COVID-19 Vaccine Discussion Framing, 2025-2026

Professor Retsef Levi, PhD, MIT

ACIP Meeting, CDC
September 19, 2025

WG Main Takeaways

- Assessments of the protection level provided by COVID-19 vaccines and especially seasonal boosters against severe outcomes (hospitalization, ICU, death, long-covid) are based on very low-quality data and analyses

- Vaccine injuries are demonstrably not recognized by current pharmacovigilance systems, leaving vaccine injured individuals abandoned and without appropriate care

- Ample published research suggests serious safety uncertainties and concerns, including potential adulteration (mRNA vaccines), that are currently not appropriately addressed

WG Recommended Actions

- The risks and uncertainties related to the COVID-19 vaccine should be appropriately communicated by CDC to patients and medical providers to enable appropriate informed consent (WG recommendations regarding the Vaccine Information Statement)

- Development and enhancement of national efforts to appropriately diagnose the vaccine injured and care for them (WG will continue discussions in coming months)

- Development and enhancement of national safety surveillance systems to address safety uncertainties and assess impact (WG will continue discussions in the coming months)

COVID-19 Vaccine Benefits: Quality of Evidence

The WG could not receive reliable assessments of the Number Needed to Vaccinate (NNV) related to different sub-groups and outcomes:

Age	NNV cases	NNV hospitalizations	NNV deaths
Non-high-risk			
18-49 y	15	15,746	1,133,330
50-64 y	16	4,897	145,755
≥65 y	12	778	14,818
High-risk			
18-49 y	15	3,351	241,229
50-64 y	16	1,227	36,522
≥65 y	12	296	5,642

Presentation to COVID-19 Work Group September 12, 2025 by the University of Michigan

Quality of Evidence re COVID-19 Vaccine Benefits

Estimates from the UK greatly differ from the CDC estimates:

Table 1a: NNV estimates for a hospitalisation by age and risk status

Age (years)	No risk	Risk (not including IS)	IS	All
15 to 19	113,700	9,800	1,100	63,500
20 to 24	102,900	10,200	1,300	69,900
25 to 29	93,800	10,500	1,500	62,100

UK Health Security Agency (UKHSA) NVV estimates for the 2024-2025 season

[Appendix A: estimating the number needed to vaccinate to prevent a COVID-19 hospitalisation in autumn 2024 in England - GOV.UK]

Age (years)	No risk	Risk (not including IS)	IS	All
30 to 34	86,700	10,700	1,700	56,000
35 to 39	82,100	10,700	1,800	50,800
40 to 44	80,000	10,400	1,900	45,100
45 to 49	80,200	9,600	1,900	37,100
50 to 54	79,700	8,600	1,800	15,500
55 to 59	75,000	7,200	1,600	12,300
60 to 64	63,700	5,700	1,400	9,000
65 to 69	46,700	4,200	1,200	6,000
70 to 74	28,500	2,900	910	3,800
75 to 79	14,900	1,900	690	2,200
80 to 84	7,000	1,200	500	1,300
85 to 89	3,000	690	360	730
over 90	1,200	410	260	420

Quality of Evidence re COVID-19 Vaccine Benefits

Estimates from the UK greatly differ from the CDC estimates:

Table 1c: NNV estimates for death by age and risk status

Age (years)	No risk	Risk (not including IS)	IS	All
15 to 19	4,859,000	3,837,300	53,800	3,497,000
20 to 24	4,406,600	1,812,900	61,300	3,473,500
25 to 29	3,970,400	879,200	68,200	2,913,800
30 to 34	3,531,300	449,400	72,300	2,317,000
35 to 39	3,080,200	248,500	71,100	1,719,600
40 to 44	2,617,900	152,600	63,400	1,168,300
45 to 49	2,145,200	105,400	50,400	708,200
50 to 54	1,649,700	78,400	36,100	206,900
55 to 59	1,154,100	59,400	23,900	132,900
60 to 64	712,100	43,300	14,900	79,200
65 to 69	375,600	28,700	8,900	43,300
70 to 74	166,100	16,600	5,300	21,500
75 to 79	63,200	8,500	3,000	9,900
80 to 84	21,500	4,000	1,700	4,300
85 to 89	6,800	1,700	1,000	1,900
over 90	2100	740	570	780

UK Health Security Agency (UKHSA) NVV estimates for the 2024-2025 season

[Appendix A: estimating the number needed to vaccinate to prevent a COVID-19 hospitalisation in autumn 2024 in England - GOV.UK]

Methodological Limitations

- WG members felt that the current working definition of the CDC regarding COVID-19 associated hospitals does not seem to meaningfully capture the clinical impact of SARS-CoV-2 infections on severe COVID-19 outcomes

- Only 30% of patients under current definition have COVID as primary discharge diagnosis

Trends in COVID-19–Attributable Hospitalizations Among Adults With Laboratory-Confirmed SARS-CoV-2—COVID-NET, June 2020 to September 2023 - Taylor - 2024 - Influenza and Other Respiratory Viruses - Wiley Online Library

Methodological Limitations

- WG members felt that the current methodology to assess vaccine efficacy (VE) is prone to major biases:

"The design cannot be used for studying the mortality effects of vaccines and is problematic for studies into the effect on hospitalization. The vaccine's effectiveness on the transmission of viruses is also potentially problematic, depending very much on the characteristics of the tests. The implication of our findings is that the test-negative designs can, at best, be seen as an indication of effectiveness in highly idealized situations that are often far away from reality."

https://onlinelibrary.wiley.com/doi/10.1111/jep.13888

Test-Negative-Design

Person with acute respiratory illness

Key features of a TND
- Real-world circumstances
- Study start is symptomatic medical encounter
- Heterogenous study population, often "all comers"

