



**NEŽÁDOUCÍ ÚČINKY OČKOVÁNÍ mRNA VAKCÍNAMI
V KARDIOLOGII - PROKÁZANÉ I POTENCIÁLNÍ**

Poslanecká sněmovna
20.11.2023
MUDr Jana Gandalovičová

Jméno:

Emailová korespondence SÚKL s rodinou
Datum: 7. 7. 2022 9:24:36

.... Data, která jsou pro vakcínu Spikevax (dříve Moderna) do současnosti známá, neukazují na zvýšené riziko vzniku srdečních onemocnění po očkování touto vakcínou. S pozdravem,

NESOUVISÍ

Oddělení farmakovigilančního hodnocení
Odbor farmakovigilance

OPRAVDU NE??



STÁTNÍ ÚSTAV
PRO KONTROLU LÉČIV

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svaloviny levé komory srdeční prokázané mikroskopicky. Dilatace srdce. Pasivní překrvení a edém plic. Pasivní překrvení dužninových orgánů. Edém mozku. Antrakóza plic a nitrohruďních lymfatických uzlin mírného stupně. Gilbertův syndrom dle klinika. Látka citalopram v krvi v terapeutické koncentraci prokázána chemicko-toxikologickým vyšetřením. Stav po přeočkování proti onemocnění COVID-19 snad 3 dny před smrtí dle sdělení rodiny. PCR SARS-CoV-2 při pitvě negativní. Stav po oživovacích pokusech.



Grieving Father Ernest Ramirez Shares Heartbreaking Story of His Teen Son's Death 5 Days After Pfizer Vaccine



Gee-Gees football player Francis Perron dies shortly after season opener



Sergio Agüero out for three months following 'cardiological evaluation'



Isaiah Harris Aged 18 - Pfizer May 2021

The Mercury News

Dumont Boy, 14, Collapses, Dies Playing Basketball

Treviso, Carlo Alberto died: the 12-year-old athlete suffering from cardiac arrest during a race

Clayton middle school student dies following youth football practice

"CAUSE UNKNOWN"

People

NEWS ENTERTAINMENT ROYALS LIFESTYLE STYLEWATCH SHOPPING PODCASTS



Mirror

17-year-old Angel Hernandez died after running his best time at a cross country race in Texas last week

Boy, 16, collapses and dies at cross country race after running personal best time

NEWS POLITICS FOOTBALL CELEBS TV CHOICE ROYALS

ENTERTAINMENT > SPORTS

Arne Espeel, 25-Year-Old Belgian Soccer Player, Dies After Saving Penalty: 'This Is a Disaster'

Dutch rider Mark Groeneveld dies age 20

Belgian goalkeeper Arne Espeel collapsed and died on the field after saving a penalty for his team.

By Jason Hahn | Published on February 14, 2023 04:49 PM

Spain's Under-15 Football Star Estrella Martin Dies Suddenly

By Jim Hoft | Jan. 26, 2023 8:16 pm | 771 Comments

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Canadian Hockey Player Eil Paireyman, 20, Loses Life During Game

By Sydney Garcia | September 3, 2022 | 156

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17-year-old dies 'suddenly and unexpectedly' after suffering cardiac arrest: 'No explanation as to why'

CHRIS ENLOE | January 12, 2023

f t in e

ANALYZING AMERICA

Another One: Teen Athlete Dies Suddenly At Golf Practice For Unknown Cause

By David Rufful - September 14, 2022



BREAKING

Sport

TRAGIC LOSS Sam Westmoreland dead aged 19: Mississippi State football star passes away as cause of death remains mystery

Israel Salas-Rodríguez

Published: 16:36 ET, Oct 19 2022 | Updated: 16:58 ET, Oct 19 2022





PŘEDČASNÉ ODSLEPENÍ RANDOMIZOVANÉ KONTROLOVANÉ STUDIE = ZCELA CHYBÍ DLOUHODOBÉ ÚDAJE O BEZPEČNOSTI

CO MĚLO PROBĚHNOUT

	VAKCINOVANÁ SKUPINA	PLACEBO SKUPINA	
2020			27. července 2020 Začíná fáze III Účastníci jsou rovnoměrně rozděleni do vakcinované a placebo skupiny o 21 000 osobách. Studie je zaslepená, tudíž účastníci nevědí, do které skupiny patří.
2021			
2022			
2023			2. května 2023 Konec fáze III klinického hodnocení. Toto je okamžik, kdy studie může být odslepena a skupině s placebem může být nabídnuta léčba, budou-li tito pacienti indikováni a budou-li souhlasit.

CO SKUTEČNĚ PROBĚHLO

	VAKCINOVANÁ SKUPINA	PLACEBO SKUPINA	
2020			27. července 2020 Začíná fáze III Účastníci jsou rovnoměrně rozděleni do skupin naočkovaných a skupiny s placebem, každá s přibližně 21 000 lidmi. Studie je zaslepená.
2021		ŽÁDNÁ DATA	31. prosince 2020 Vydána zpráva obsahující data za 2 měsíce. Studie je předčasně odslepena. Dochází k přesunu Účastníci ze skupiny s placebem dostali možnost využít očkování a do začátku roku 2021 se většina z nich přesunula do naočkované skupiny. Již se nejedná o randomizovanou kontrolovanou studii, neboť kontrolní skupina již neexistuje.
2022		ŽÁDNÁ DATA	
2023		ŽÁDNÁ DATA	2. května 2023 Konec fáze III klinického hodnocení Údaje o dlouhodobé bezpečnosti, které měly být v tomto bodě zhodnoceny, již není možné získat, protože skupina s placebem se o dva roky dříve přesunula do druhé skupiny.



ZPRÁVA O FARMAKOVIGILANCI SPOLEČNOSTI PFIZER PO UVEDENÍ NA TRH

- 17. listopadu 2021 vydala FDA první část z 329 000 stran, jak bylo soudem nařízeno na základě žádosti o svobodném přístupu k informacím podané skupinou Public Health and Medical Professionals for Transparency, která požadovala přístup k údajům, na jejichž základě FDA schválila vakcínu společnosti Pfizer COVID-19 (FDA u soudu požadovala více než 50-ti letou lhůtu na zveřejnění dokumentů).
- Jedna ze zpráv o postmarketingové farmakovigilanci předložené FDA, kde společnost Pfizer sledovala skutečné nežádoucí účinky, k nimž došlo během prvních 2,5 měsíců po povolení nouzového použití, je obzvláště znepokojivá.
 - Více než 1200 mrtvých
 - Více než 25 000 nežádoucích účinků týkajících se nervového systému
 - V části „Bezpečnostní obavy“ Pfizer uvádí Anafylaxi a Vakcínou způsobené zhoršení nemoci

Tento dokument by měl být kompromitující pro každou agenturu, která jej viděla a nazvala vakcínu „bezpečnou.“

HOME JOIN COURT DOCUMENTS PFIZER'S DOCUMENTS MEDIA INQUIRIES

Public Health and Medical Professionals for Transparency

This nonprofit, made up of public health professionals, medical professionals, scientists, and journalists exists solely to obtain and disseminate the data relied upon by the FDA to license COVID-19 vaccines. The organization takes no position on the data other than that it should be made publicly available to allow independent experts to conduct their own review and analyses. Any data received will be made public on this website.

