shows evidence of novel antineuronal antibodies from COVID. This patient responded favorably to IVIG.

b6 remains symptomatic, now b6 Most of her testing has b6
b6 Her care teams are attempting to treat symptoms, with no response.

Your thoughts on this? Any updates from b6

Thanks,
b6

https://www.biologicalpsychiatryjournal.com/action/showPdf?pii=S0006-3223%2821%2901215-4

From: b6
Sent: 5/5/2021 4:06:26 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6
Subject: Novel anti-neuronal antibodies
Attachments: PIIS0006322321012154.pdf

Dr. Nath,

b6

b6 The attached pre-print shows evidence of novel antineuronal antibodies from COVID. This patient responded favorably to IVIG.

b6 remains symptomatic, now b6 Most of her testing has b6

b6 Her care teams are attempting to treat symptoms, with no response.

Your thoughts on this? Any updates from b6

Thanks,
b6

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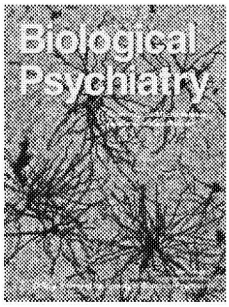
Journal Pre-proof



Remission of subacute psychosis in a COVID-19 patient with an anti-neuronal autoantibody after treatment with intravenous immunoglobulin

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Title: Remission of subacute psychosis in a COVID-19 patient with an anti-neuronal autoantibody after treatment with intravenous immunoglobulin

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During the course of treatment, we obtained surrogate consent to use surplus cerebrospinal fluid for research. After regaining capacity, the patient provided written informed consent for this case report. This work has not previously been published in any form.

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To the Editor:

COVID-19 patients are at increased risk for developing new or recurrent psychosis.(1) Viral infections—including SARS-CoV-2 (2-4)—can cause psychosis in the context of autoimmune encephalitis.(5) However, some individuals with para-infectious psychosis do not meet criteria for autoimmune encephalitis, yet respond to immunotherapy.(6, 7) We present a case of COVID-19-associated subacute psychosis that did not meet criteria for autoimmune encephalitis, yet remitted after treatment with intravenous immunoglobulin (IVIg). We subsequently identified a novel IgG class anti-neuronal autoantibody in the patient's cerebrospinal fluid (CSF).

Case:

A 30-year-old man without medical, psychiatric, or substance use history developed fever and malaise. The following day, he developed a delusion that the "rapture" was imminent. On day 2, a nasopharyngeal swab was positive for SARS-CoV-2 by RT-PCR. He began a 14-day isolation but maintained daily contact with family. He did not have anosmia, ageusia, or respiratory symptoms, nor did he receive treatment for COVID-19. He initially suffered from hypersomnia and slept 22 hours per day. He then developed insomnia, sleeping only 3-4 hours per day. During this time, he began pacing and rambling about "lights." He worried that he was dying and said that he had been speaking to deceased relatives and God.

On day 22, he kicked through a door and pushed his mother, prompting an emergency department (ED) evaluation. In the ED, he endorsed speaking with the dead, falsely claimed to

be a veteran, and worried about being experimented on with "radiation." He did not have suicidal ideation, homicidal ideation, or hallucinations. Non-contrast head computed tomography was normal, and urine toxicology was negative. He was started on haloperidol 5 mg by mouth twice daily with significant improvement of his agitation and delusions. After 48 hours he was discharged to outpatient follow-up. Outpatient magnetic resonance imaging (MRI) of the brain with and without gadolinium was unremarkable.

After discharge, his restlessness, insomnia, and cognitive slowing recurred, as did his fears that he would be experimented on "like a guinea pig." On day 34, he punched through a wall and was hospitalized to be evaluated for autoimmune encephalitis. A detailed neurological exam was unremarkable. He had a flat affect, slowed speech, and akathisia, which resolved after decreasing haloperidol and starting benztropine and lorazepam. A 12-hour video electroencephalogram was normal. Blood studies were notable for an elevated ferritin and D-dimer, suggesting systemic inflammation (Table 1). CSF studies, including a clinical autoimmune encephalitis autoantibody panel, were only notable for an elevated IgG of 4.8 mg/dL (ref. 1.0—3.0 mg/dL) with a normal IgG index (see Table 1).

Lacking focal neurologic symptoms, seizures, MRI abnormalities, or CSF pleocytosis, his presentation did not meet consensus criteria for autoimmune encephalitis.(7) Nevertheless, his subacute psychosis, cognitive slowing, and recent SARS-CoV-2 infection raised concern for autoimmune-mediated psychosis. Therefore, starting on day 35, he received a total of 2 grams/kilogram of IVIg over 3 days. His cognitive slowing and psychotic symptoms remitted

after the first day of treatment. His sleep cycle normalized, and he was discharged without scheduled antipsychotics. He returned to work immediately after discharge and remained symptom-free three months later.

Because his robust response to IVIg indicated an underlying autoimmune process, we tested his CSF for anti-neural autoantibodies using anatomic mouse brain tissue staining (8); a validated and standard method performed by incubating rodent brain sections with CSF and counterstaining with a human IgG-specific antibody. At a 1:4 dilution, his CSF produced a novel immunostaining pattern that we have not observed in over 500 screens of CSF from other patients with neuroinflammatory disorders.

His IgG prominently immunostained Satb2-expressing upper layer (layer II/III) pyramidal neurons in the anteromedial cortex (Figure 1a), a population of excitatory callosal projection neurons necessary for the integration of intercortical information.(9) We also observed relatively uniform puncta in the corpus callosum (Figure 1b), consistent with immunostaining of callosal projections. In the olfactory bulb, mitral cell bodies and the external plexiform neuropil were immunostained (figure 1c). In the dentate gyrus, linearly organized puncta resembling axonal transport vesicles and oblong neurons were apparent in the hilus (Figure 1d). In the thalamus, linear and less organized punctate staining was observed (Figure 1e). In the cerebellum, Purkinje cell bodies were modestly stained, while the overlying molecular layer was densely stained with variably size puncta (Figure 1f).

Discussion:

We identified a candidate novel neuronal autoantibody in the CSF of a COVID-19 patient with antipsychotic-refractory subacute psychosis, whose symptoms rapidly and completely remitted after treatment with IVIg. This autoantibody primarily localized to layer II/III callosal cortical neurons, which have been implicated in schizophrenia.(10) Although anti-neural autoantibodies are present in some neurologically impaired COVID-19 patients(11-13), autoantibody studies are rarely performed in cases of COVID-19-associated psychosis.(14-22)

Importantly, early initiation of immunotherapy for autoimmune disorders of the central nervous system significantly improves outcomes. (23) Although autoimmune encephalitis can be established on clinical grounds, the diagnosis requires neurologic, MRI, and/or CSF abnormalities.(7) To identify individuals with potentially immune-responsive acute psychosis without neurological impairment, Pollak et. al. proposed criteria for autoimmune psychosis. (24) While "possible" autoimmune psychosis relies solely on clinical factors, "probable" and "definite" require abnormal imaging or laboratory studies.