Case

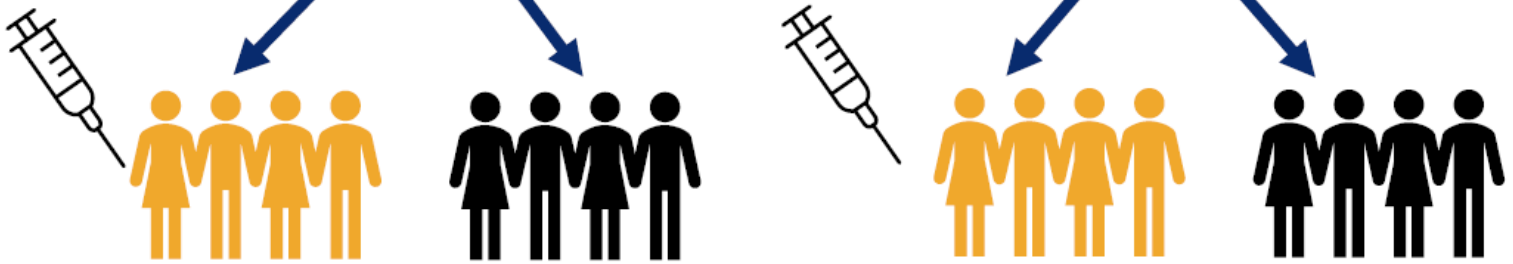
Control

N = population size= $N_v + N_{uv}$

Pathogen test
(e.g., SARS-CoV-2, RSV, flu, etc.)

Unknown number of vaccinated (N_v) and unvaccinated (N_{uv})

Immunization status



C_v = # of vaccinated covid cases

C_{uv} = # of unvaccinated covid cases

O_v = # of vaccinated controls

O_{uv} = # of unvaccinated covid controls

Effectiveness = 1 – (odds ratio) x 100% Odds ratio = $\frac{Odds\ of\ immunization_{cases}}{Odds\ of\ immunization_{controls}}$

NTD - Main Idea

- Ideally the relative risk would be calculated as $1-(C_v/C_{uv})\div(N_v/N_{uv})$, but $\mathbf{N_v/N_{uv}}$ not observed!

- Approximate it with the observed $\mathbf{O_v/O_{uv}}$ assuming the control cases are not affected by/correlated with vaccination status and therefore are drawn at random from the population

- Attempt to mitigate biases because health-seeking behavior (people who arrived to the hospital)

- Under assumptions provide an unbiased estimator of the relative risk reduction

Potential Biases of NTD

- The estimate of $\mathbf{O_v/O_{uv}}$ (for unobserved $\mathbf{N_v/N_{uv}}$) is prone to many biases:
  - Hospitalizations of controls (and cases) might be triggered by other (non-respiratory) medical conditions
  - Vaccinated test more when they have a cold
  - Vaccine could make vaccinated more vulnerable to other cold infections
  - Healthy vaccinee effect (HVE)

    https://www.nejm.org/doi/full/10.1056/NEJMc2306683

Other VE Assessment Approaches

- Matched cases (exact on based on propensity scores)
- Use of negative controls to capture unobserved biases
- Randomized control clinical trials (RCTs)

Note:

RCTs of mRNA vaccines did not show benefits for all cause mortality & hospitalizations

https://pubmed.ncbi.nlm.nih.gov/37163200/
https://pubmed.ncbi.nlm.nih.gov/36055877/

Other Concerns regarding VE

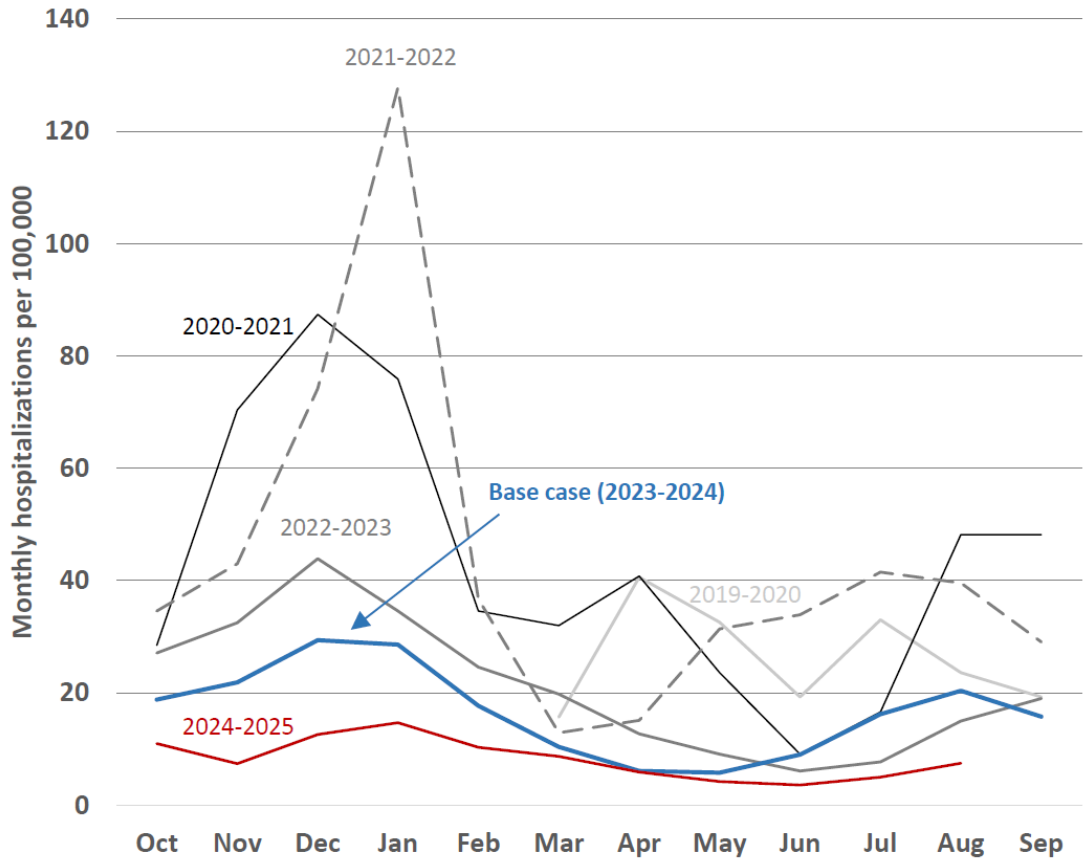
- WG members were concerned that the boosters' protection seems to be short-term