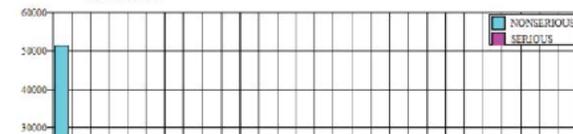
JOIN

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

	Characteristics	Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17	175 ^a
	18-30	4953
	31-50	13886
	51-64	7884
	65-74	3098
	≥ 75	5214
	Unknown	6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

^a in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness



BNT162b2

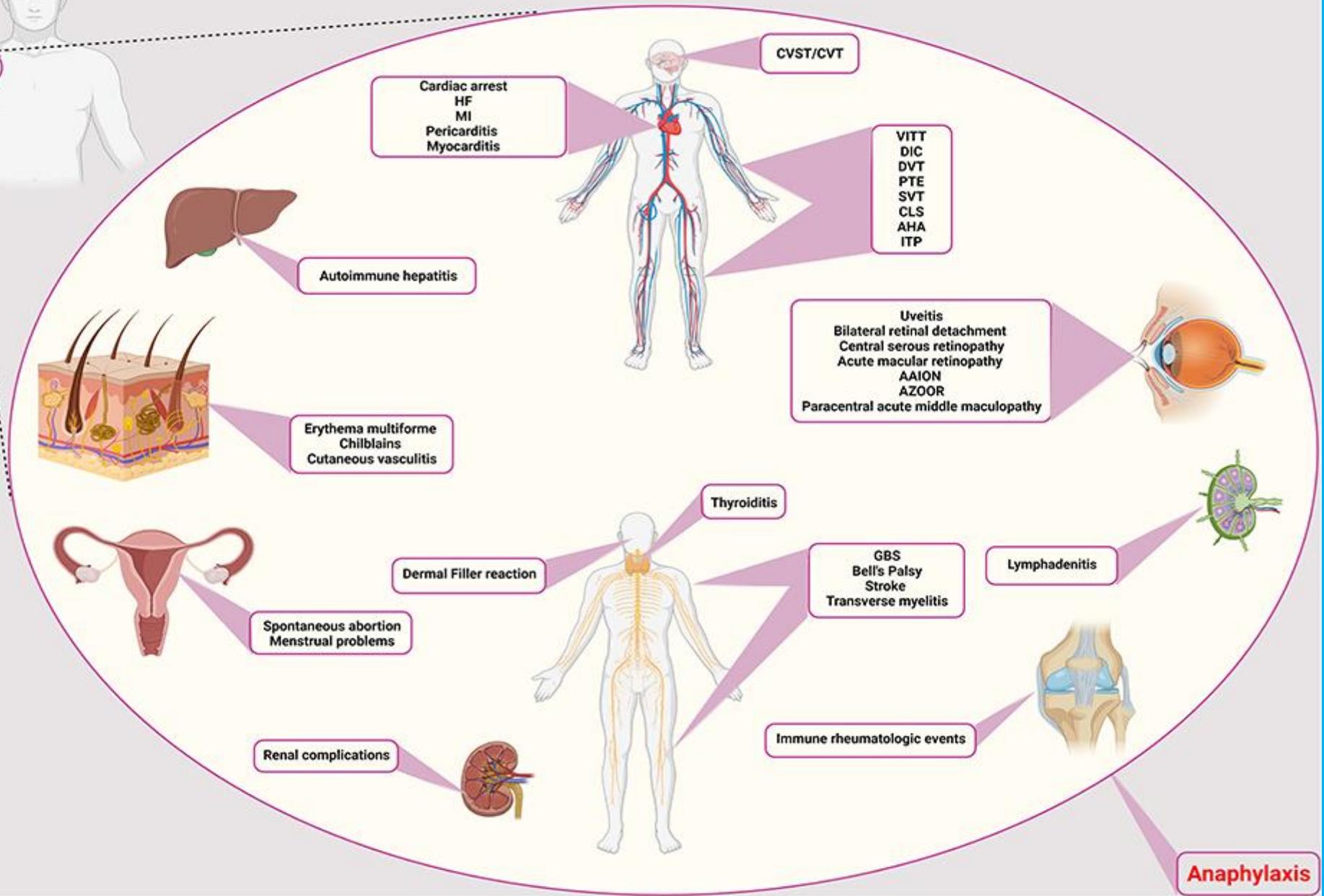
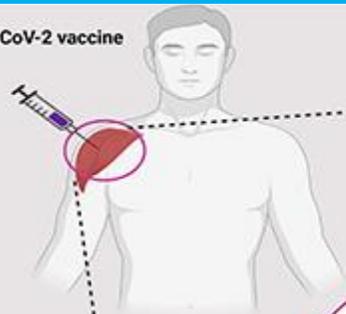
5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

Table 1 below presents the main characteristics of the overall cases.