Our patient's subacute psychosis and cognitive dysfunction qualified him for possible autoimmune psychosis. However, he had several "red flags" for autoimmune psychosis: infectious prodrome, rapid progression, and insufficient response to antipsychotics.(24) Moreover, his mood dysregulation, cognitive slowing, and hypersomnia were evocative of the mixed symptomatology more typical of autoimmune encephalitis.(25, 26) Given his overall clinical picture, we administered IVIg with apparent clinical response. Although our patient

might have later developed autoimmune encephalitis, consideration of autoimmune psychosis can prompt earlier immunotherapy and potentially improve outcomes. Only by relying on ancillary criteria were we able to justify immunotherapy for our patient, suggesting that re-evaluating the criteria for autoimmune psychosis may improve its sensitivity.(27)

Even so, this case should be interpreted with caution. Psychotic disorders are protean by nature, mixed symptomatology does occur, and most psychotic presentations are unlikely to be immune-mediated. However, given the scale of the COVID-19 pandemic, psychiatric practitioners should consider autoimmune psychosis in patients with COVID-19-associated psychosis.

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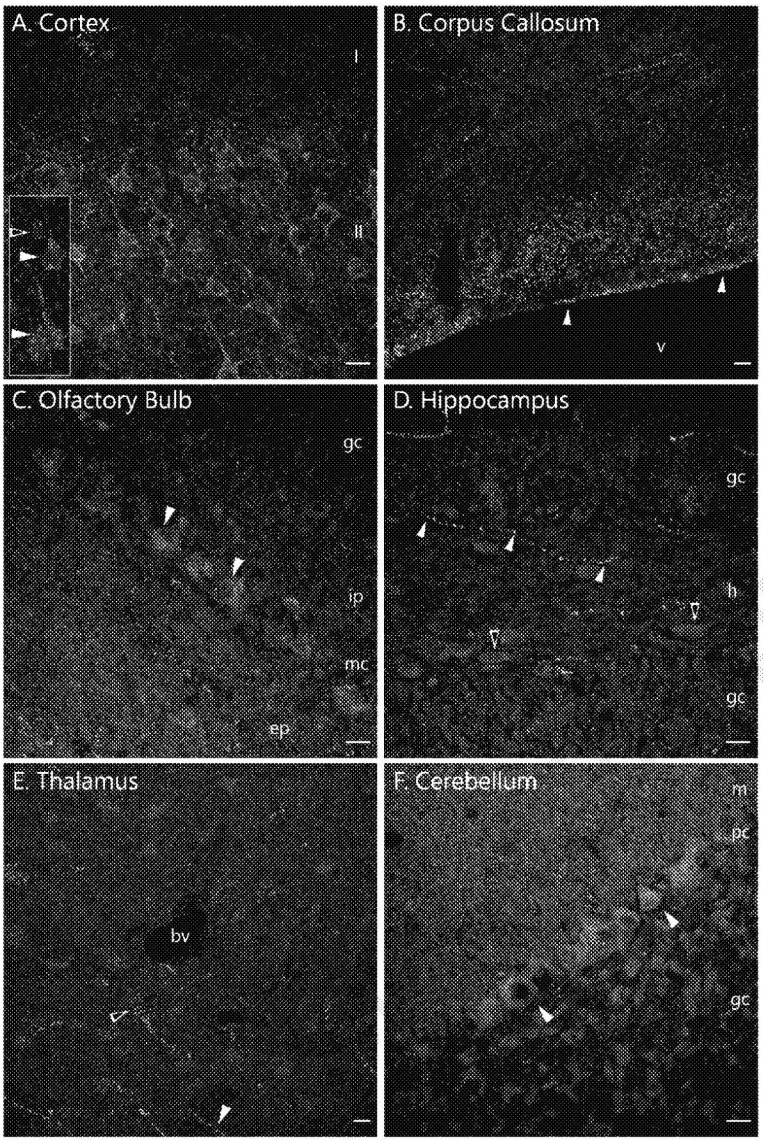
Table 1. Clinical Studies.

Source	Test	Result (reference)
Nasopharyngeal Swab	SARS-CoV-2 RNA PCR	Day 2: Positive Day 34: Negative
Urine	9 drug toxicology screen	Negative
Serum	Basic Metabolic Panel	Within acceptable limits: Na 146 mmol/L (136-144 mmol/L) K 3.1 mmol/L (3.3-5.1 mmol/L)
	Prothrombin time	11.5 seconds (9.6-12.3 seconds)
	International normalized ratio (INR)	1.07
	Complete blood count	Day 24 WBC: 6.9 (4.0 – 10.0 x 1,000/µL) Day 34 WBC: 5.4 (4.0 – 10.0 x 1,000/µL) MPV 11.6 fL (6.0-11.0 fL)
	Thyroid Stimulating Hormone	2.520 uIU/mL (0.270-4.200 uIU/mL)
	D-dimer	1.89 mg/L (<= 0.50 mg/L)
	Liver enzymes	AST 156 U/L (<35 U/L) ALT 372 U/L (<59 U/L)
	C-reactive protein	1.7 mg/L (<1.0 mg/L)
	Ferritin	1124 ng/mL (30-400 mg/mL)
	Ammonia	27 umol/L (11-35 umol/L)
	Albumin	4.2 g/dL (3.6-4.9 g/dL)
	IgG	1230 mg/dL (700-1600 mg/dL)
CSF	Cell Count	0 nucleated cells
	Protein	41.2 mg/dL (15-45 mg/dL)
	Glucose	60 mg/dL (40-70 mg/dL)
	Culture	No growth
	Oligoclonal banding	None
	Albumin	25.8 mg/dL (10-30 mg/dL)
	IgG	4.8 mg/dL (1.0-3.0 mg/dL)
	IgG Index	0.67 (<0.7)
	Autoimmune encephalopathy panel	Negative for AMPA Ab, amphiphysin Ab, anti-glial nuclear Ab, neuronal nuclear Ab (types 1, 2, and 3), CASPR2, CRMP-5, DPPX, GABA-B receptor, GAD65, GFAP, IgLON5, LGI1-IgG, MGLUR1, NIF, NMDA receptor, Purkinje Cell Cytoplasmic Ab (types Tr, 1, and 2)
Imaging	CT Head without contrast	No acute intracranial findings.
	MRI Brain with contrast	No acute intracranial abnormality or definitive structural abnormality identified. Specifically, no imaging findings suggestive of encephalitis or acute demyelination.
	Electroencephalography	Normal prolonged (>12h) awake and asleep inpatient video EEG

Figure 1. Characterization of anti-neuronal antibody staining. Mice were perfused with 4% paraformaldehyde. 12µm frozen sagittal brain sections were immunostained with cerebrospinal fluid (CSF) at a 1:4 dilution and counterstained with an anti-human IgG secondary antibody (green) (Jackson #709-545-149 at 2µg/mL). Nuclei were labeled with DAPI (blue). In all panels, scale bars are 10µm. **A.** Cortical immunostaining of pyramidal neuron cell bodies and proximal processes in layer II of the anteromedial cortex. Staining of neuropil was also observed. Inset – CSF immunostains Satb2-expressing (red) neurons (filled arrowheads) but not surrounding Satb2-negative cells (unfilled arrowhead) (Abcam #ab51502 at 1µg/mL); **B.** Relatively uniform punctate staining along the ventricular wall (filled arrowheads) and overlying corpus callosum; **C.** Olfactory bulb immunostaining of mitral cell bodies (filled arrowheads) and neuropil of the external plexiform layer (ep). gc = granule cell layer, ip = internal plexiform layer, mc = mitral cell layer; **D.** Hippocampal immunostaining of an axon-like process in the hilus of the dentate gyrus (filled arrowheads) and a subset of hilar cell bodies (unfilled arrowheads). gc = granule cell layer, h = hilus. v = ventricle; **E.** Thalamic axon-like (filled arrowhead) and scattered (unfilled arrowhead) punctate immunostaining. bv = blood vessel; **F.** Immunostaining of cerebellar Purkinje cell bodies (filled arrowheads) and neuropil of the molecular layer (m). gc = granule cell layer, pc = Purkinje cell layer.