- WG members were concerned by published and unpublished research that suggest negative efficacy or increased vulnerability to other respiratory viruses:

  https://academic.oup.com/ofid/article/10/6/ofad209/7131292?login=false
  https://www.nature.com/articles/s43856-025-01046-8
  https://www.medrxiv.org/content/10.1101/2023.12.07.23298573v3

COVID-19 Burden Decreases

Weekly rates of COVID-19 associated hospitalizations by season, all ages



Source: COVID-NET

Presentation to COVID-19 Work Group September 12, 2025 by the University of Michigan

Safety Concerns and Uncertainties

WG members felt that CDC currently does not appropriately acknowledge several safety concerns & uncertainties:

- Outcomes and prognosis of myocarditis and other cardiovascular adverse events
- Clinically documented prolonged vaccines injuries, specifically post vaccine syndrome (PVS)
- Multiple documented unintended mechanisms of action of the mRNA vaccines and seemingly regulatory violations

Deaths from Myocarditis

Autopsies of 2 teenage boys in the US who died in their sleep 3 & 4 days post Pfizer Dose 2

Volume 146, Issue 8
August 2022

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FEBRUARY 14 2022

Autopsy Histopathologic Cardiac Findings in 2 Adolescents Following the Second COVID-19 Vaccine Dose

James R. Gill, MD ; Randy Tashjian, MD; Emily Duncanson, MD

Arch Pathol Lab Med (2022) 146 (8): 925–929.
https://doi.org/10.5858/arpa.2021-0435-SA **Article history**

Split-Screen Views PDF Share Tools

Context.—
Myocarditis in adolescents has been diagnosed clinically following the administration of the second dose of an mRNA vaccine for coronavirus disease 2019 (COVID-19).

Objective.—
To examine the autopsy microscopic cardiac findings in adolescent deaths that occurred shortly following administration of the second Pfizer-BioNTech COVID-19 dose to determine if the myocarditis described in these instances has the typical histopathology of myocarditis.

Regardless of the etiology of the fibrosis, the extent of scarring by itself is potentially arrhythmogenic and may be a contributing factor with the acute postvaccine myocardial injury. Similarly, the cardiac hypertrophy in case B may have made the heart more susceptible to an arrhythmia. The key point is that since these boys died suddenly and unexpectedly in their sleep without resuscitation, if the arrhythmia had been due to the myocardial scar (boy A) or cardiomegaly (boy B), then the fulminant, global myocardial injury would not be an expected finding. These 2 clinical histories support the etiology of the acute myocardial injury as a primary factor, not a secondary agonal or postresuscitative artifact.

Deaths from Myocarditis

CDC response

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APRIL 08 2022

Autopsy Histopathologic Cardiac Findings in 2 Adolescents Following the Second COVID-19 Vaccine Dose

Christopher D. Paddock, MD, MPHTM; Sarah Reagan-Steiner, MD, MPH; John R. Su, MD, PhD, MPH; Matthew E. Oster, MD, MPH; Roosecelis B. Martines, MD, PhD; Julu Bhatnagar, PhD; Tom T. Shimabukuro, MD, MPH, MBA

Arch Pathol Lab Med (2022) 146 (8): 921–923.

https://doi.org/10.5858/arpa.2022-0084-LE **Article history**

Split-Screen Views PDF Share Tools

To the Editor.—We read with concern the manuscript by Gill et al[1] that described autopsy findings for 2 adolescents who died after COVID-19 vaccination. The authors correctly stated that the Centers for Disease Control and Prevention (CDC) performed testing for SARS-CoV-2 and found no evidence of SARS-CoV-2 infection in autopsy tissues from the decedents. However, the authors did not include findings from far more thorough immunohistochemical and molecular testing performed by the CDC for each patient. We believe that all of the CDC's findings should be considered carefully, and that the omission of these data has important implications for the

Immunohistochemical localization (red) of intact *Clostridium septicum* bacilli and clostridial antigens, demonstrating hematogenous dissemination in the microvasculature of multiple organs, including hepatic sinusoids and small vessels of the liver (A), capillaries of the zona reticularis of the adrenal cortex (B), glomerular and cortical capillaries of the kidney (C), and splenic red pulp (D) (immunoalkaline phosphatase with naphthol–fast red and hematoxylin counterstain, original magnification ×20).

The conclusion of IDPB, based on the composite histologic, immunohistochemical, and molecular findings, was death attributable directly to *C septicum* sepsis. This conclusion is supported further by several salient and well-recognized clinicopathologic characteristics of this disease. *Clostridium septicum* sepsis is characteristically a fatal and fulminating infection that often presents with nonspecific signs and symptoms. The infection is lethal in approximately 60% to 70% of cases, and death typically occurs within 12 to 48 hours of symptom onset.[7-9] In contrast to the report by Gill et al,[1] information reported to the Vaccine Adverse Event Reporting System[10] noted that the patient described “flu-like symptoms” for 2 days before death.

