

# Myositis: More Evidence of Immune System Damage from COVID-19 mRNA Vaccines

16 cases explored - Pfizer mRNA was found in severely inflamed muscle one month after injection!

Theme: Science and Medicine

By Dr. William Makis

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**COVID Intel** 

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2022 May - Philadelphia, PA - 39 year old Yashira Cruz (pictured below) developed myositis after one dose of COVID-19 vaccine - "at one point I thought of crashing my car to end with my life."



Its almost the end of the month and I want to share my journey just in case there someone here that is still not diagnosed and fighting for the diagnosis and correct treatment.

#myositisawareness

It all started with a rash on my thigh. I did not paid attention, had my first dose of vaccine and of course my immune system went from hyper to wild King Kong. I had symptoms of fatigue and extreme pain, I noticed it was taking me more time to recover from my runs but I thought it was my age, 39 at the moment. Stupid right!

Once my eyes got swollen of course first diagnosed is allergies. Fast track to 4 months. No one knew. 4 hospitals, my main doctor, 3 specialist including a ophthalmologist, dermatologist and rheumatologists.

They diagnosed me with Lupus by symptoms not by blood results. It got worst. It started attacking my lungs.

Penn Medicines finally decided to keep me because of low oxygen.

Symptoms: fever, itch, extreme fatigue. I never lost strength, I actually kept on running and hiking to the end which of course made me worst. I even went to a natural doctor and spent \$400 on natural stuff.

At one point I thought of crashing my car to end with my life. I felt like an addict scratching. I lost my appetite and all my desire for life.

My daughter saw me faint at the doctors hospital. She had to drive me. She was only 19 at the time, I regret that moment for her. No child need to see their parent on that condition.

A year has passed and I am 75% myself. Under Myositis that is like a whole new life. I know there is many here fighting with so much more that with what I fought.

Steroids make me sicker so is a constant fight for me to stay away, not normal under this condition. What saved me: Tacromil; IVIG and Rituxan. Unfortunately you have to be very sick to get these. Specialist I see every 3 months: rheumatologists and pulmonologist. Dermatologist as need it

It seems I got this on time and this the reason for this post. Spread awareness. This is Dermamyositis.

Stay well warriors, you are not alone!







2023 June 4 – Julie Jo Koehler developed myositis after 2nd Pfizer COVID-19 mRNA vaccine.



Hi, I'm new. Was previously managed systemic lupus patient until Pfizer shot 2.

Pics from day after mRNA shot. Had immune system reaction.

Caused myositis, internal tremors, ibs-c, tmj, tinnitus, strabismus, ida, worsened trigeminal neuralgia & motor peripheral neuropathies, raynauds, chilblains, erythromyalgia, uveitis, rashes, sacroilliitis, pfd, lymphadenitis, thrombocythemia.

No longer trust doctors and specialists after being gaslit &referred back and forth like a yoyo for over 2 years. In PT for muscle retraining. Adopted less is more attitude on medications.

I can deal with most of it, it's the internal tremors and anxiety that concern me the most. What works for the tremors?

I heard it's similar to css- central sensitization syndrome and cipd-chronic inflammatory demyelinating polyneuropathy and treated with steroids and ivig.



2023 March – Saint Petersburg, FL – Emanuel Sferios got his COVID-19 booster shot in January. 10 days later he was in hospital for severe muscle pain and was diagnosed with myositis.







Health update #8: First, let me say I am not someone who identifies with being sick. I'm angry about what has happened to me (even as I don't have anyone to be angry at, and despite repeated bouts of feeling sad for myself and what has happened).

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I appreciate you're empathy, which means "understanding" much more than it means sympathy, or even compassion. The thing I value the most in the world is the connection that comes from mutual understanding, from the "touch" that occurs at the moment of true communication. In those moments the seemingly isolated self expands to include another, and is a reminder that we are all one and the same being (in reality, not metaphorically).