A. Cortex
I
II
B. Corpus Callosum
v
C. Olfactory Bulb
gc
ip
mc
ep
D. Hippocampus
gc
h
gc
E. Thalamus
bv
F. Cerebellum
m
pc
gc

From: b6
Sent: 10/5/2021 3:48:02 AM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6
Subject: Re: Update
Attachments: Cov-Sars2 Vaccine Persistent Neuro Symptoms Survey 10-5.pdf

Good evening Dr Nath.
I do hope you are faring well.

I am doing good after b6 Feeling the best I have since this started.
My doc wants to b6
b6 thinks that b6 Any thoughts on this? I guess we will find out.

I am hopeful that I will be able to finally b6 soon and if the next few months consistently stay on this trajectory, maybe I can b6

———————————

Attached, find our updated survey. I went back to our survey pool and asked some follow-up questions regarding timelines and symptoms progression.
New slides are at the end of the document.

b6

b6

———————————

On the FDA front, I expressed my concerns to Dr Woodcock regarding their refusal to investigate, and then met with Peter Marks today. He recognized that it is challenging for the VAERS system to identify syndromes that consist of a myriad of symptoms. He committed to work with his programmers, and the several neuropathy terms we gave him, in order to develop a system that may identify the more easily overlooked safety signals.

He assumed that paresthesias (and other issues) was a temporary short-term issue, so he was surprised when I mentioned it is consistently one of the top 3 complaints people have.
The GOOD news is he didn't try to send me off to another agency again! :)

b6

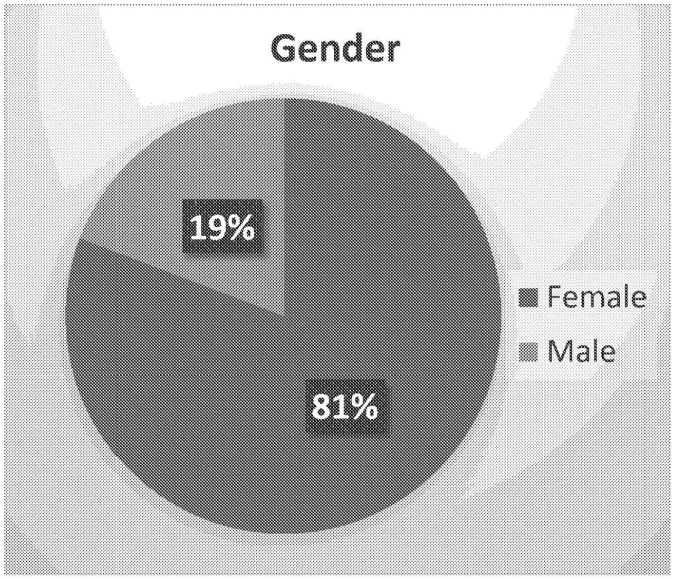
b6

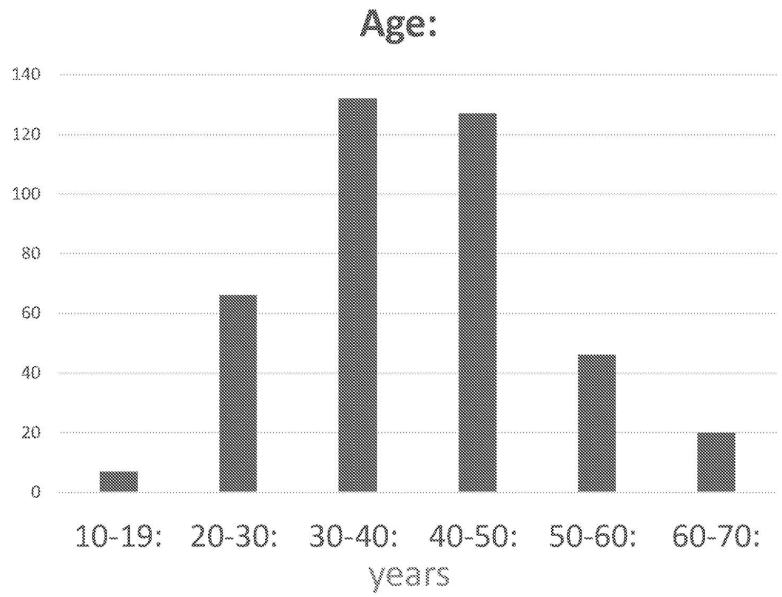
REACT 19

RESEARCH . EDUCATION . ACTION . COVID-19 . THERAPEUTICS

Covid Vaccine Persistent Symptoms Survey

Survey Gathered from 508 patients suffering persistent neurological symptoms after receiving the Sars-Cov2 Vaccine in the United States - 10/5/21