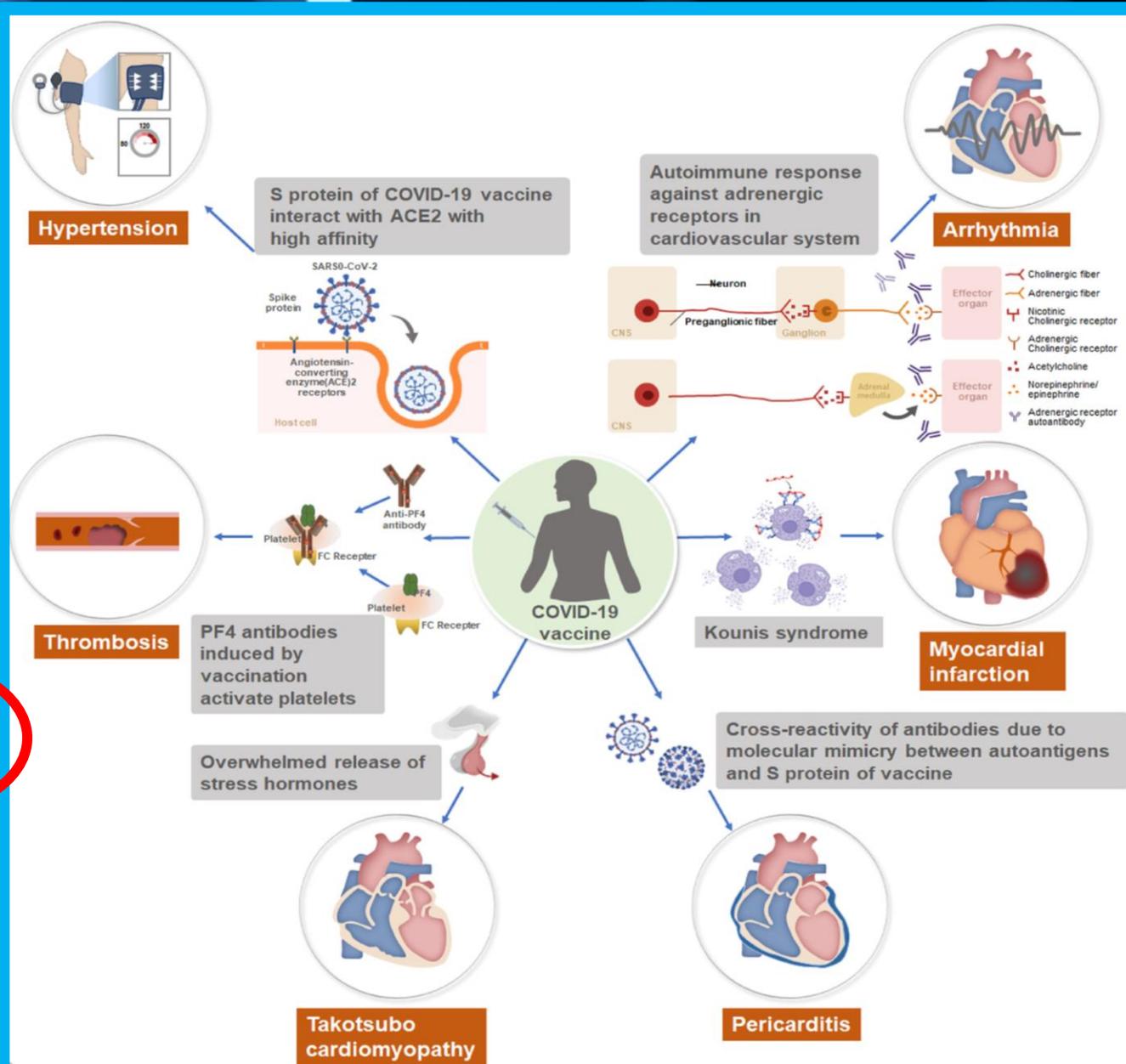
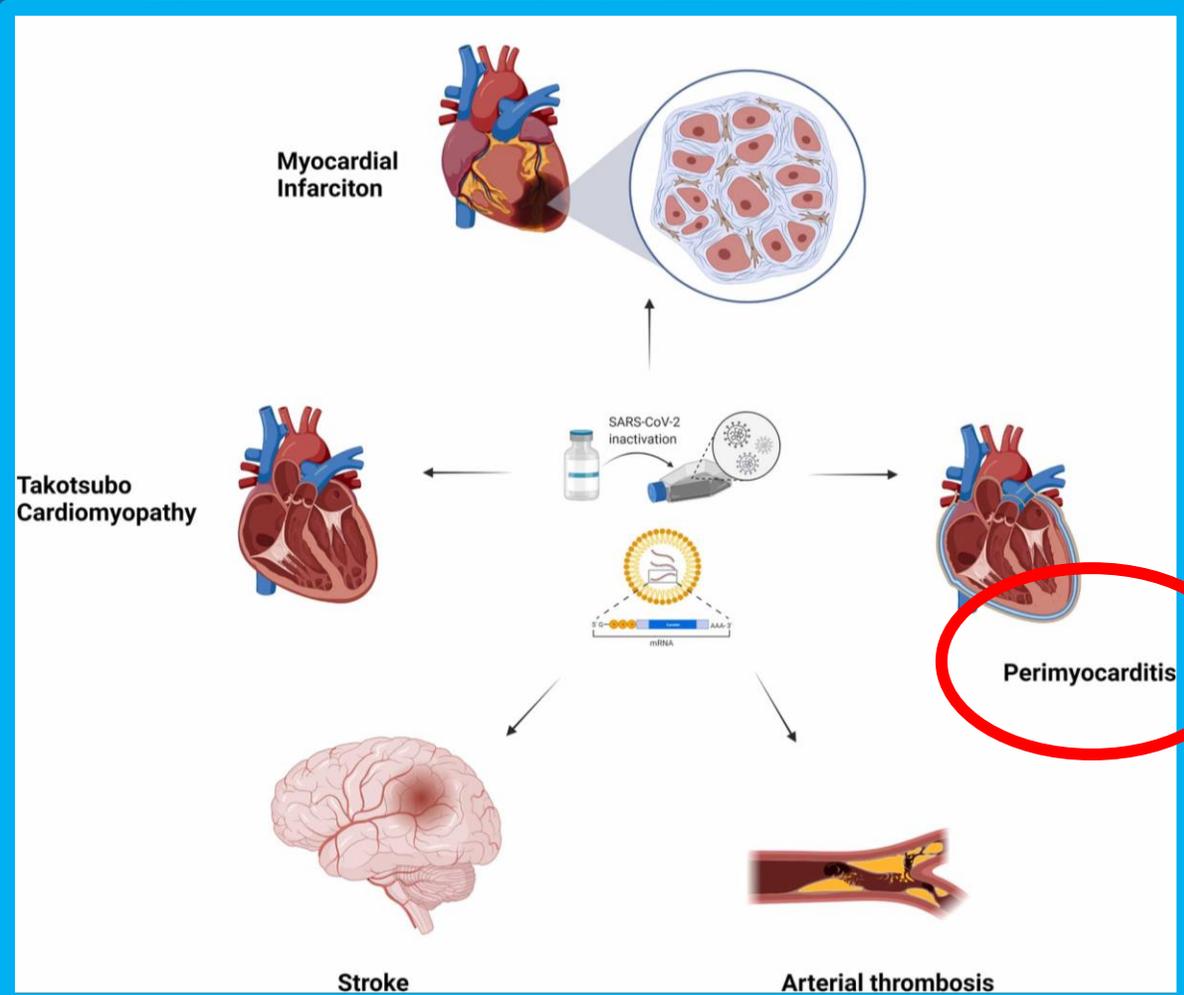
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	Unknown	9400