So, for those who don't yet know, on January 4th I got my covid booster, and ten days later I ended up in the hospital with severe muscle pain and disability. I have (unfortunately and with certainty now) myositis. It was absolutely and without question caused (not just triggered) by the vaccine. My doctors know it. The science is behind it. I could explain all the little details of how they know, but the main point is this...

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The mRNA vaccines temporarily hijack our muscle cells, causing them to create covid spike proteins. This is supposed to cause our B-cells to create antibodies against the spike protein, but my B-cells also created antibodies against my muscle cells. And now my muscles are the target of my immune system. Macrophages and other cytokines are attacking my muscles and literally breaking them down.

Under normal circumstances, myositis is an extremely rare autoimmune disease. One of the rarest diseases known. It has a high mortality rate, determined mostly by the subtype. We do not yet know the subtype I have. I need to get a muscle biopsy first, which should be happening in a few weeks. High dose prednisone right now is keeping most of the symptoms and damage at bay. I have mild pain and tenderness in my upper legs and shoulders. But when I had reduced my presnisone, I was barely able to walk.

The problem is that prednisone (a corticosteroid) is not good to be on long term. It causes all sorts of problems. But until they start me in other immune suppressant drugs, I'm stuck with this medicine right now.

One main cause of death in myositis patients is secondary lung infections, partly due to one main Lause of use an in mystis patients is sectionary fung intercoins, party due to prednisone and other immune suppressant drugs. To prevent this, I have started a prophylactic antibiotic three times a week. Prednisone also causes osteoporosis, so they have started me on Alendronate, 70mg once a week. The emotional side effects of prednisone I will just have to deal with.

Very soon I will also take my first dose of methotrexate (also once a week), another imm suppressant drug. After 4-6 weeks, if it works, it should allow me to slowly reduce the pr The goal is to get me from 25mg to 5mg or less, where the dangers of pneumonia and osteoporosis no longer exist.

However, the methotrexate right now is just a stop gap measure. It might not be the right drug for me, because they don't know the subtype of myositis I have yet. After the muscle biopsy it may tell me I have a more aggressive type that requires different drugs, including IV infusions. Hopefully this won't be the case.

I am hoping that the auto-antibodies my B-cells created from the vaccine will fade in six months, just like the good antibodies do, and that this will be over (or at least I can be on less dangerous doess of immunosuppressand fruigs). But they don't know anything yetc ases like mine, while growing in number, are still new. The research is still just getting started.

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I was a vocal advocate for the vaccines, as anyone who knows me knows. I refuse to entertain the question, "why me?" because it leads nowhere I can find useful. But the irony does not escape me. I hope now that my case (and many others) will help educate the medical profession.

I usually spend my thought time thinking about helping others. I am blessed to have made a career out of harm reduction. But now I have to spend most of my time researching only for myself, about a rare disease that somehow chose to afflict me. I am not used to doing this. It doesn't give me joy reading about myositis treatments, methotrexate side effects, and incidence rates of PCP permonoia. If a father be developing new Xylazine test strips (which I am) or otherwise continuing my activism.

I am also emotionally changed. This is partly because that's simply what presnisone does. But it's also being confronted with a painful and potentially debilitating and fatal disease. I've taken my health for granted and try every day to feel grateful that I got 53 years of perfect health. Not everyone has been as lucky as me.

If you've made it this far, thank you for reading. And thank you Stathia (my sister) and Jill (my partner, in the photo) for being there for me every day.



### mRNA booster shot and developed myositis and myocarditis.





Growing Kids Pediatrics LONG POST BUT WORTH A READ...

I held off on this post until after Caleb was discharged from the hospital as per his request. He has given me permission to share his journey.

Caleb had an eventful Thanksgiving week to say the least. Caleb received his Pfizer booster the Friday before Thanksgiving as it was offered to those 16-17 year olds in the earlier trial.

Friday evening into Sunday morning he had some typical vaccine side effects (tired, achy, low grade fevers, chills and headaches. Sunday morning he felt much better (he went to church and played dodgeball with some friends). On Monday afternoon he began to complain of joint pain and muscle pain (described as upper arms, neck and upper middle back pain). He took ibuprofen and felt better. These pains came and went on Monday but he still played hoops and went to work.