www.reAct19.org

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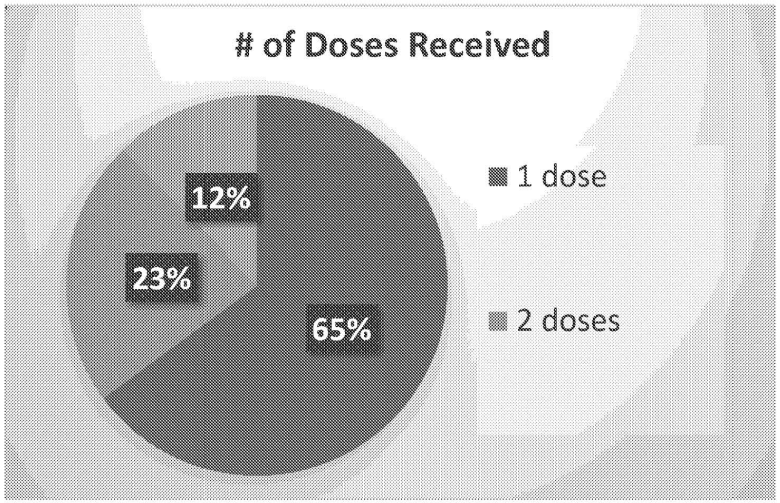
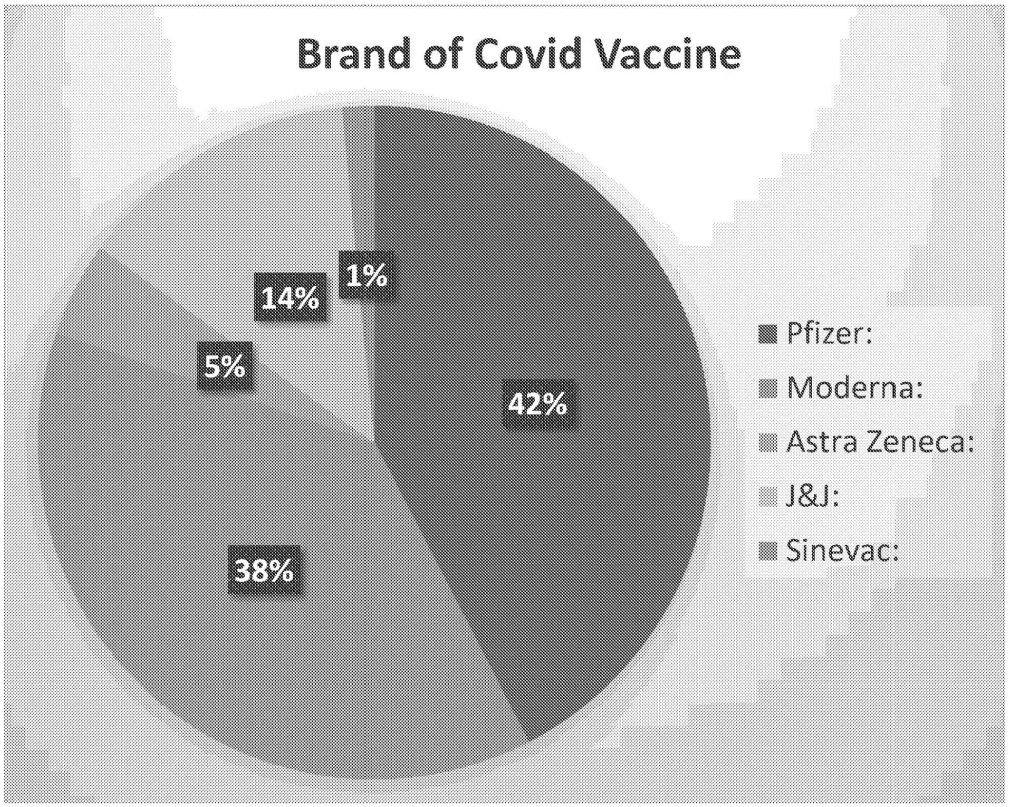

# of Doses Received
12%
23%
65%
1 dose
2 doses


Brand of Covid Vaccine
1%
14%
5%
42%
38%
Pfizer:
Moderna:
Astra Zeneca:
J&J:
Sinevac:

Medical History

Have you ever had a positive Covid infection?	
No:	85%
Yes:	4%
Don't know:	11%
PRE-EXISTING HEALTH CONDITION:	
NO:	71%
Yes:	29%
Prior to Covid vaccination, have you ever reacted to any previous vaccine you had received?	
NO:	94%
YES:	6%

Are you the only one in your family to have a persistent adverse reaction to the vaccine?

Yes: 142
No: 13

Have you had EBV in the past:

Yes: 30
No: 24

High Cholesterol pre vax:

No: 101
Yes: 23

Do you have any known mutations to the mthfr gene?

Never been tested: 93
Yes: 19
No: 13

Top Reported Symptoms

Constitutional

Fatigue:	411
Exercise Intolerance:	178
Insomnia:	150
Chills:	53
Night Sweats:	66
Excessive Sleep:	60
Weight Loss:	40

Neurologic

Paresthesia (burning, tingling):	343
Brain Fog:	346
Dizziness:	277
Persisting Headaches:	209
Nerve Pain:	211
Memory Loss:	125
Difficulty with Speech:	34
Paralysis:	14

HEENT

Tinnitus:	180
Visual disturbance / loss:	141
Sound Sensitivity:	83
Dry eyes:	72
Light Sensitivity:	62
Sore Throat:	41
Jaw Pain:	55

Respiratory:

Shortness of Breath:	154
Cough:	30

Cardiovascular:

Palpitations:	275
Tachycardia:	182
Chest Pain:	160
High Blood Pressure:	74
Low Blood Pressure:	50
Arrythmia:	17

Gastrointestinal

Nausea:	146
Diarrhea:	76
Abdominal Pain:	102
Dysphagia:	12
Heart Burn/Indigestion:	74
Bloody Stool:	4

Genitourinary/ Reproductive

Frequent Urination:	65
Irregular Menstrual Periods:	81

Endocrinologic

Heat Intolerance:	143
Adrenaline Surges:	118
Increased Thirst:	83
Hair Loss:	41
Disturbance in glucose levels:	29

Allergy/Immunology

Lymphadenopathy:	96
New Food Allergies:	44

Musculoskeletal

Muscle Twitching:	254
Joint Pain:	226
Muscle Aches:	204
Heaviness in Lower Extremities:	194
Muscle Atrophy:	82
Swelling in Extremities:	40