1223



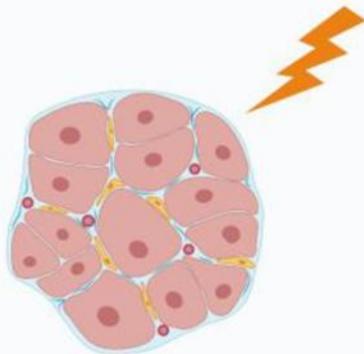
Kardiovaskulární kompli



Myokarditidy - průběh

Phase I

Direct damage to the myocardium

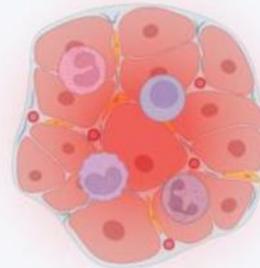


Direct myocardial damage by:

- Viruses
- Bacteria
- Parasites
- Fungi
- Autoimmunity
- Drugs
- Toxins

Phase II

Immune-mediated disease

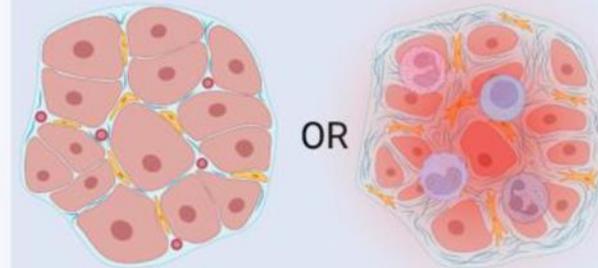


Immune response:

- Cytokine release
- Immune cell infiltration
- Molecular mimicry
- Anti-heart antibodies
- T cell response against self-antigens

Phase III

Chronic disease or resolution

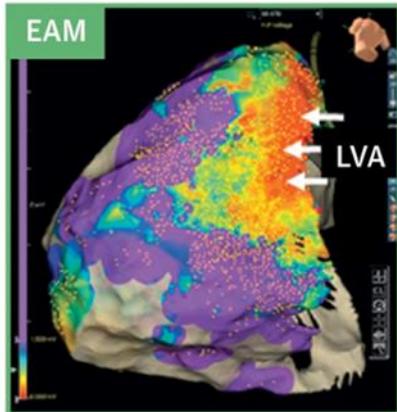


Possible outcomes:

- Resolution of inflammation and full recovery
- Chronic inflammation, fibrosis and inflammatory cardiomyopathy
- Progression to dilated cardiomyopathy

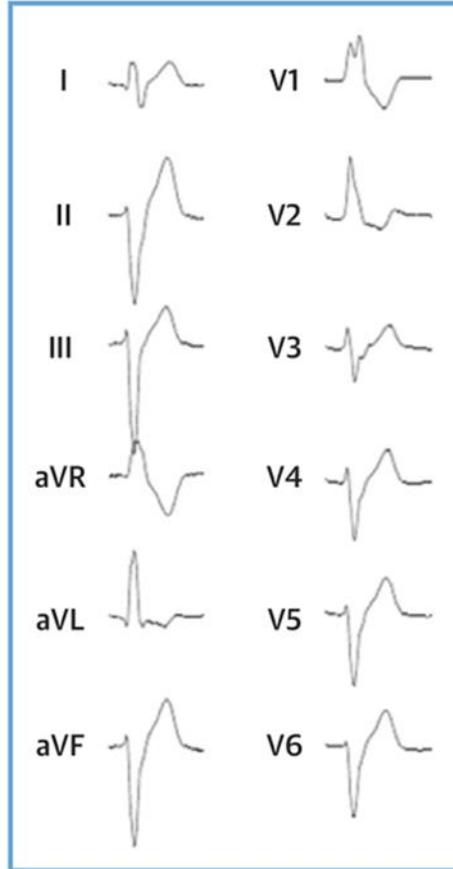
CENTRAL ILLUSTRATION: Ventricular Arrhythmias in Myocarditis

Substrate Localization



Inferoposterior LV wall
Subepicardial - Midwall

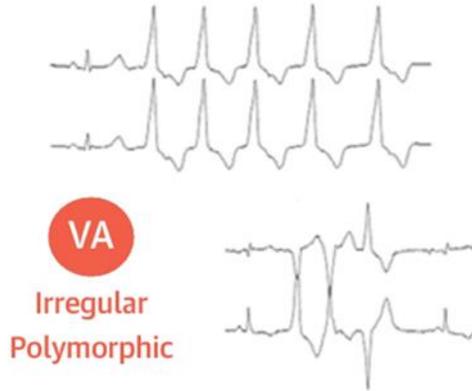
Dominant Morphology



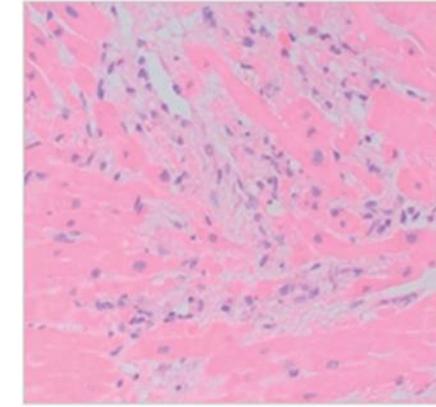
RBBB Superior axis

Relationship with Myocardial Inflammation

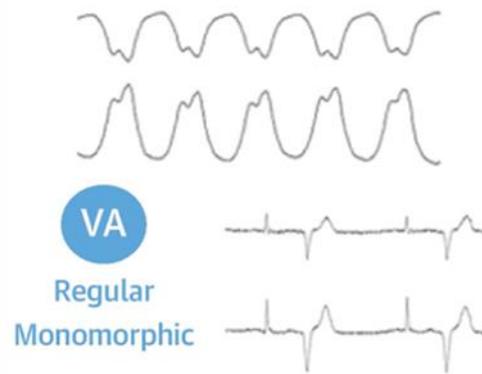
Active Myocarditis



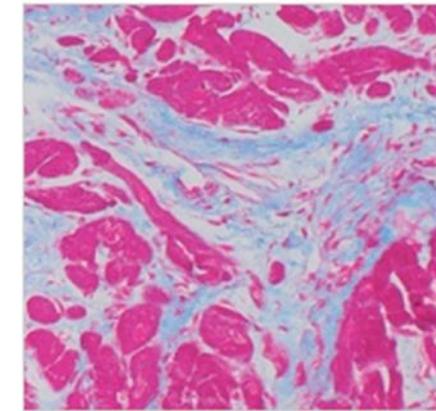
Inflammation



Previous Myocarditis



Fibrosis



Preliminary myocarditis/pericarditis reports to VAERS following **dose 2** mRNA vaccination, Exp. vs. Obs. using **7-day** risk window (data thru Jun 11, 2021)