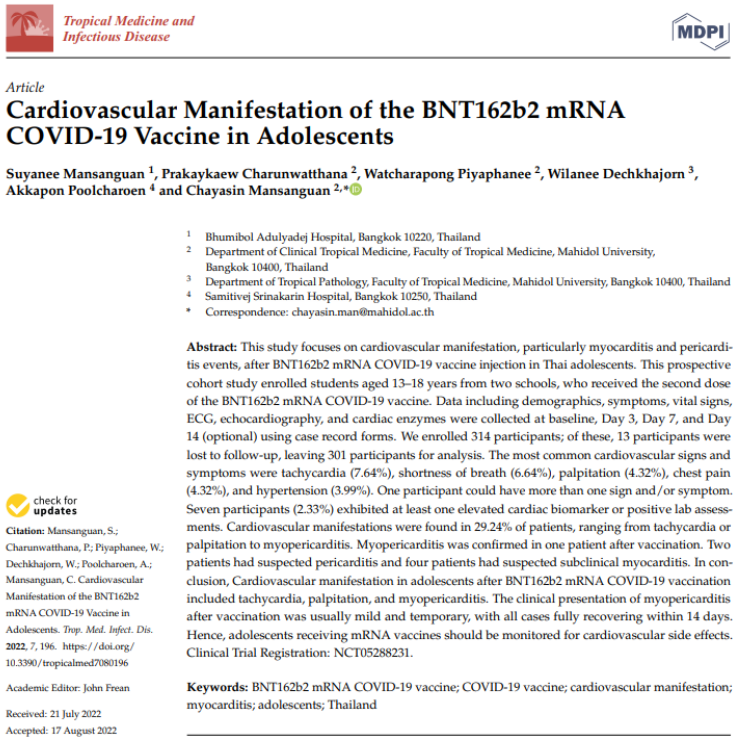
Deaths from Myocarditis

Pathologist response

For patient A, we agree that for completeness the parvovirus B (PVB) results should have been included in our report. We note that the CDC also did not diagnose this death as caused by PVB19 myocarditis. It noted in its report that "the significance of this finding is unclear as parvovirus-19 likely has long-term persistence in heart tissues, and is frequently detected in heart tissues from autopsies with no clinical or histopathologic evidence of myocarditis.[1,2]"[4,7,8] In a study[4] using 84 persons who died by suicide as a control group, PVB genomes were detected by polymerase chain reaction in 44% of the hearts. The authors concluded "that a positive PVB polymerase chain reaction test in cardiac autopsy specimens most likely represents a persistent infection with no or limited association to myocarditis. Hence, caution should be taken when interpreting the results for establishing the cause of death."[4] The histologic features in patient A were not those of viral myocarditis, nor would the ischemic injury be explained by such an infection. Thus, we conclude that the detection of the PVB genome is an incidental finding.

Subclinical myocarditis may occur in up to 3% post vaccination

Teenage boys post dose 2



Tropical Medicine and Infectious Disease

MDPI

Article

Cardiovascular Manifestation of the BNT162b2 mRNA COVID-19 Vaccine in Adolescents

Suyanee Mansanguan [1], Prakaykaew Charunwatthana [2], Watcharapong Piyaphanee [2], Wilanee Dechkhajorn [3], Akkapon Poolcharoen [4] and Chayasin Mansanguan [2,*]

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Abstract: This study focuses on cardiovascular manifestation, particularly myocarditis and pericarditis events, after BNT162b2 mRNA COVID-19 vaccine injection in Thai adolescents. This prospective cohort study enrolled students aged 13–18 years from two schools, who received the second dose of the BNT162b2 mRNA COVID-19 vaccine. Data including demographics, symptoms, vital signs, ECG, echocardiography, and cardiac enzymes were collected at baseline, Day 3, Day 7, and Day 14 (optional) using case record forms. We enrolled 314 participants; of these, 13 participants were lost to follow-up, leaving 301 participants for analysis. The most common cardiovascular signs and symptoms were tachycardia (7.64%), shortness of breath (6.64%), palpitation (4.32%), chest pain (4.32%), and hypertension (3.99%). One participant could have more than one sign and/or symptom. Seven participants (2.33%) exhibited at least one elevated cardiac biomarker or positive lab assessments. Cardiovascular manifestations were found in 29.24% of patients, ranging from tachycardia or palpitation to myopericarditis. Myopericarditis was confirmed in one patient after vaccination. Two patients had suspected pericarditis and four patients had suspected subclinical myocarditis. In conclusion, Cardiovascular manifestation in adolescents after BNT162b2 mRNA COVID-19 vaccination included tachycardia, palpitation, and myopericarditis. The clinical presentation of myopericarditis after vaccination was usually mild and temporary, with all cases fully recovering within 14 days. Hence, adolescents receiving mRNA vaccines should be monitored for cardiovascular side effects. Clinical Trial Registration: NCT05288231.

check for updates

Citation: Mansanguan, S.; Charunwatthana, P.; Piyaphanee, W.; Dechkhajorn, W.; Poolcharoen, A.; Mansanguan, C. Cardiovascular Manifestation of the BNT162b2 mRNA COVID-19 Vaccine in Adolescents. *Trop. Med. Infect. Dis.* **2022**, *7*, 196. https://doi.org/10.3390/tropicalmed7080196

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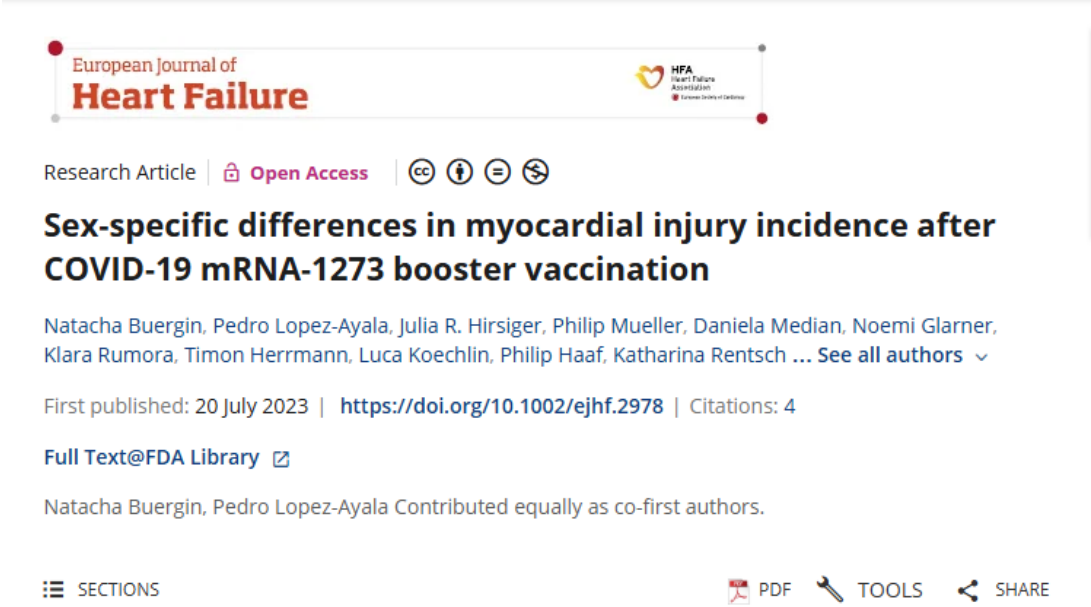
Keywords: BNT162b2 mRNA COVID-19 vaccine; COVID-19 vaccine; cardiovascular manifestation; myocarditis; adolescents; Thailand

Adult healthcare workers post booster dose



European Journal of Heart Failure

HFA Heart Failure Association

Research Article | Open Access

Sex-specific differences in myocardial injury incidence after COVID-19 mRNA-1273 booster vaccination

Natacha Buergin, Pedro Lopez-Ayala, Julia R. Hirsiger, Philip Mueller, Daniela Median, Noemi Glarner, Klara Rumora, Timon Herrmann, Luca Koechlin, Philip Haaf, Katharina Rentsch ... See all authors

First published: 20 July 2023 | https://doi.org/10.1002/ejhf.2978 | Citations: 4

Full Text@FDA Library

Natacha Buergin, Pedro Lopez-Ayala Contributed equally as co-first authors.

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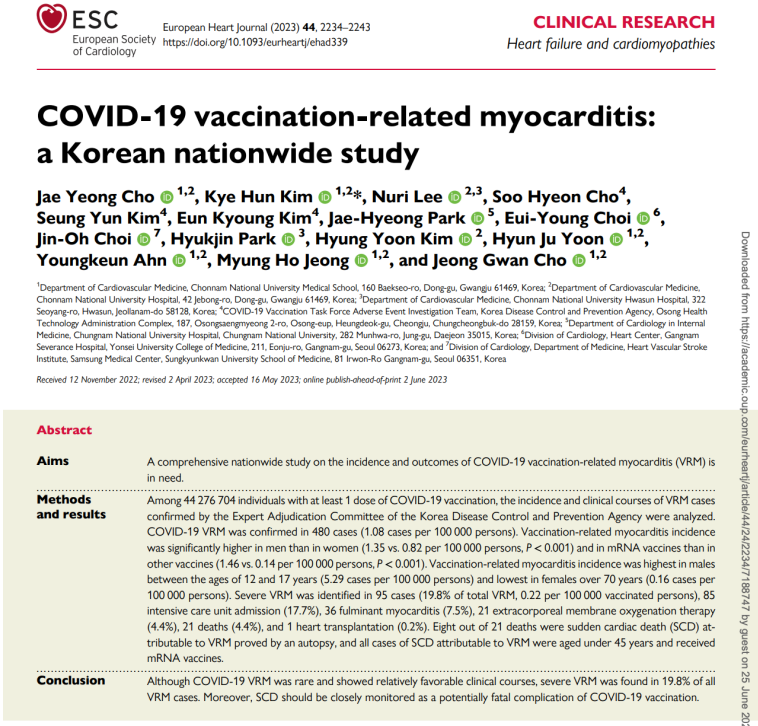
ACIP Meeting, CDC
September 19, 2025

Deaths from Subclinical Myocarditis

Korean study of 44 million vaccinated

- 95 cases severe vaccine related myocarditis
- 85 ICU admissions
- 36 cases of fulminant myocarditis
- 21 deaths (12 males & 9 females)
- 8 of the deaths were sudden cardiac death autopsy-found myocarditis without prodrome (subclinical myocarditis) all in <45 year olds who had received mRNA vaccines



ESC European Society of Cardiology
European Heart Journal (2023) **44**, 2234–2243
https://doi.org/10.1093/eurheartj/ehad339
CLINICAL RESEARCH
Heart failure and cardiomyopathies

COVID-19 vaccination-related myocarditis: a Korean nationwide study

Jae Yeong Cho [1,2], Kye Hun Kim [1,2]*, Nuri Lee [2,3], Soo Hyeon Cho[4], Seung Yun Kim[4], Eun Kyoung Kim[4], Jae-Hyeong Park [5], Eui-Young Choi [6], Jin-Oh Choi [7], Hyukjin Park [3], Hyung Yoon Kim [2], Hyun Ju Yoon [1,2], Youngkeun Ahn [1,2], Myung Ho Jeong [1,2], and Jeong Gwan Cho [1,2]

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Received 12 November 2022; revised 2 April 2023; accepted 16 May 2023; online publish-ahead-of-print 2 June 2023

Abstract

Aims A comprehensive nationwide study on the incidence and outcomes of COVID-19 vaccination-related myocarditis (VRM) is in need.