Dermatologic

Skin Redness or Swelling:	35

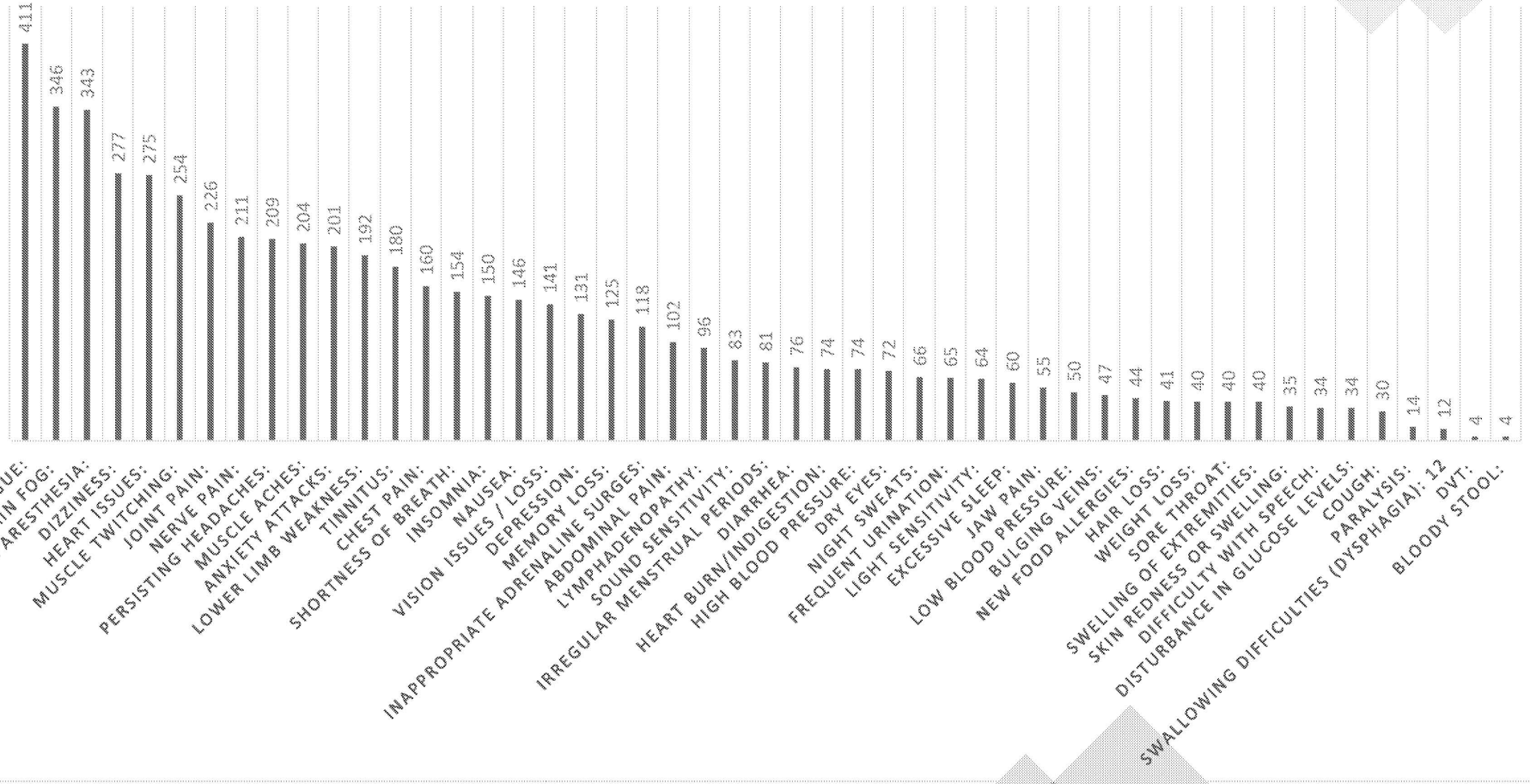
Psychiatric

Depression:	131
Anxiety Attacks:	201

Hematologic

DVT:	4
Bulging Veins:	47

SYMPTOMS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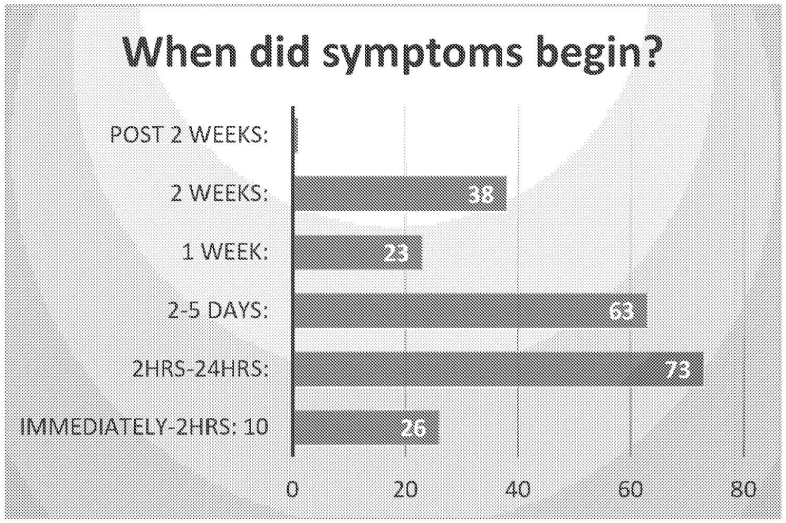
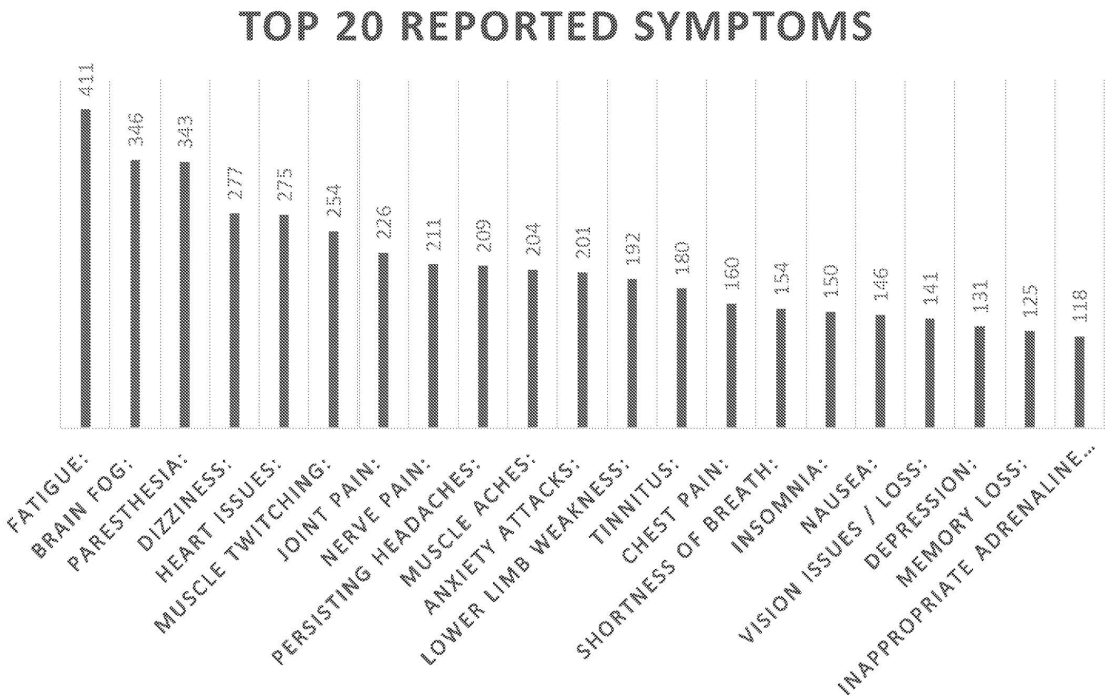
FATIGUE:
BRAIN FOG:
PARESTHESIA:
DIZZINESS:
HEART ISSUES:
MUSCLE TWITCHING:
JOINT PAIN:
NERVE PAIN:
PERSISTING HEADACHES:
MUSCLE ACHES:
ANXIETY ATTACKS:
LOWER LIMB WEAKNESS:
TINNITUS:
CHEST PAIN:
SHORTNESS OF BREATH:
INSOMNIA:
NAUSEA:
VISION ISSUES / LOSS:
DEPRESSION:
INAPPROPRIATE ADRENALINE SURGES:
MEMORY LOSS:
ABDOMINAL PAIN:
LYMPHADENOPATHY:
IRREGULAR MENSTRUAL PERIODS:
SOUND SENSITIVITY:
HEART BURN/INDIGESTION:
DIARRHEA:
HIGH BLOOD PRESSURE:
DRY EYES:
NIGHT SWEATS:
FREQUENT URINATION:
LIGHT SENSITIVITY:
EXCESSIVE SLEEP:
JAW PAIN:
LOW BLOOD PRESSURE:
BULGING VEINS:
NEW FOOD ALLERGIES:
HAIR LOSS:
WEIGHT LOSS:
SORE THROAT:
SWELLING OF EXTREMITIES:
SKIN REDNESS OR SWELLING:
DIFFICULTY WITH SPEECH:
DISTURBANCE IN GLUCOSE LEVELS:
COUGH:
PARALYSIS:
SWALLOWING DIFFICULTIES (DYSPHAGIA): 12
DVT:
BLOODY STOOL:

SYMPTOMS TIMELINE AND OVERVIEW





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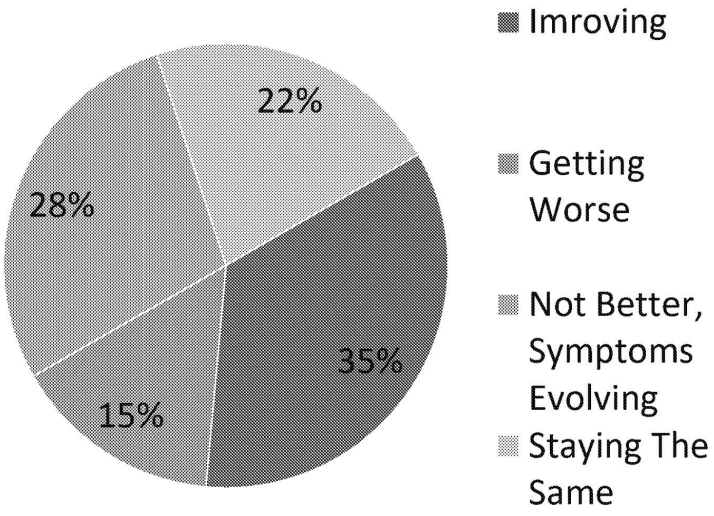
Are you improving? Staying the same? Getting worse?

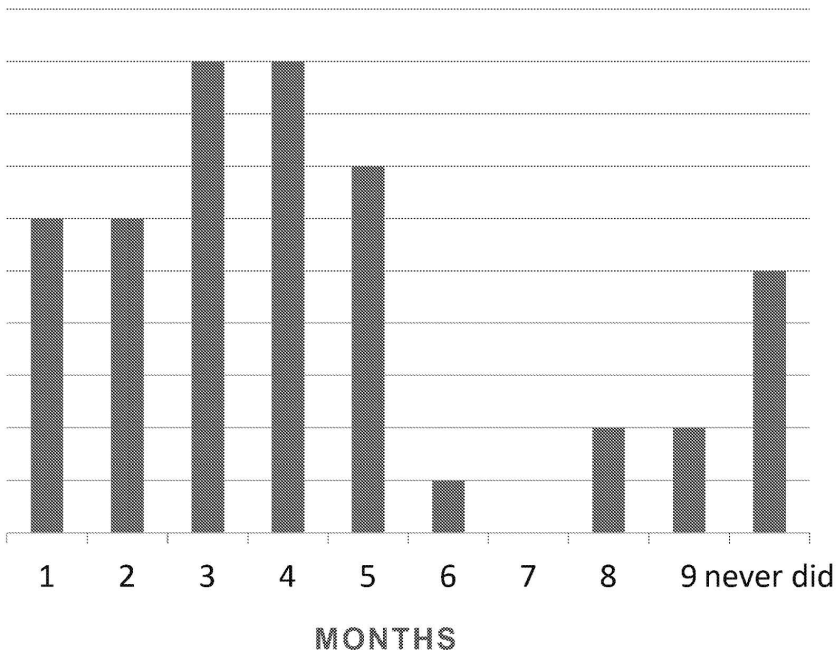


HELPING WITH SYMPTOMS:	
Time	110
Rest	80
Supplements	59
Gentle Exercise	36
Anti-inflammatory Diet	28
Positive Outlook	25
Antihistamines	28
Meditation, vague nerve exercise	6
Acupuncture	4
Distraction	12
Fasting	11
Ivermectin	7
Steroids	10
Red Light therapy	2
Miraviroc	2
Gabapentin	8
Antidepressants fluvox / doxepin	4
IVIG	3

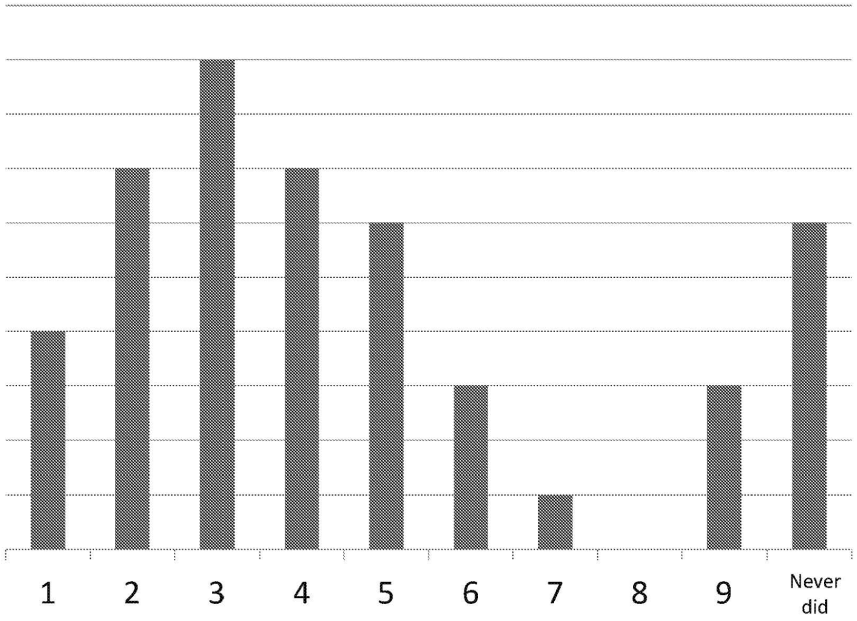
CAUSES SYMPTOMS TO WORSEN:	
Lack of Sleep	93
Stress:	92
Overdoing:	67
Heat:	55
Menstrual Cycle:	36
Sunlight:	23
Humidity:	19
Heavy Endurance Training:	19
Unhealthy food:	13
Dairy:	12
Walking:	11
Gluten	10
Too much screen time:	10
Those with Neuropathy warm water:	9
Those with Neuropathy cold water:	4
Caffeine:	9
Greasy foods:	3

SYMPTOMS TIMELINE

IN WHAT MONTH DID SYMPTOMS BEGIN TO LEVEL OFF?



IN WHAT MONTH DID SYMPTOMS BEGIN TO IMPROVE?