Age groups	Females			Males		
	Doses admin	Expected ^{*,†}	Observed [*]	Doses admin	Expected ^{*,†}	Observed [*]
12–17 yrs	2,189,726	0–2	19	2,039,871	0–4	128
18–24 yrs	5,237,262	1–6	23	4,337,287	1–8	219
25–29 yrs	4,151,975	0–5	7	3,625,574	1–7	59
30–39 yrs	9,356,296	2–18	11	8,311,301	2–16	61
40–49 yrs	9,927,773	2–19	18	8,577,766	2–16	34
50–64 yrs	18,696,450	4–36	18	16,255,927	3–31	18
65+ yrs	21,708,975	4–42	10	18,041,547	3–35	11
Not reported	—	—	1	—	—	8

„Anti-SARS-CoV-2 vaccine-induced myocarditis – real but, in general, rare and mild“

Article

Intramyocardial Inflammation and Endomyocardial Biopsy-Pro

Christian Baumeier ^{1,*}, Ganna Aleshcheva ¹, Dom
Birgit Assmus ³, Ralf Westenfeld ⁴, Malte Kelm
Albrecht Elsässer ⁷, Mudather Gailani ⁸, Christian
Johann

ARTICLE OPEN

Check for updates

Duration of SARS-CoV-2 mRNA vaccine persistence and factors associated with cardiac involvement in recently vaccinated patients

Aram J. Krauson ¹, Faye Victoria C. Casimero ^{1,2}, Zakir Siddiquee ¹ and James R. Stone ^{1,2}

Cardiac Findings in 2 and COVID-19 Vaccine

Yu ², Matthew E Oster ²,
Curo ²

Vol. 148, No. 5 > Cardiovascular Assessment up to One Year After COVID-19 Vacci

Cardiovascular Assessment up to One Year Associated Myocarditis

Clement Kwong-man Yu, Sabrina Tsao, Carol Wing-kei Ng, Gilbert T. Chua, K
Mike Yat-wah Kwan and Yiu-fai Cheung

Originally published 31 Jul 2023 | <https://doi.org/10.1161/CIRCULATIONAHA.123.0647>

Circulation

RESEARCH LETTER

Cardiovascular Assessment up to One Year After COVID-19 Vaccine-Associated Myocarditis

Clement Kwong-man Yu, MBBS; Sabrina Tsao, MBBS; Carol Wing-kei Ng, MBBS; Gilbert T. Chua, MBBS;
Kwok-lap Chan, MBChB; Julia Shi, MBBS; Yumi Yuk-ting Chan, MSc; Patrick Ip, MBBS;
Mike Yat-wah Kwan, MBBS, MSc (Applied Epidemiology); Yiu-fai Cheung, MD

Rapid Communication

Cardiac side effects of RNA-based SARS-CoV-2 vaccines: Hidden cardiotoxic effects of mRNA-1273 and BNT162b2 on ventricular myocyte function and structure

Rolf Schreckenber¹, Nadine Woitasky¹, Nadja Itani¹, Lauren Czech¹, Péter Ferdinandy^{2,3},
Rainer Schulz¹

<https://doi.org/10.1016/j.jpeds.2022.03.032> • Check for updates

magnetic resonance imaging findings in 16 patients, aged 12-17 years, with
of the Pfizer mRNA coronavirus disease 2019 vaccine. Although all patients showed
persistent cardiac magnetic resonance imaging findings at 3- to 8-month follow-up.

European Society of Cardiology guidance for the diagnosis and management of cardiovascular disease during the COVID-19 pandemic: part 1—epidemiology, pathophysiology, and diagnosis

The Task Force for the management of COVID-19 of the European Society of Cardiology

[European Society of Cardiology guidance for the diagnosis and management of cardiovascular disease during the COVID-19 pandemic: part 1—epidemiology, pathophysiology, and diagnosis - PMC \(nih.gov\)](#)

While initial studies suggested that myocarditis may occur early during COVID-19, more recent studies have been less convincing in showing an association between myocarditis and SARS-CoV-2 infection. A definitive diagnosis of myocarditis should be based on endomyocardial biopsies or autopsy using established histologic and immunohistochemical criteria.¹⁰⁸ While the presence of virus has