Methods and results Among 44 276 704 individuals with at least 1 dose of COVID-19 vaccination, the incidence and clinical courses of VRM cases confirmed by the Expert Adjudication Committee of the Korea Disease Control and Prevention Agency were analyzed. COVID-19 VRM was confirmed in 480 cases (1.08 cases per 100 000 persons). Vaccination-related myocarditis incidence was significantly higher in men than in women (1.35 vs. 0.82 per 100 000 persons, $P < 0.001$) and in mRNA vaccines than in other vaccines (1.46 vs. 0.14 per 100 000 persons, $P < 0.001$). Vaccination-related myocarditis incidence was highest in males between the ages of 12 and 17 years (5.29 cases per 100 000 persons) and lowest in females over 70 years (0.16 cases per 100 000 persons). Severe VRM was identified in 95 cases (19.8% of total VRM, 0.22 per 100 000 vaccinated persons), 85 intensive care unit admission (17.7%), 36 fulminant myocarditis (7.5%), 21 extracorporeal membrane oxygenation therapy (4.4%), 21 deaths (4.4%), and 1 heart transplantation (0.2%). Eight out of 21 deaths were sudden cardiac death (SCD) attributable to VRM proved by an autopsy, and all cases of SCD attributable to VRM were aged under 45 years and received mRNA vaccines.

Conclusion Although COVID-19 VRM was rare and showed relatively favorable clinical courses, severe VRM was found in 19.8% of all VRM cases. Moreover, SCD should be closely monitored as a potentially fatal complication of COVID-19 vaccination.

Long Term Prognosis of Myocarditis

Higher risk (almost 2.5 fold) of CV death 10 years after a myocarditis diagnosis

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RESEARCH ARTICLE: OBSERVATIONAL STUDY

Increased risk of ventricular tachycardia and cardiovascular death in patients with myocarditis during the long-term follow-up

A national representative cohort from the National Health Insurance Research Database

Te, Abigail Louise D. MD[a]; Wu, Tao-Cheng MD[a,b]; Lin, Yenn-Jiang MD, PhD[a,b,*]; Chen, Yun-Yu MPH[a,c]; Chung, Fa-Po MD[a,b]; Chang, Shih-Lin MD, PhD[a,b]; Lo, Li-Wei MD[a,b]; Hu, Yu-Feng MD[a,b]; Tuan, Ta-Chuan MD[a,b]; Chao, Tze-Fan MD[a,b]; Liao, Jo-Nan MD[a,b]; Chien, Kuo-Liong MD, PhD[c]; Lin, Chin-Yu MD[a]; Chang, Yao-Ting MD[a]; Chen, Shih-Ann MD[a,b]

Editor(s): Tarantino., Giovanni

Author Information

Medicine 96(18):p e6633, May 2017. | **DOI:** 10.1097/MD.0000000000006633

group. The long-term risks of life-threatening ventricular arrhythmias and mortality in patients with a history of myocarditis were investigated by an adjusted Cox proportional hazards regression. After a mean follow-up of 10.4 ± 2.94 years (interquartile range: 12, 10.19–12), the myocarditis patients showed a higher incidence of new onset VT events compared with healthy controls (5.4% [519 per 100,000 person-year] in the myocarditis group vs, 0.47% [43 per 100,000 person-year] in the healthy controls; adjusted hazard ratio [HR]: 16.1, 95% confidence interval [CI]: 12.4–20.9; $P < .001$). A higher incidence of cardiovascular death was noted in the myocarditis group than healthy controls (6.52% vs 3.18%; HR: 2.42, 95% CI: 2.14–2.73; $P < .001$) after adjusting for the multivariate confounders including sex, age, underlying comorbidities, and medications. The results of this study suggested that there was higher incidence of life-threatening VT and mortality during the very long-term follow-up in patients with a history of myocarditis. Future work should focus on an in-depth risk stratification of VT in myocarditis patients.

Unknown if this will apply to COVID-19 vaccine associated myocarditis

Post Vaccine Syndrome (PVS)

- The injuries associated with PVS are prolonged, debilitating and involve diverse symptoms and conditions, many overlapping with long COVID injuries

- Symptoms include among others dysautonomia (POTS), immune dysregulation, autoimmune disorders, severe neuropathy, cardiovascular & neurovascular injuries and severe clotting

Post Vaccine Syndrome (PVS)