Tuesday morning Caleb came into our room at 4 am complaining of the same pain but much more intense. He took more ibuprofen and felt better. These pains came and went throughout the day and were bothersome but he still was able to go out for lunch and see a movie with his brothers. Around 4 pm, he started having indigestion (later described as left sided chest pain) but said it was from the El Nopal he ate for lunch . By 6:30 pm he called me at work as his pain was so intense and he was just miserable. I raced home and we headed straight for NCH Brownsboro ED.

In the ED, my suspicion was confirmed that he had myositis and myocarditis from his booster shot (muscle and heart inflammation). His Troponin level was elevated as were his other inflammatory markers and his EKG showed ST elevation all consistent with myocarditis. We then headed to NCH downtown ED where he had an ECHO to make sure he was stable enough for admission to the cardiac floor.

Caleb's hospitalization consisted of multiple blood draws to follow his Troponin levels and other inflammatory markers. He received only naproxen (a type of nonsteroidal anti inflammatory) twice a day and Tylenol every 4 hours for pain. He had several ECHOs (that were all normal with NORMAL heart function), several EKGs to help watch his heart rhythm closely, and close monitoring of his other vitals. He had a cardiac MRI to look at the areas of his heart inflammation. Infectious disease was consulted and ran a gazillion tests to prove the myocarditis was not caused by anything else. He had such amazing care by everyone that was on his team!

After 4 days at NCH, he was discharged feeling great, but tired because he had so many tests done throughout the night that interrupted his sleep. He can exercise, but not strenuously, and will have another cardiac MRI in two months with follow up appointments with Cardio and Infectious Disease.

Caleb is such a trooper!!! Post-Vax myocarditis is most commonly seen in Caleb's age group. It occurs almost exclusively in young men 16 to 30 years at a rate of 1/14,000 (0.00714%) after the 2nd vaccine dose. It is almost always self limited and does not cause any permanent cardiac damage as shown by multiple studies. The FDA continues to monitor this closely. The heart function in post-vax myocarditis is almost always normal which differentiates it from COVID-19 myocarditis where the heart function is decreased.

We aren't sure why young men his age are affected the most (it could be testosterone) and they are still trying to figure out the exact mechanism and if there is any predisposition.

Are Caleb and I upset he got the booster?? No, as we understand the pain and suffering this disease has caused people we know and love. As with any other medication or vaccine, serious adverse events are incredibly rare but do happen.

Will my other boys get boosted?? Yes, when their time comes.

The risk of myocarditis from the shot is incredibly small. In fact, the cardiac nurses at NCH said that Caleb is the first case they have seen. They also remarked that they have had many teens with COVID-19 myocarditis who have been very sick. In fact, during Caleb's hospitalization, there were several kiddos in the ICU battling COVID-19 (and several on vents).

I hate COVID and I LOVE my son. I have seen how this disease can ravage even the healthiest of kids and teens. I have seen long COVID in my own patients. Many who continue to struggle with daily, sometimes debilitating symptoms. I have had patients on ventilators, on ECMO, in the ICU, have GI bleeds, and MIS-C due to this beast of a disease.

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What is Pfizer doing to monitor for myocarditis in trial participants? There is one ongoing trial in 12-15 year olds that will evaluate Troponin levels after the second shot and there are other upcoming trials that will look at Troponin levels with the booster.

I wish it wasn't my kid but that is the risk we took. Everyday, as a parent I assume far greater risk than 0.00714%. Caleb is a teenage driver with a greater chance of being in an accident than myself.

In terms of COVID-19, compared to other age groups, people under 18 are at much lower risk of serious illness and death from Covid-19. However, the death rate for U.S. kiddos under 18 who are infected is about 0.01%. Yes, the majority of those deaths occurred in children with underlying conditions, but many occurred in happy, healthy children. So, overall risk of dying from COVID-19 if < 18 years is 0.01%. While small, it is a much higher risk than 0.00714%.