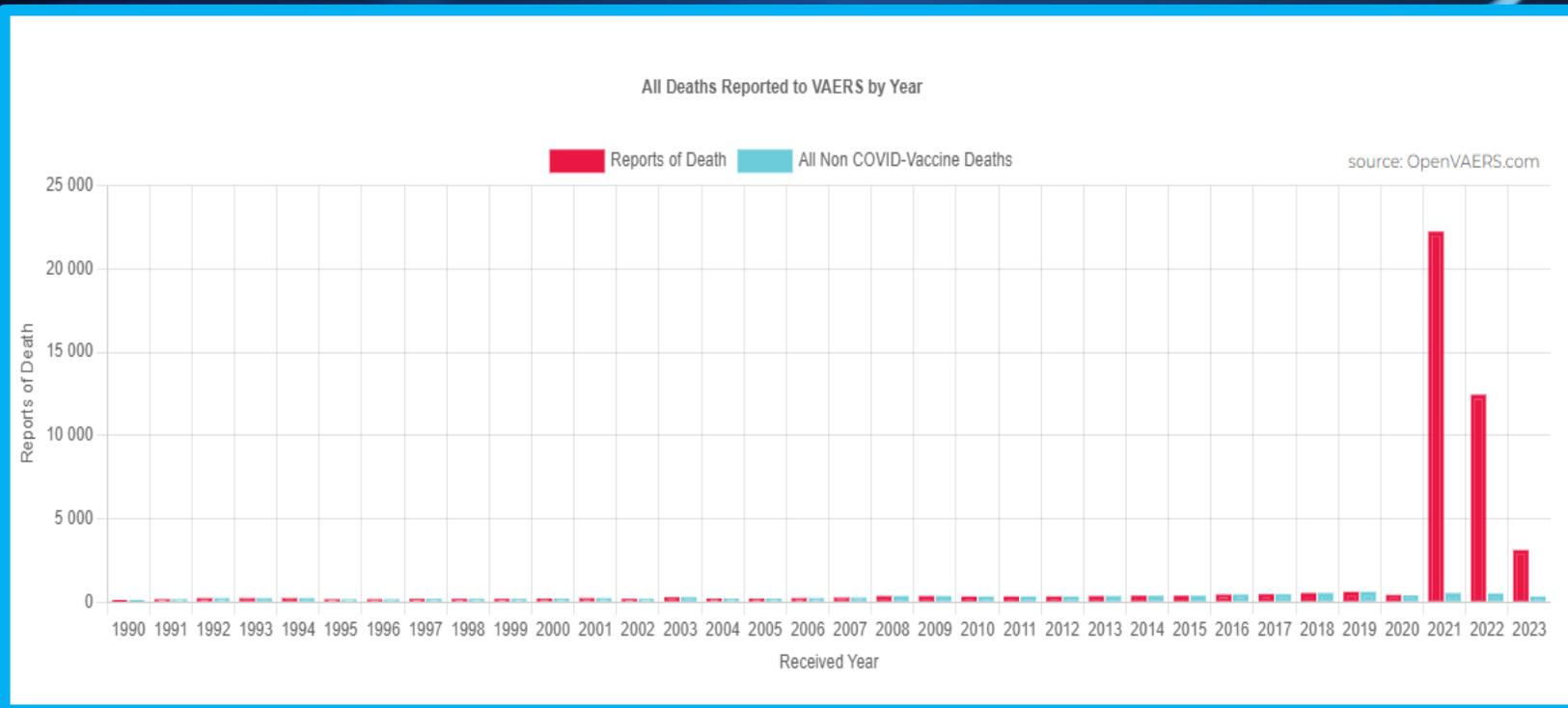
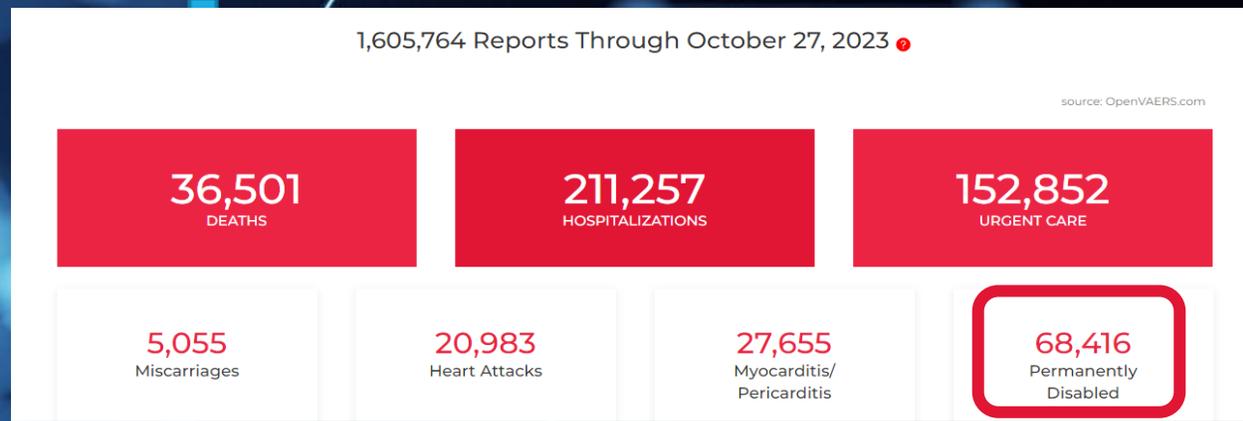
been demonstrated in the heart from patients who died from COVID-19,¹⁰⁹ the endomyocardial biopsy criteria for myocarditis, with the classic type of acute lymphocytic myocarditis or lymphocytic inflammatory cardiomyopathy, have yet to be convincingly demonstrated. Thus, myocarditis seems to be an uncommon complication in the course of SARS-CoV-2 infection.¹¹⁰

COVID Vaccine Data – OpenVAERS

1 605 764 hlášení k 27.10.2023

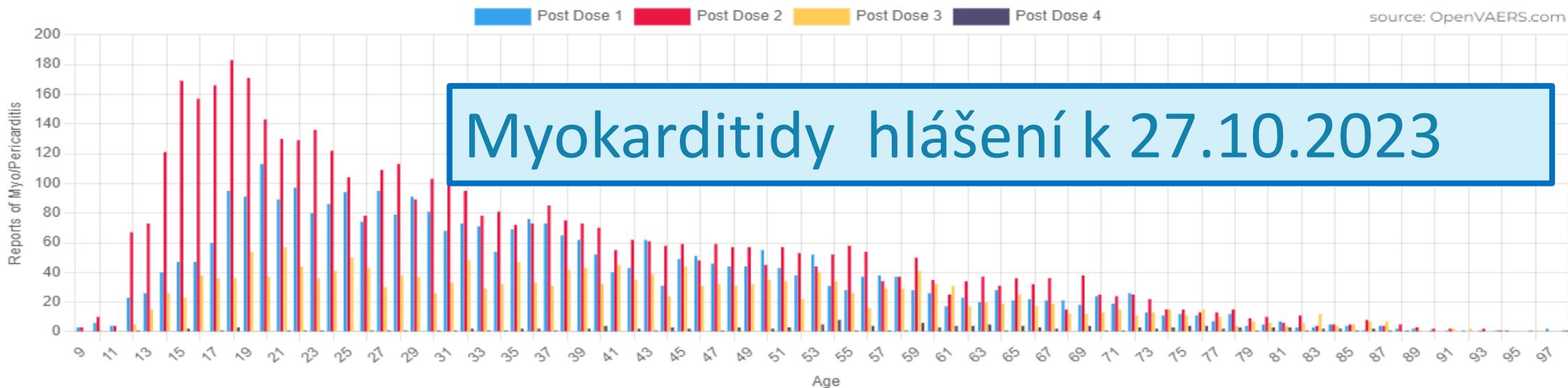
86% je hlášeno profesionály

Hlásí se cca 5% podezření na NÚ

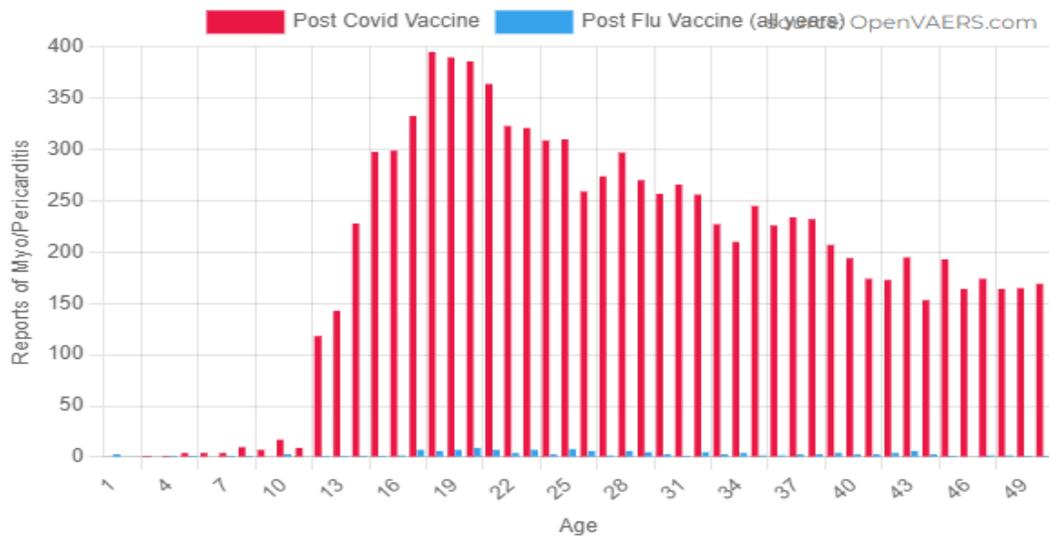


AGE	CASES
0.5-5	27
5-12	85
12-25	2,377
25-51	18,221
51-66	10,853
66-81	5,950
81-121	1,556
Unknown	29,332
All Ages	68,416