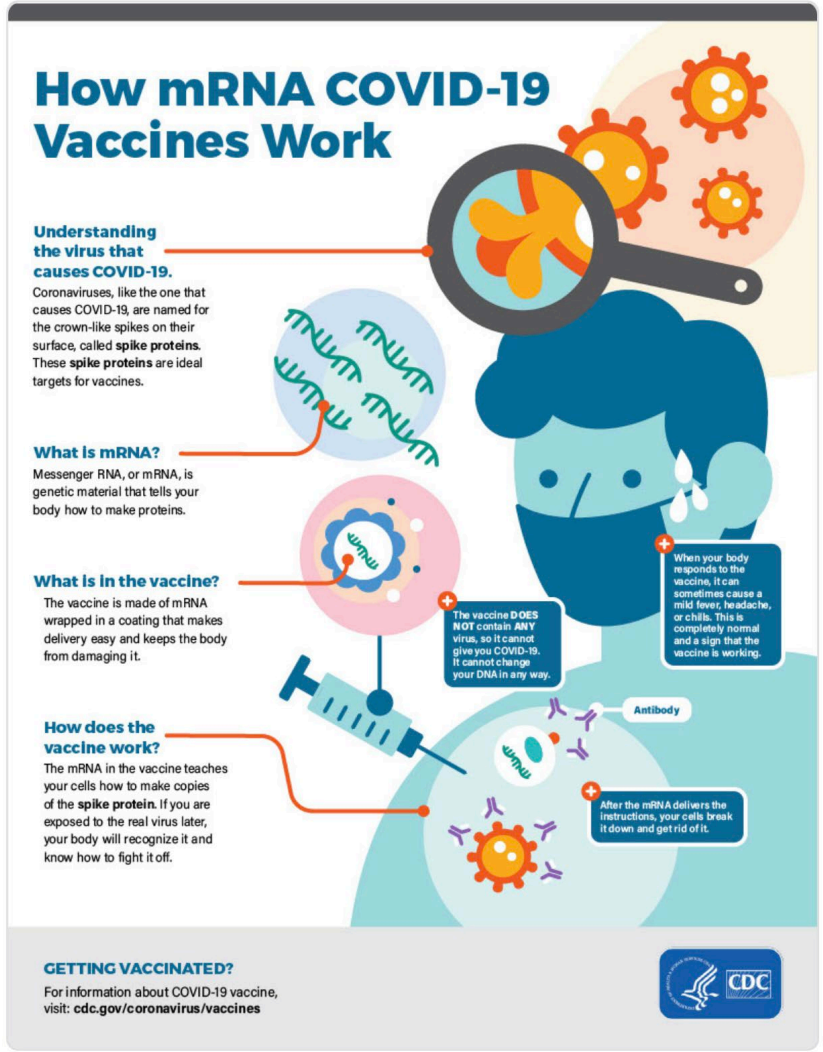
- The frequency of PVS and related risk factors are currently not well understood

- Do not fit existing diagnosis codes and often have common post vaccination symptoms but prolonged, therefore not likely to be captured by existing pharmacovigilance systems

Identification of Potential Adverse Events After COVID-19 mRNA Vaccines in Danish Children Using Healthcare Registries

mRNA Vaccines Don’t Work as Intended

- Wide biodistribution and prolonged persistent of Spike, mRNA and nano-lipid particles
- Not understood prolonged immune response (e.g., IgG4 switch class and cytokine profile)
- Frame shift leading to production of unintended proteins and related immune response
- DNA contamination (regulatory violation)



How mRNA COVID-19 Vaccines Work

Vaccination in Pregnancy

Most WG members felt that the current data not only do not support recommendation to vaccinate during pregnancy, but to the contrary support NOT to recommend:

- No appropriate randomized clinical trials to show efficacy and safety

- In the single (small) clinical trial (Pfizer) there was observed numerical imbalance of higher number of fetal anomalies among babies born to vaccinated women (8 vs. 2)

Vaccination in Pregnancy

- Observational studies are of very low-quality with structural biases, and some raise concerns

https://pubmed.ncbi.nlm.nih.gov/36794918/
https://obgyn.onlinelibrary.wiley.com/doi/10.1111/1471-0528.17721
https://bmcpregnancychildbirth.biomedcentral.com/articles/10.1186/s12884-025-07784-w

Vaccine-Specific Recommendations

The WG felt that there weren't sufficient data and time to arrive at recommendations specific to a vendor or a platform, but this seems likely to be a plausible approach in the future:

- In RCTs adenovirus vaccines reduced all cause mortality vs. mRNA vaccines that didn't

  https://pubmed.ncbi.nlm.nih.gov/37163200/

- Studies show Moderna may have higher protection and lower AEs compared to Pfizer

  https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2793236
  https://www.nejm.org/doi/full/10.1056/NEJMoa2115463

- Other vaccines, including not currently authorized in the US should be evaluated

Public Trust

Members in the WG felt that there a concerning gap between CDC ‘safe and effective’ narrative and public perception that erodes trust:

- In a recent poll over 56% suspect COVID-19 vaccines caused death:

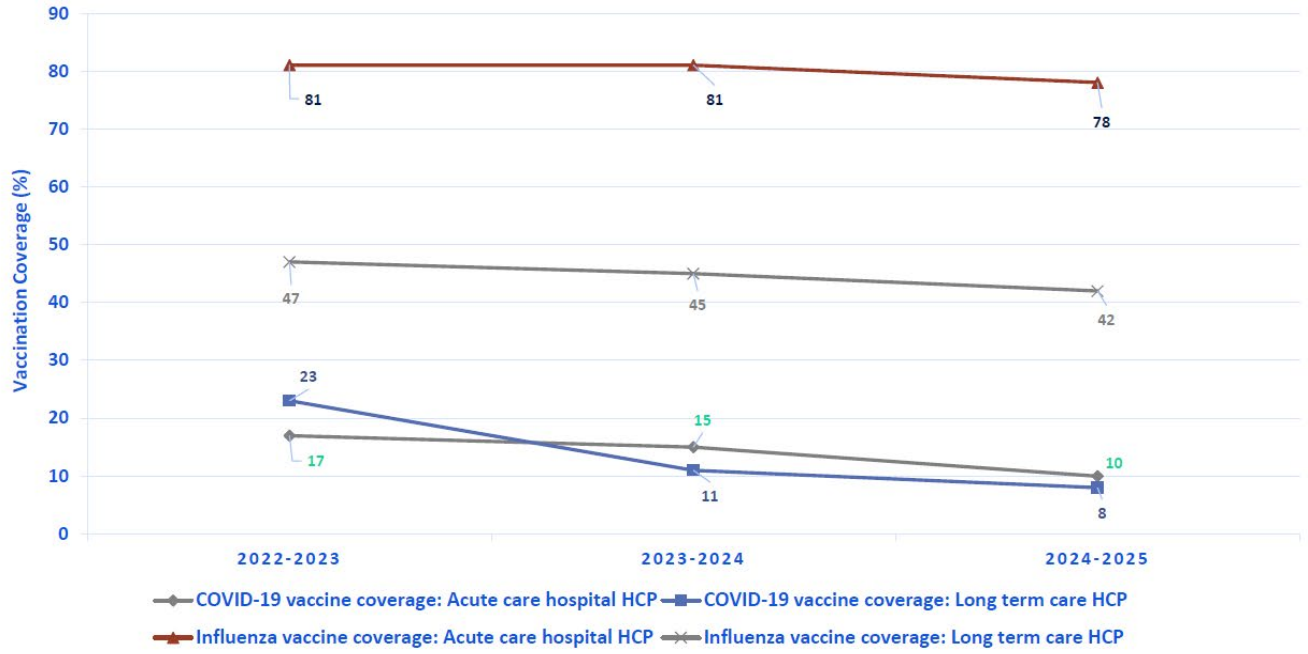
  https://www.rasmussenreports.com/public_content/politics/trump_administration_second_term/56_suspect_covid_19_vaccines_caused_deaths

- In another poll, 25% think they know someone who died from COVID-19 vaccines

  https://issuu.com/indiabookofrecords/docs/chugalkhor_times_mar_2023_issue_4/s/20904385

Trust of Healthcare Workers

COVID-19 and influenza vaccine coverage among healthcare personnel (HCP) 2022-2025*



References:
1. Influenza and Up-to-Date COVID-19 Vaccination Coverage Among Health Care Personnel — National Healthcare Safety Network, United States, 2022–23 Influenza Season | MMWR
2. Influenza and COVID-19 Vaccination Coverage Among Health Care Personnel — National Healthcare Safety Network, United States, 2023–24 Respiratory Virus Season | MMWR

*2024-2025 Data were collected from acute care hospitals and nursing homes on HCP influenza and up-to-date COVID-19 vaccination coverage for the week ending March 30, 2025. NHSN defined up-to-date COVID-19 vaccination during that time as the receipt of ≥1 dose of a 2024–2025 COVID-19 vaccination.

Discussion of the Recommendations for ACIP Vote

Recommended Updates to the Vaccine Information Statement

Most of the WG members were concerned that the existing administration processes of the COVID-19 vaccination products do not ensure a meaningful informed consent:

Taylor & Francis
Taylor & Francis Group

Human Vaccines & Immunotherapeutics

ISSN: 2164-5515 (Print) 2164-554X (Online) Journal homepage: www.tandfonline.com/journals/khvi20

Is informed consent correctly obtained for vaccinations?

Dhriti Jagadish, Nathaniel Mamo, Felicia Pasadyn & Arthur Caplan

Recommended Updates to the Vaccine Information Statement

"To inform is not merely to provide written or verbal notification of risks and benefits. Information disclosures, both in their content and mode of delivery, must spur earnest contemplation and autonomous decision-making."

"Each VIS must have a description of a vaccine's 1) benefits, 2) risks, 3) a statement of availability of the VICP, and 4) any other information deemed relevant. VISs must be presented before every vaccine dose in all clinical settings, regardless of whether there is a *learned intermediary* present or not."

Recommended Updates to the Vaccine Information Statement

The WG recommendation is that the CDC engages in effort to create more consistent and comprehensive informed consent processes, and as part of that considers adding language accessible to patients and medical providers to describe the following risks and uncertainties:

Recommended Updates to the Vaccine Information Statement

1. Current assessments regarding the protection provided by COVID-19 vaccines and especially seasonal COVID-19 boosters against severe outcomes (e.g., death, hospitalization and long COVID) are of low quality. At best, the additional protection provided by a seasonal booster is moderate and of short duration.

Recommended Updates to the Vaccine Information Statement

2. There is evidence that repeated seasonal mRNA boosters cause acquired changes in the immune system and may be associated with increased vulnerability to future infections, including SARS-CoV-2 and other respiratory viruses. These risks, as well as potential risks of autoimmunity, chronic inflammation, immune tolerance and impaired immune surveillance including immune fatigue or suppression, are currently not well understood.

Recommended Updates to the Vaccine Information Statement

3. There are documented deaths from symptomatic and subclinical myocarditis, pericarditis and potentially other cardiovascular conditions post COVID-19 vaccination, including of healthy children, with probable causal relationship to the mRNA vaccines. This risk is likely relatively small but currently not well understood.

Recommended Updates to the Vaccine Information Statement

4. Clinical reports demonstrate that in some cases COVID-19 vaccines can cause prolonged and debilitating post vaccine syndrome (PVS). The injuries associated with PVS involve diverse symptoms and conditions, many overlapping with long COVID injuries. Some of the observed symptoms and conditions may include insomnia, chronic pain and fatigue, dysautonomia (e.g., POTS), immune dysregulation and deficiency, autoimmune disorders, severe neuropathy and other neurodegenerative conditions, cardiovascular and neurovascular injuries, and severe clotting. The frequency of PVS and related risk factors are currently not well understood.

Recommended Updates to the Vaccine Information Statement

5. There is evidence that in some individuals vaccinated with mRNA COVID-19 vaccines, the resulting spike protein, the mRNA and the nano-lipids formulation components persist in different body organs, including lymph nodes and the heart, for a prolonged period of months and possibly years in some patients. Prolonged and persistent exposure to spike, mRNA and nano-lipids particles is associated with post-vaccine syndrome (PVS) injuries as well as potentially other side effects that are currently only partially understood.

Recommended Updates to the Vaccine Information Statement

6. The safety and the efficacy of COVID-19 vaccination during pregnancy have never been tested in appropriately powered randomized clinical trials. In one randomized trial there was observed numerical imbalance of higher number of babies with congenital malformation among those born to vaccinated women.

Recommendations for 2025-2026

Guiding principles:

- Access within the FDA authorized population
- Benefits, risks and uncertainties must be communicated as part of proper informed consent
- Debated between Individual-based decisions to group recommendations