Another risk that I'm not willing to assume as a mom is my child being affected by long COVID. There have been many studies with differing numbers, but the most recent study from the British Medical Journal showed 14% of 11 to 17 year-olds who contracted COVID were still suffering from symptoms 15 weeks later and teenagers are the most at risk for this.

Dying of COVID-19 is NOT a risk I am willing to accept for any of my children and neither is long COVID as I have personally seen how debilitating this can be.

Do not minimize more common risks for your children, when known risks for something that could save their lives is much, much smaller.

\*\*\*\*I do not want division, divisive comments, or debate. I will delete those that are not appropriate. I am happy to address questions in a private manner. \*\*\*\*

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## **Medical Literature**

<u>2023 June 30 (Tosunoglu et al)</u> – 21 year old woman had Pfizer COVID-19 mRNA vaccine. Two days later, she complained of pain in her arm and came to neurology 20 days later with difficulty in sitting and getting up, pain in her legs, difficulty climbing stairs. She was diagnosed with myositis, responded only partially to steroids and then fully with IVIG.

2023 June (Jung Won Han et al) – 49 year old woman developed myositis and arm swelling 1 week after Pfizer COVID-19 mRNA vaccine. She was treated with Celebrex.

<u>2023 March 20 (Nushida et al)</u> – 14 year old girl died unexpectedly 2 days after receiving 3rd dose of Pfizer COVID-19 mRNA vaccine. Autopsy findings showed myositis, among many other findings.

<u>2023 March 16 (Syrmou et al)</u> – 67 yo Greek woman had 2nd Pfizer mRNA dose. Two days after she noticed a pruritic maculo-papular rash, left arm edema and bilateral symmetric proximal arm and leg muscle weakness. She presented to ER 20 days after Pfizer and was diagnosed with myositis, and put on steroids, methotrexate and hydroxychloroqine.





<u>2022 Dec (Jack Pepys et al)</u> – A rare presentation of rapidly progressing myopathy in an adolescent.

16 year old boy of British and East-Asian descent had 2nd Pfizer COVID-19 vaccine. After 3 hours he developed unusual weakness and deteriorated dramatically over following few weeks. He was unable to dress himself , had shortness of breath on the slightest exertion.

He was extremely difficult to treat, didn't respond to steroids or IVIG and stayed in the hospital 107 days.

He needed immuno-suppressive drugs used for transplant patients (mycophenolate mofetil) AND chemotherapy (cyclophosphamide) (!!)

2022 July 16 (Eli Magen et al) – 34 year old Israeli woman had 1st dose of Pfizer COVID-19 mRNA vaccines. 4 days later she presented with severe muscle weakness, pain and tenderness.

The authors did some extensive genomic testing of the patient's blood and muscle tissue biopsy samples. They found mRNA present in the severely inflamed muscle, a full month after COVID-19 vaccine injection! In this case, the mRNA was causing the myositis.

### 3.2. Evaluation of Vaccine mRNA Expression in Blood and Muscle Tissue Biopsy Samples

To understand the association of BNT162b2 mRNA expression with the development of myositis, we sequenced the patient's blood and muscle tissue biopsy samples. After generating raw sequence reads from control and patient blood samples, quality control was performed, followed by the removal of index and adapter sequences. Next, trimmed reads were further used for mapping to the human reference sequences + BNT162b2 vaccine spike mRNA using Bowtie2 [45]. Then, total mapped reads to the vaccine spike mRNA sequence region were calculated. A total of 17,626 and 639 reads were mapped to the vaccine <mark>spike protein</mark> mRNA sequence in the RNA-seq data of the control and the patient, respectively. Upon visualizing the spike mRNA reads mapping region using the Integrative Genomics Viewer (IGV) [46], we found that in the control sample, reads covered and were equally mapped across 98% region of the vaccine <mark>spike protein</mark> mRNA sequence. In the patient sample, reads were mapped to just a few regions covering only 36% of the vaccine <mark>spike protein</mark> mRNA sequence (<u>Figure 3</u>I). Partial mapping of the vaccine <mark>spike protein</mark> mRNA sequence in the patient's sample indicated an unusual pattern of vaccine mRNA expression in blood cells, namely, "chopped" parts of the mRNA vaccine molecules from the Pfizer vaccine. This was supported by the low level of anti-SARS-CoV-2 IgGs detected, suggesting that the mRNA vaccine was not translated into the spike protein in this patient, resulting in no immune response to SARS-CoV-2.

Next, to understand the development of vaccine-induced myositis, we performed a DNA sequencing analysis of a right quadriceps muscle biopsy sample from the patient one-month post-vaccination. We did not find any mapped reads of the vaccine spike mRNA sequence in the genomic DNA sequencing data. It can thus be inferred that the vaccine mRNA sequences did not integrate into the patient's genome. Next, to check whether vaccine mRNA expression could be detected in the RNA of the tissue biopsy sample, we performed a nested PCR using two sets of primers against the 3'UTR (untranslated region) of the vaccine mRNA. A synthetic construct containing the 3'UTR of the BNT162b2 mRNA vaccine served as a control for PCR validation of the mRNA vaccine. To achieve maximum sensitivity and specificity in PCR in efforts to detect the presence of vaccine mRNA in the quadriceps muscle tissue, a nested PCR was developed in which the forward primers annealed to the TLE5 3'UTR sequence and the reverse primers annealed to the mito-nc sequence of the BNT162b2 vaccine sequence. The expected size of the vaccine mRNA sequence was thus 75 bp. We observed a band of this size in the total tissue RNA, confirming the expression of the BNT162b2 vaccine mRNA in the biopsy samples of the right quadriceps muscle one month after BNT162b2 vaccination (<u>Figure 3</u>II). This result highlights that although the BNT162b2 vaccine mRNA was not properly expressed in blood cells seven days after receipt of the first vaccine dose, it was still expressed in muscle tissue distant from the vaccination site one month after receipt of the first vaccine dose. This suggests that the unusual BNT162b2 mRNA expression pattern observed in muscle cells may be related to the development of myositis.

<u>2022 July (Gabriele De Marco et al)</u> – A Large Cluster of New Onset Autoimmune Myositis in the Yorkshire Region Following SARS-CoV-2 Vaccination.

15 cases of myositis after COVID-19 vaccination are reported in this paper, 5 after dose #1, 7 after dose #2 and 3 after dose #3.

6 cases were from Pfizer and 9 were from AstraZeneca, so it's clearly not just an mRNA vaccine issue.

<u>2022 March 21 (Ji Hyoun Kim et al)</u> – 30 year old man had 2nd dose of Pfizer COVID-19 mRNA vaccine. 6 days later he presented to ER with fever, skin rash and polymyalgia. He was treated with steroids, azathioprine and tacrolimus.

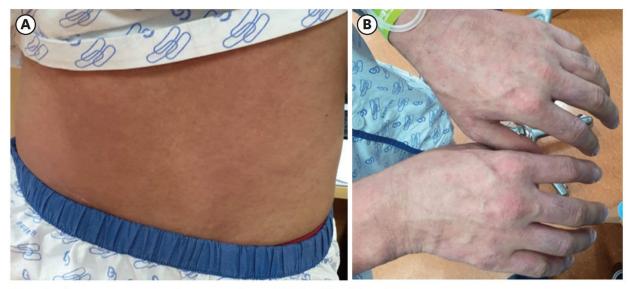


Fig. 1. Erythematous purpuric plaques on the trunk (A) and both hands (B).

<u>2022 Feb.17 (Al-Rasbi et al)</u> – 37 year old man in Oman, presented to ER 12 days after 1st Pfizer COVID-19 mRNA vaccine with left upper limb swelling, paresthesia and shortness of breath.

He was diagnosed with severe myositis, also had rhabdomyolysis, acute kidney injury, myocarditis with pulmonary edema, pulmonary hemorrhage and thrombocytopenia.

He was treated with steroids and IVIG.

<u>2022 Feb.7 (Wesam Gouda et al)</u> – 43 year old Asian Indian woman had 2nd dose of Pfizer COVID-19 mRNA vaccine. About 10 days later, she presented to ER with an itchy, erythematous rash all over her face, trunk and hands, inability to walk, difficulty rising from a chair and climbing stairs

She was treated with steroids, hydroxychloroquine, mycophenolate and physiotherapy.



<u>2022 Jan. 30 (Vutipongsatorn et al)</u> – Inflammatory myopathy occurring shortly after severe acute respiratory syndrome coronavirus 2 vaccination: two case reports.

55 year old South East Asian woman had 1st dose of Pfizer COVID-19 mRNA. Two days later she developed a facial and torso rash and presented to ER with worsening proximal

myopathy.

72 year old Caucasian woman had 2nd dose of Pfizer COVID-19 mRNA. She developed a proximal myopathy the next day and presented to ER 2 weeks later.

Both patients didn't respond to steroids but did respond to IVIG therapy.

<u>2021 Dec (Ramalingam et al)</u> – Cleveland Clinic Journal of Medicine – 81 year old man had 2nd dose of mRNA vaccine. The next day he noticed swelling, pain and redness in left arm. He was diagnosed with myositis and cellulitis. He was treated with steroids.



My Take...

Myositis refers to a group of conditions that share common features of muscle inflammation, resulting in muscle weakness and damage.

WHO VigiAccess reports 1729 cases of myositis after COVID-19 vaccination, however this is probably a significant under-reporting, as many cases are mis-diagnosed and very few cases are biopsied.

Clinical picture is as follows:

- Myositis begins usually within a few days of COVID-19 vaccination but could appear weeks after
- more common in women (3:2 ratio), average age is 56
- starts as an itchy maculopapular rash, usually on extremities, face, or trunk
- accompanied by swelling and pain in the extremities
- often involves proximal muscle weakness to the point where the patient has trouble getting up from sitting position, or going up the stairs.
- Diagnosis: MRI will show muscle edema but muscle biopsy is definitive, although findings will vary widely.
- Treatment usually starts with steroids and is then followed by IV immunoglobulin (IVIG) if needed
- Some cases are very difficult to treat and require very strong immunosuppressants like those used for transplant patients

When COVID-19 mRNA vaccines cause myositis, it is an abnormal auto-immune reaction, indicative that something has gone haywire with the immune system.

This abnormal auto-immune response can occur anywhere in the body and is further evidence of immune system damage caused by COVID-19 mRNA vaccines.

Possible mechanisms of immune system damage:

"Immunological cross-reactivity and molecular mimicry, involving spike dominant epitopes and myositis-related auto-antigenic targets, have been considered a likely mechanism for myositis induced by COVID-19 and its relevant vaccines. Kanduc and Shoenfeld (2020) described a striking oligopeptide homology between SARSCoV-2 spike glycoprotein and human and murine peptides, providing strong evidence towards immunogenicity of the virus and its spike in humans and mice"

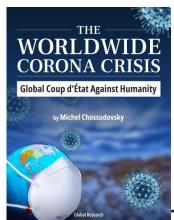
"mRNA vaccines can trigger immune reactions not only by coding specifc antigenic epitopes (proteins) but also themselves as nucleic acids. This mRNA is surrounded by nanoparticles or liposomes that keep it intact and help it escape cleavage by RNases. These particles transfer the mRNA in the cytosol by fusion to cellular membrane and endocytosis. However, while in the cytosol, mRNA can bind to several pattern recognition receptors (PRRs), including Toll-like receptors (TLRs), retinoic acid-inducible gene 1(RIG-1), and melanoma differentiation-associated protein 5 (MDA5) stimulating pro-infammatory cascades via type 1 interferon and transcription factor nuclear factor (NF)-kB"

COVID-19 mRNA vaccine induced myositis can be severe and potentially life-threatening. Fortunately, most cases seem to respond to steroids and IVIG.

P. S. Special thanks to Twitter user <u>Nashville Angela</u> for keeping track of some of these post COVID-19 vaccine myositis cases and warning others about this severe auto-immune reaction.

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