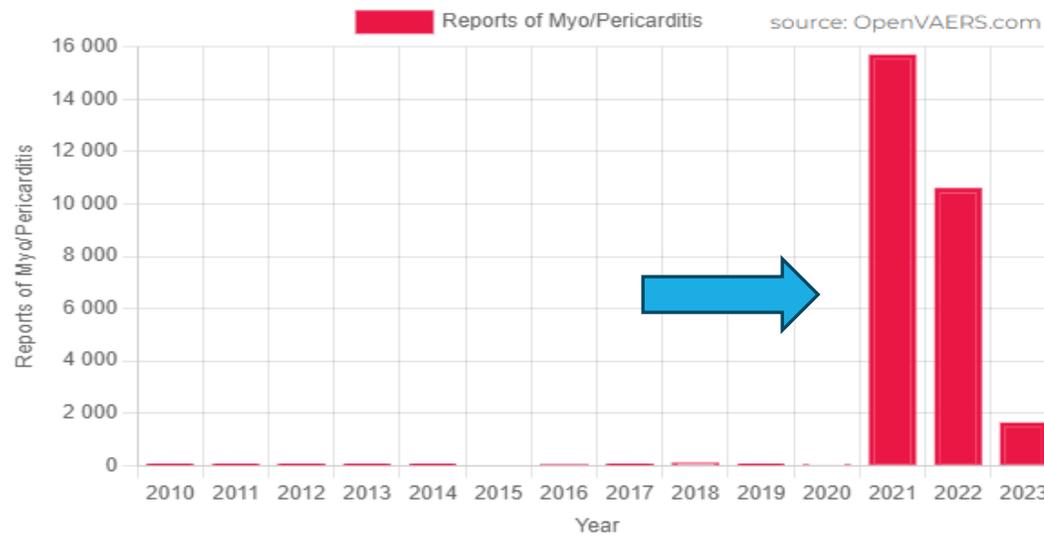
All Myo/Pericarditis Reported to VAERS Post COVID Vaccine by Dose



All Myo/Pericarditis Reported to VAERS COVID Vaccine vs. FLU Vaccine (all years)



All Myo/Pericarditis Reported to VAERS by Year (all vaccines)

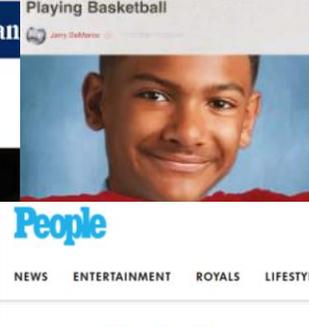




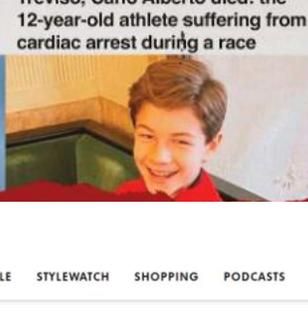
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Spain's Under-15 Football Star Estrella Martin Dies Suddenly



Arne Espeel, 25-Year-Old Belgian Soccer Player, Dies After Saving Penalty: 'This Is a Disaster'

Nový fenomén SADS syndrom náhlého úmrtí dospělého

ANALYZING AMERICA

Another One: Teen Athlete Dies Suddenly At Golf Practice For Unknown Cause

By David Rufful - September 14, 2022



Canadian Hockey Player Eli Palfreyman, 20, Loses Life During Game

By Sydney Garcia September 3, 2022



17-year-old dies 'suddenly and unexpectedly' after suffering cardiac arrest: 'No explanation as to why'

CHRIS ENLOE | January 12, 2023

BREAKING
Sport
TRAGIC LOSS Sam Westmoreland dead aged 19: Mississippi State football star passes away as cause of death remains mystery

Israel Salas-Rodríguez
Published: 16:36 ET, Oct 19 2022 | Updated: 16:58 ET, Oct 19 2022



SADS – SUDDEN ADULT DEATH SYNDROME

- Tento fenomén však **NENÍ** nový.
- Nový je **nárůst nevysvětlitelných úmrtí z kardiovaskulárních příčin.**
- r. 1977 popsán syndrom náhlé srdeční smrti – Sudden Cardiac Death/ Sudden Arrhythmic Death Syndrome – náhlá srdeční smrt (vědecká literatura zabývající se tímto syndromem je rozsáhlá).
- Příčiny: **nejčastěji životu nebezpečné komorové arytmie** v důsledku dříve nediodnostikovaných onemocnění. U starších sportovců **akutní koronární příhody.**
- **Komorové arytmie jsou známou komplikací myokarditid,** právě zvýšený výskyt myokarditid je spojován s aplikací mRNA vakcín

Fans and clubs mourn the sudden tragic death of 16-year-old football star Charlotte Vellar

By Chris King · 20 March 2023 · 20:51



Image of Charlotte Vellar. Credit: Twitter@MSVDulsburg

US Nato War Economy Civil Rights Environment Poverty Media Justice 9/11 War Crimes Militarization History Science

A 10-year-old Canadian Hockey Player From Hamilton, Ontario, Died Suddenly on March 11, 2023. Canada's COVID-19 Vaccine Mandates for Athletes Ages 12+ Are a Serious Crime

By Dr. William Makis

Global Research, March 20, 2023
COVID Issue: 19 March 2023

Translate Website



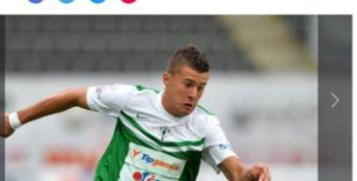
Evan Lloyd Corson, a 10 year old hockey player from Hamilton School.