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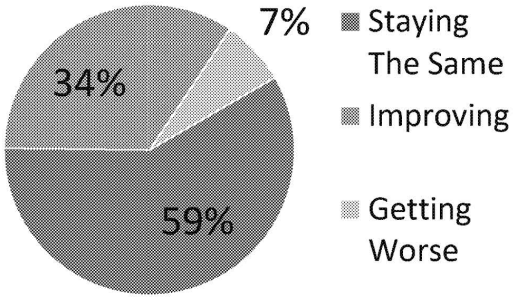
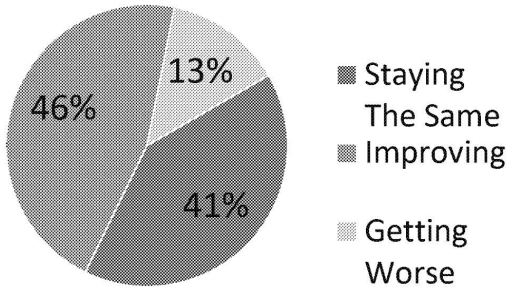
SYMPTOMS PROGRESSION - 1

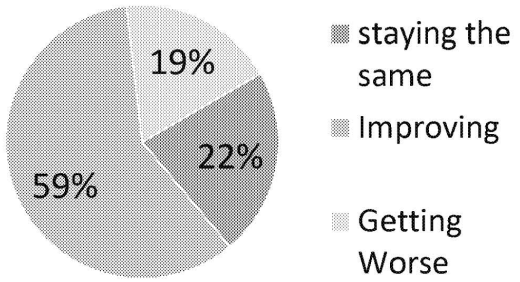
Fatigue



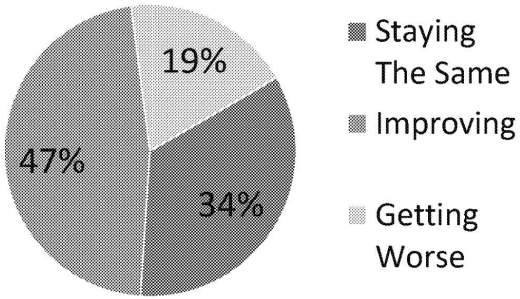
Brain Fog



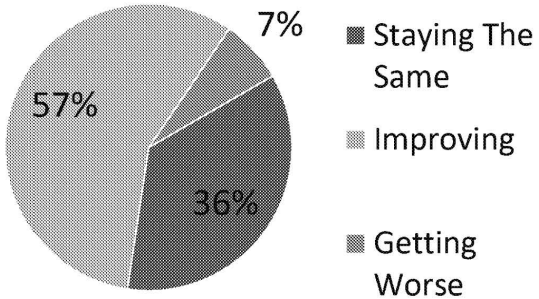
Burning Sensation



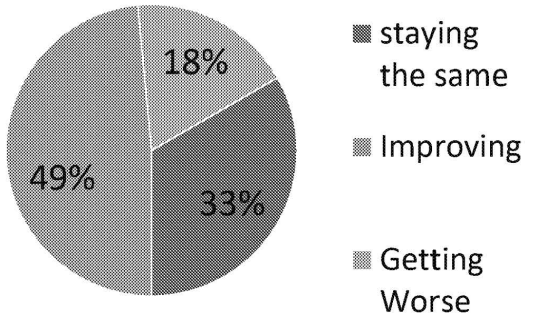
Tingling / Numbness



Dizziness



Muscle Twitching



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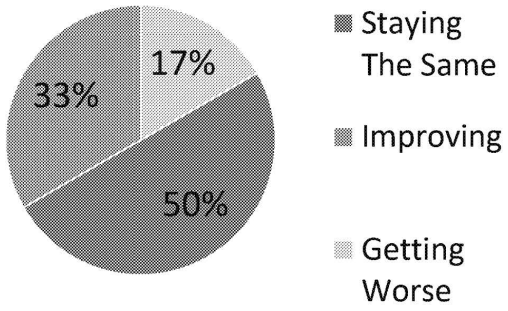
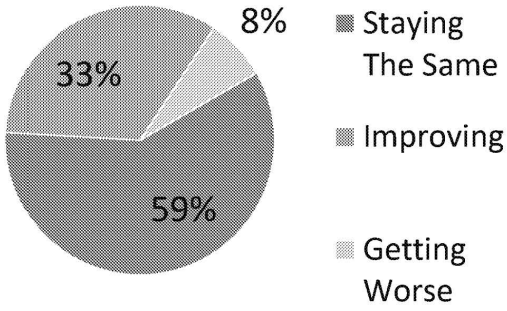
SYMPTOMS PROGRESSION - 2

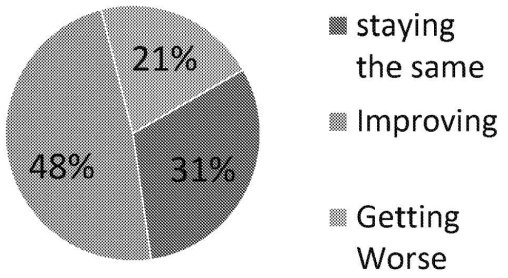
Heaviness In Legs



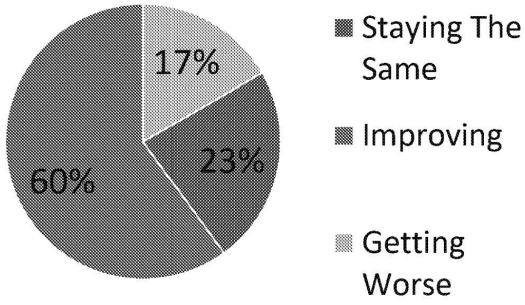
Internal Vibrations



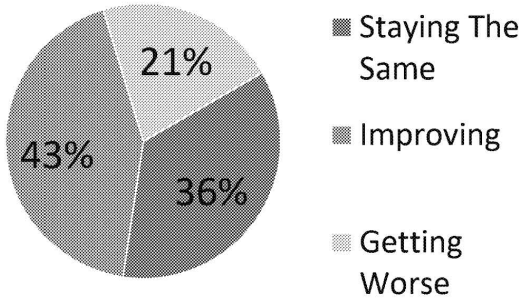
Tinnitus



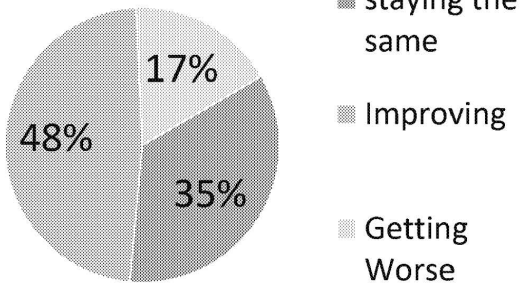
Heart Palpitations



Nerve Pain



New Persistent Headaches



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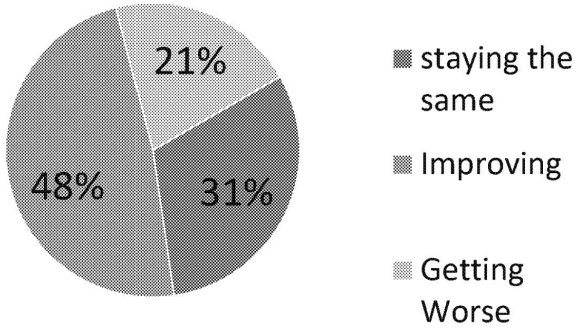
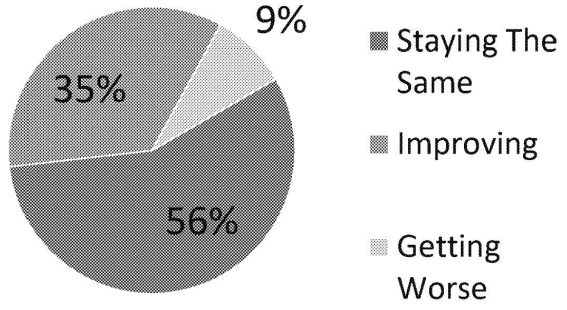
SYMPTOMS PROGRESSION - 3

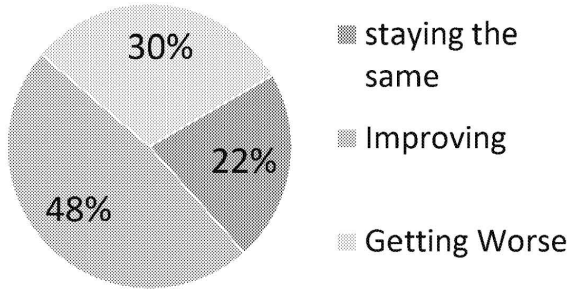
Insomnia



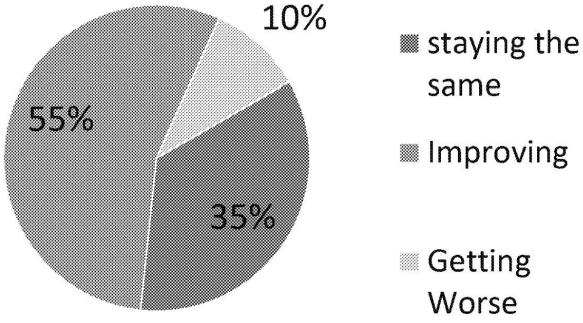
Visual Disturbances



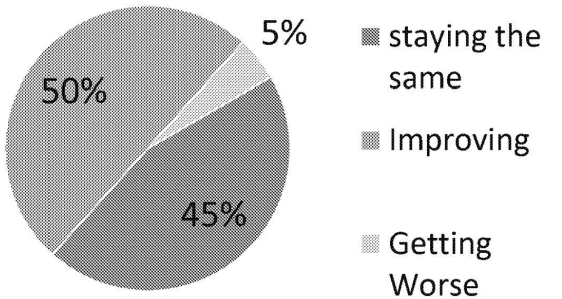
Anxiety



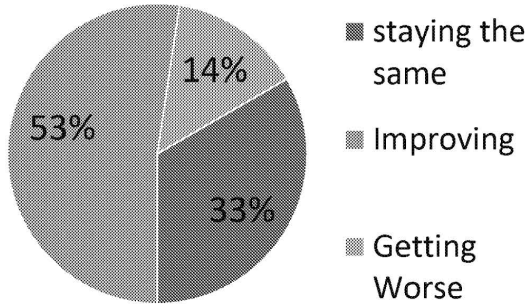
Lymphadenopathy



Irregular Menstrual Cycle



Tremors



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From: b6
Sent: 9/19/2021 6:18:40 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6b6
b6
Subject: Re: b6

Excellent,
How can he contact you to give consent- he is cc'd above on this email for any information you need from him.
I will contact the fellow to arrange at time to present his case thus far. It could be b6
b6
Thank your for all of your help.
Best
b6

On Sat, Sep 18, 2021 at 4:37 PM Nath, Avindra (NIH/NINDS) [E] b6 wrote:

> Wonderful. We have a Neuro-ID/immunology case presentations every Monday at 12 noon-1 pm. One of us would need to present him to our group. A decision would then be made by the group to see if he would meet the criteria for our protocol and what the plan would be for his further workup. I have copied Yair Mina, our clinical fellow who directs the meetings. Would it be possible for you to do a brief presentation? I have also copied our research nurse who can consent the patient. Our protocol requires that the patient or their legal guardian directly contact us for that purpose.
>
> Agree, he has some very unique findings and would be good to get to the bottom of it.
>
> Best.
>
> Avi
>
> Avindra Nath MD
>
> Chief, Section of Infections of the Nervous System
>
> Clinical Director,
>
> National Institute of Neurological Disorders and Stroke
>
> National Institutes of Health, Bethesda, MD
>
> b6 (Office)
>
> (cell)
>
> b6

From: b6
Date: Saturday, September 18, 2021 at 9:10 AM
To: Nath, Avindra (NIH/NINDS) [E] b6
Cc: b6
Subject: Re: b6

I will send off b6

How do I facilitate him going to see you at the NIH for a clinical appointment and testing? Should I have him contact anyone in particular and should I have him block off a number of days for testing etc?

I am so grateful for your help. He is a very special patient and I am concerned and perplexed.

Best,

b6

On Fri, Sep 17, 2021 at 10:11 PM Nath, Avindra (NIH/NINDS) [E] b6 wrote:

That is fine. Still good to send b6

Avi

From: b6
Date: Friday, September 17, 2021 at 6:04 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Cc: b6
Subject: Re: b6

Thank you so much!

b6

Should I send him to see you? This is all so new - and only since the J&J vaccine. He is a healthy athletic b6
b6

On Fri, Sep 17, 2021 at 5:26 PM Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Looks like b6

b6

b6

Hope this helps.

Avi

Avindra Nath MD

Chief Section of Infections of the Nervous System

Clinical Director, NINDS, NIH

Bldg 10; Rm 7C-103

10 Center Drive

Bethesda, MD 20892

b6

From: b6
Date: Friday, September 17, 2021 at 3:37 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Cc: b6
Subject: b6

His b6 is cc'd as well.

Any guidance is most appreciated!

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b6

b6

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b6

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b6

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b6

b6

From: b6
Sent: 9/18/2021 11:56:04 AM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6
CC: b6
Subject: Re: b6

Thank you for keeping me in the loop on this.
He called me last night that he feels like he had a setback over the last couple days. He feels like his walking to getting worse. I am going to see him next week in the office. I can b6

b6

On Sep 17, 2021, at 10:11 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

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Avi

From: b6
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Hope this helps.

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Avindra Nath MD

Chief Section of Infections of the Nervous System

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Bethesda, MD 20892

b6

From: b6
Date: Friday, September 17, 2021 at 3:37 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Cc: b6
Subject: b6

His b6 is cc'd as well.

Any guidance is most appreciated!

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b6

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b6

From: b6
Sent: 9/17/2021 7:35:42 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6-b6
CC:
Subject: b6
Attachments:

His b6 is cc'd as well.
Any guidance is most appreciated!

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From: Nath, Avindra (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B81CA051950B4D458D74037A6A86EAD6-b6]
Sent: 5/12/2021 6:07:15 AM
To:
Subject: b6

I talked to a research lab in b6 since they had set up the assay similar to what had been done in Germany. They said they will get back to me soon.
Avi

From: b6
Date: Tuesday, May 11, 2021 at 9:31 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Re: b6

Dr. Nath,

Any updates from b6 that might aid her local care team in providing care? I know that your team has been treating other vaccine reaction patients at the NIH, what is helping them?

Thank you,
b6

On May 5, 2021, at 8:43 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Sorry, for not getting back to you. Let me look into it further and then get back to you.
Avi

From: b6
Date: Wednesday, May 5, 2021 at 12:08 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: b6

Dr. Nath,

b6
b6 The attached pre-print shows evidence of novel antineuronal antibodies from COVID. This patient responded favorably to IVIG.

b6 remains symptomatic, now b6 Most of her testing has b6
b6 Her care teams are attempting to treat symptoms, with no response.

Your thoughts on this? Any updates from b6

Thanks,
b6

https://www.biologicalpsychiatryjournal.com/action/showPdf?pii=S0006-3223%2821%2901215-4