Fotbalový svět v slzách: Zemřel bývalý útočník Jablonce Crnkič (+30)

6. srpna 2023 · 13:08

Author: ...

f t o



TRAGIC: 17-Year-Old Football Player Dies Suddenly In His Sleep Following A "Cardiac Arrest"

By Cullen Linebarger · Feb. 13, 2023 7:15 am · 491 Comments

Truth Gettr Gab Parler Telegram Share Tweet



FREE ACCESS LETTER

No Association Between Out-of-Hospital Cardiac Arrest and COVID-19 Vaccination

Elizabeth D. Paratz, Ziad Nehme, Dion Stub and Andre La Gerche
Originally published 24 Apr 2023 | <https://doi.org/10.1161/CIRCULATIONAHA.122.063753> | Circulation. 2023;147:1309–1311

Details Related References Figures

Circulation

scientific reports

OPEN

Increased emergency cardiovascular events among under-40 population in Israel during vaccine rollout and third COVID-19 wave

Christopher L. F. Sun^{1,2}, Eli Jaffe^{3,4} & Retsef Levi^{1,5}

Cardiovascular adverse conditions are caused by coronavirus disease 2019 (COVID-19) infections and reported as side-effects of the COVID-19 vaccines. Enriching current vaccine safety surveillance systems with additional data sources may improve the understanding of COVID-19 vaccine safety. Using a unique dataset from Israel National Emergency Medical Services (EMS) from 2019 to 2021, the study aims to evaluate the association between the volume of cardiac arrest and acute coronary syndrome EMS calls in the 16–39-year-old population with potential factors including COVID-19 infection and vaccination rates. **An increase of 25% was detected** in both call types during January–May 2021, compared with the years 2019–2020. Using negative Binomial regression models, the weekly emergency call counts were significantly associated with the rates of 1st and 2nd vaccine doses administered to this age group but were not with COVID-19 infection rates. While not establishing causal relationships, the findings raise concerns regarding vaccine-induced undetected severe cardiovascular side-effects and underscore the already established causal relationship between vaccines and myocarditis, a frequent cause of unexpected cardiac arrest in young individuals. Surveillance of potential vaccine side-effects and COVID-19 outcomes should incorporate EMS

Check for updates

- Ventricular Tachycardia
- Ventricular Fibrillation



“SUDDEN ADULT DEATH SYNDROME”

ESC CONGRESS 2022

PROFESSOR CHRISTIAN MUELLER, DIRECTOR CARDIOVASCULAR RESEARCH INSTITUTE
DEPARTMENT OF CARDIOLOGY, UNIVERSITY HOSPITAL BASEL

[SEX-SPECIFIC DIFFERENCES IN MYOCARDIAL INJURY INCIDENCE AFTER COVID-19 MRNA-1273 BOOSTER VACCINATION - PUBMED \(NIH.GOV\)](#)

MACIS

Myocardial Injury after COVID-19 mRNA booster vaccination

Investigator-initiated, industry-independent, active surveillance study

Professor Christian Mueller, University Hospital Basel, Switzerland

On behalf of the MACIS Investigators

August 28, 2022

CRIB
Cardiovascular Research
Institute Basel

ESC CONGRESS 2022
Barcelona & Online



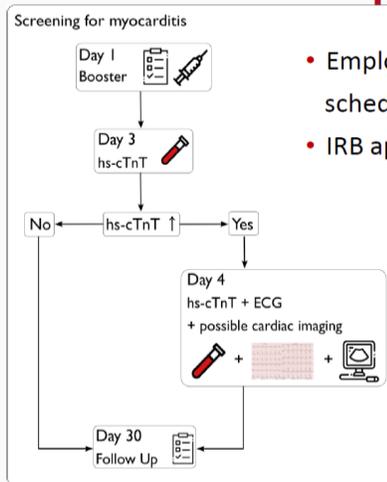
Hypothesis:

- Vaccine-associated myocardial injury is much more common, as symptoms may be mild & unspecific or even absent.
- Evaluating the true incidence is of major importance, as this information is required for informed decision making for patients, physicians, and public health authorities given the apparent **need for repetitive** (possibly yearly) **booster vaccinations** for billions of humans worldwide due to diminishing protection months after the last COVID-19 vaccination.

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METHODS



- Employees of the University Hospital Basel, Switzerland, scheduled to receive mRNA-1273 booster vaccination
- IRB approval, Written ICF

Exclusion criteria:
cardiac events or cardiac surgery 30d prior to vacc.

PE: Adjudicated **acute myocardial injury** >ULN (myocarditis), without evidence of an alternative cause

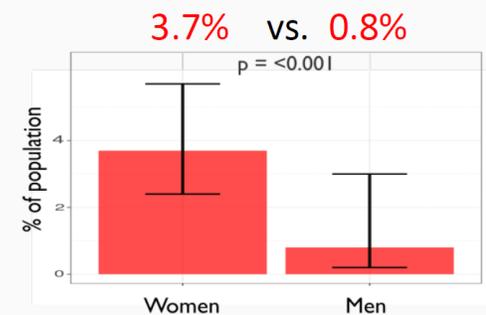
Active surveillance & Immediate response

Avoidance of exercise until hs-cTnT ↓

MACIS

RESULTS

Incidence of myocardial injury: **2.8%** [95%CI, 1.7-4.3%]



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Our STN: BL 12574

BioNTech Manufactu
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Dear Mr. Patel:

Please refer to your
May 18, 2021, under
COVID-19 Vaccine,

POSTMARKETING

Section 505(o) of the
require holders of ap
postmarketing studie
findings required by t

We have determined
reported under sectio
serious risks of myoc
subclinical myocardit

Furthermore, the pha
section 505(k)(3) of t

Therefore, based on
required to conduct t

Postmarket Requirements and Commitments

SOURCE: FDA Postmarketing Requirements and Commitments Database

<https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarket-requirements-and-commitments>

[Revise Search](#) | [New Search](#)

Date Looked up: 21 Oct 2023

You searched for: Both CBER and CDER; bion; comirnaty; 125742; All Statuses; Neither

« « 1 of 1 » »

Applicant:	BioNTech Manufacturing GmbH
Product:	COMIRNATY, COVID-19 Vaccine, mRNA
NDA/BLA Number:	125742
NDA/BLA Approval Date:	08/23/2021
Annual Report Due Date: <small>(must be submitted within 60 days of this date)</small>	08/23/2023
Annual Report Received:	10/20/2022

Requirement/Commitment Number: 9

Required Under:	FDAAA Section 505(o)(3)
Original Projected Completion Date:	12/31/2022
Description:	Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.
Current Status:	Delayed
Explanation of Status:	The study completion date has passed, and the study has not yet been completed.

ON TO FDA
s, age 16-30

2023
s overdue
MPLETED

ence of subclinical myocarditis following
participants 16 to 30 years of age.

ot yet been completed.

incidence of subclinical
COMIRNATY in a subset of

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ng schedule: