

Global Health Cast 9

Thanks for joining!



Dr. Melvin Sanicas



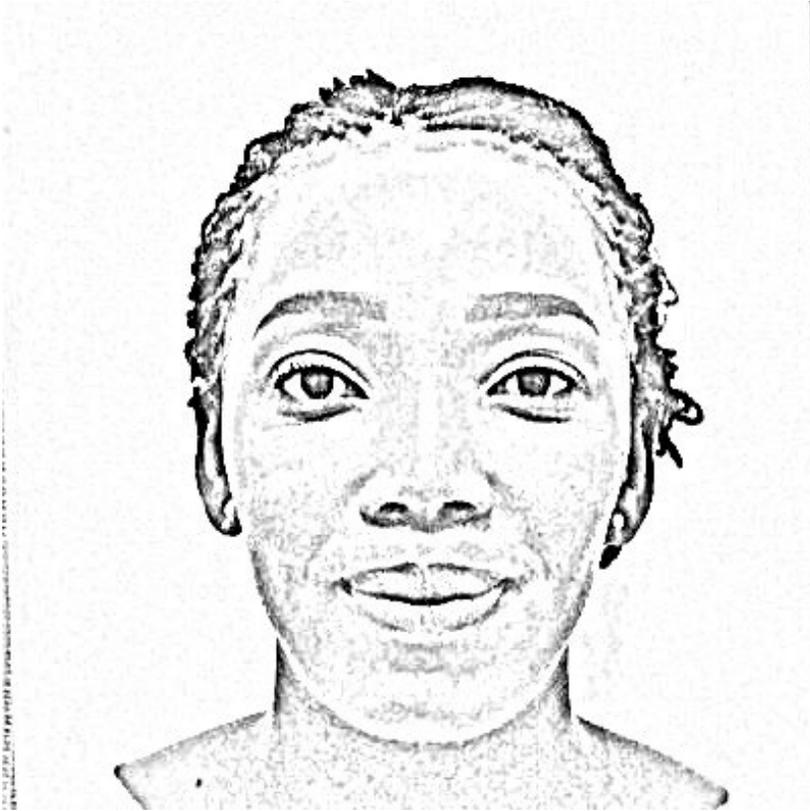
Prof. Dr. Joe Schmitt

Every Tuesday

12.00 noon - CET

August 9th, 2022

Our special guest today



Dr. Rapi Nteene

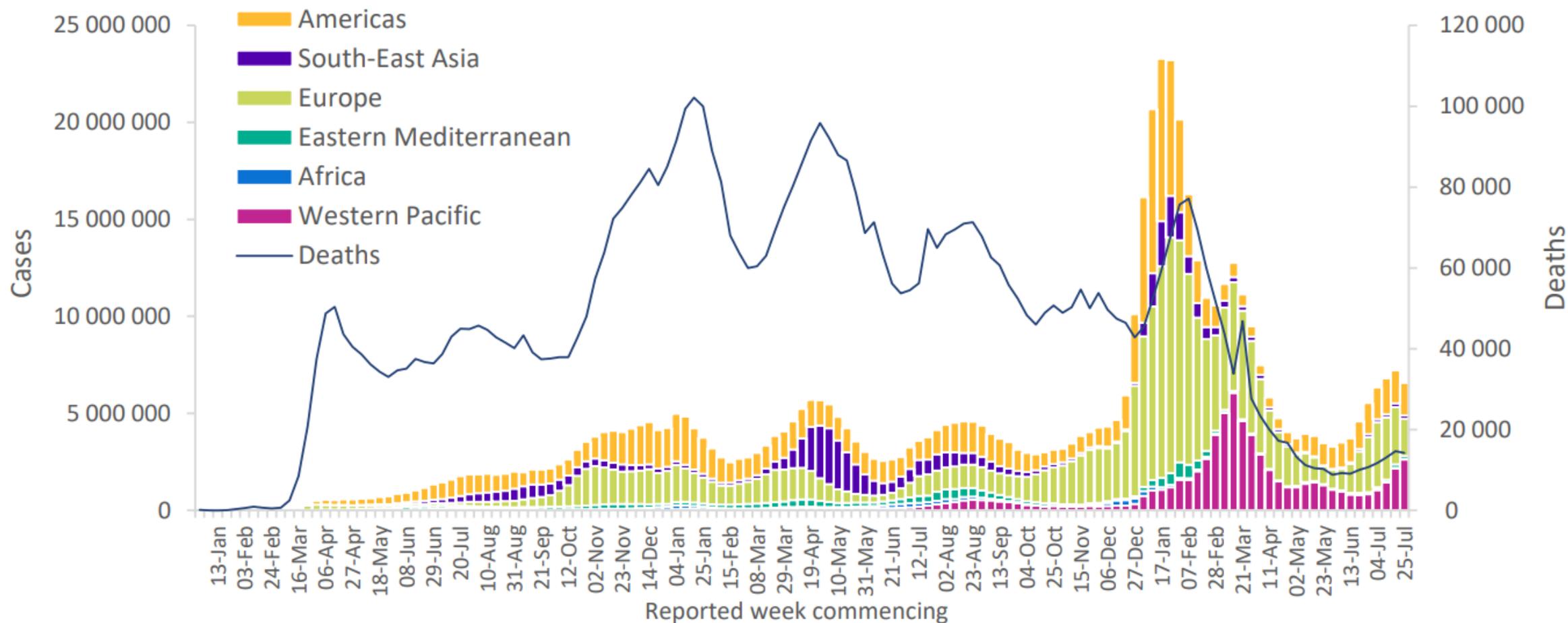
Rapi Nteene, MD, MSc (Vaccinology)

- ▶ Director, Vaccines, Global Pharmacovigilance
SANOFI PASTEUR
- ▶ Siena University lecturer
- ▶ Former WHO consultant

What we talk about today:

- ▶ COVID-19 update
- ▶ Monkeypox update
- ▶ Adverse events following vaccination

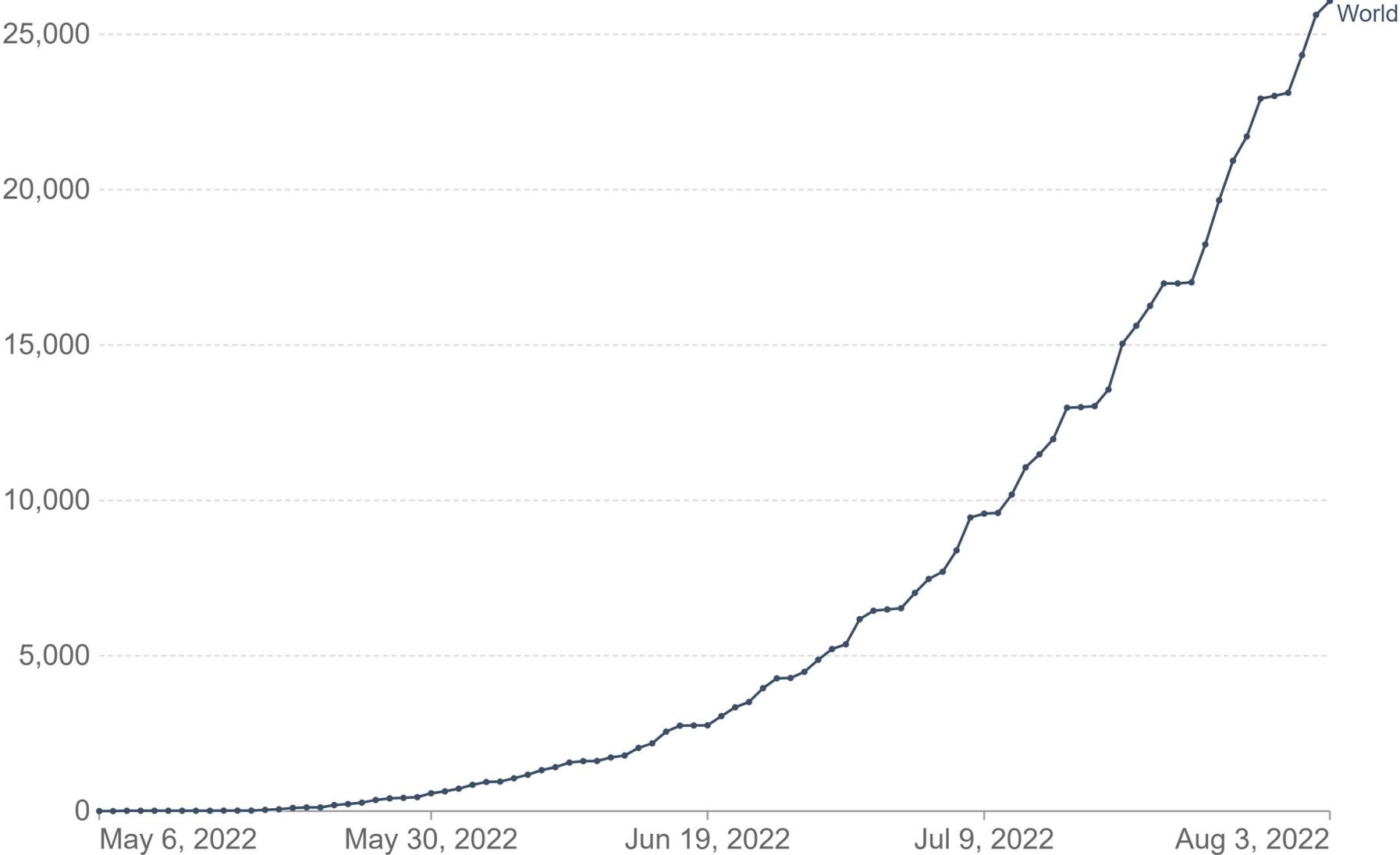
Figure 1. COVID-19 cases reported weekly by WHO Region, and global deaths, as of 31 July 2022**



**See [Annex 1: Data, table, and figure notes](#)

Number of weekly cases decreased by 9% during the week of 25 to 31 July 2022 as compared to the previous week, with over 6.5 million new cases reported

Monkeypox: Cumulative confirmed cases



Source: Data produced by the 'Global.health' team — available at github.com/globaldothealth/monkeypox

Adverse Events (AE) – and Side Effects (SE)

Adverse Events vs. Side Effects



Adverse Events

„**Adverse events**“ (AE)
„disliked“ events and they may be

1. Related
2. Unrelated
3. Or unknown in relation to **vaccine** administration



Side Effect

„**Side effect**“ is an event that is **caused** by a vaccine or any medical intervention



Causality Assessment

To distinguish between **Adverse Event** and **Side Effect** you need a “**causality assessment**” (causality vs. coincidence): Biological plausibility, timing of events, specificity, clinical studies



β -error

It is **NEVER** possible to exclude causality by observational studies because of the **β -error**, so „safety“ can never be proven



Safety Profile

„**Safety profile**“ is the summary of all safety data and established by pre-licensure studies and by post-licensure surveillance



Concept

CONCEPT: Benefit-risk assessment

Package Insert for Hazelnut Chocolate

- ▶ Package inserts inform about **Adverse Events**, not **Side Effects**!
- ▶ A potential package insert for hazelnut chocolate (if the chocolate was a vaccine) would read:

„After eating this chocolate, the following AE were observed:

Anaphyhaxis, diabetes mellitus, high blood pressure, stroke, dental caries, ..., rheumatoid arthritis, lymphatic leukemia, myocardial infarction, ...“

**Most common
Vaccination
Side-Effect:
Technical Errors**



Types of Side Effects of Vaccines

1. Reactogenicity (local, general)
2. Anaphylaxis
3. Technical errors
4. Vaccine-specific side effects

Disease complications versus Vaccine Side-Effects

Risk-Benefits Analysis

Disease	Diseases Complication/ Adverse Event	Frequency	Vaccine AE/SE frequency
Polio	Paralysis Death	1:200 infected 5-10% of paralyzed die	OPV only: 1:450,000 ? rare
Tuberculosis	Dissemination Death	100% of infected 1.5 mio 2021	BCG: 1:500,000*
Influenza	Death	USA: 12,0000 – 52,000 / year	Single cases
	Guillain-Barré-Syndrome (GBS)	Background rate rare (0.4-4/100,000) Up to logfold less post vaccination versus disease	
H1N1 ASO3 (Pandemrix)	Narcolepsia	?	1 : 18,400 doses
Tetanus	Polyneuritis, GBS	50% with no full recovery	Single cases
Diphtheria	Polyneuritis, GBS	10% case fatality	Single cases
Any vaccine	Anaphylaxis	n.a.	1:400,000 – 1: 1,200,000
Anything else?	?	?	?

* Only in patients with (inborne) T-cell deficiency



Vaccine Scares

“Diseases“ *NOT* Caused by Vaccines

- ▶ Encephalopathy post DTwP
- ▶ MS post HBV
- ▶ Encephalitis post MMR
- ▶ Crohn’s disease post MMR
- ▶ Autism post MMR

Statistically significant findings, but no causality:

- ▶ German language post Infanrix hexa late 1990ies
- ▶ Pregnancy post hepatitis A-vaccination

South Africa's reported the first death tied to a Covid-19 vaccine



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Last Updated 7 hours ago

South Africa reports first death causally linked to COVID vaccine

Reuters

3 minute read



The person presented with rare neurological disorder **Guillain-Barre Syndrome** soon after being given J&J's vaccine, after which the person was put on a ventilator and later died, senior scientists told a news conference.

“The benefit of vaccination still far outweighs the risk,” Boitumelo Semete-Makokotlela, chief executive of the South African Health Products Regulatory Authority (SAHPRA).

“In our context we have administered about **9 million (doses) of the Janssen (J&J) vaccine**, and this is the **first causally linked case of GBS.**”



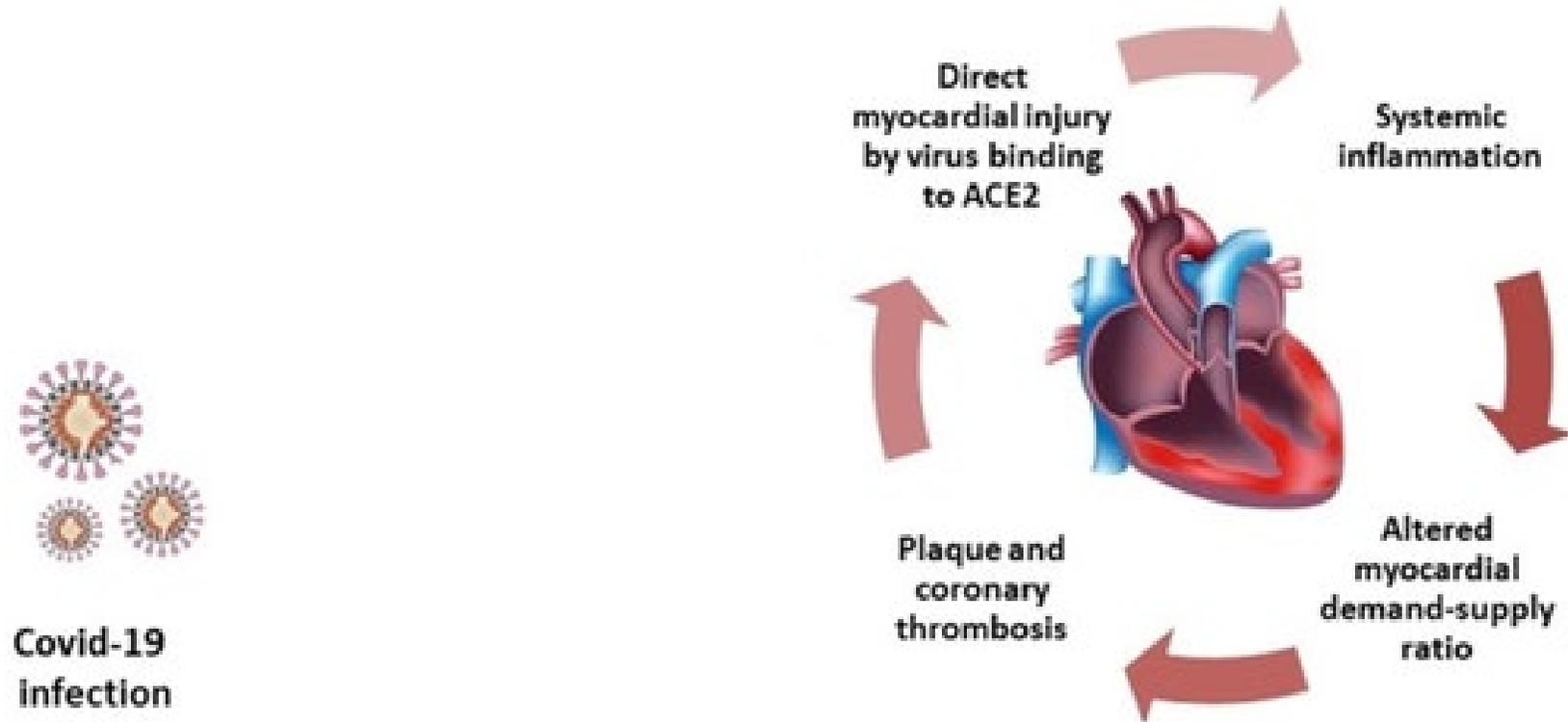
Disease complications versus COVID19-Vaccine Side-Effects Risk-Benefits Analysis

Disease	Diseases Complication/ Adverse Event	Disease Frequency	Vaccine AE frequency
COVID19	Deaths	1,4% of infected	? single cases
	Myocarditis*	1:2.222 (young males)	1:10,000 – 1:40,000
	TTS**	Higher than after ChAdOx1**	(ChAdOx1) Risk increase x 5.67
	Facial paralysis	40/100,000	43 (Comirnaty) – to 67 (CoronaVac) /10 ⁵
	Long COVID	~ 50%	Lower in the vaccinated

Different studies may produce different numbers, but there is a consistent pattern showing that vaccination risk is lower than disease risk

*Varies by age and gender
 **varies largely by age group

Myocarditis (heart inflammation)



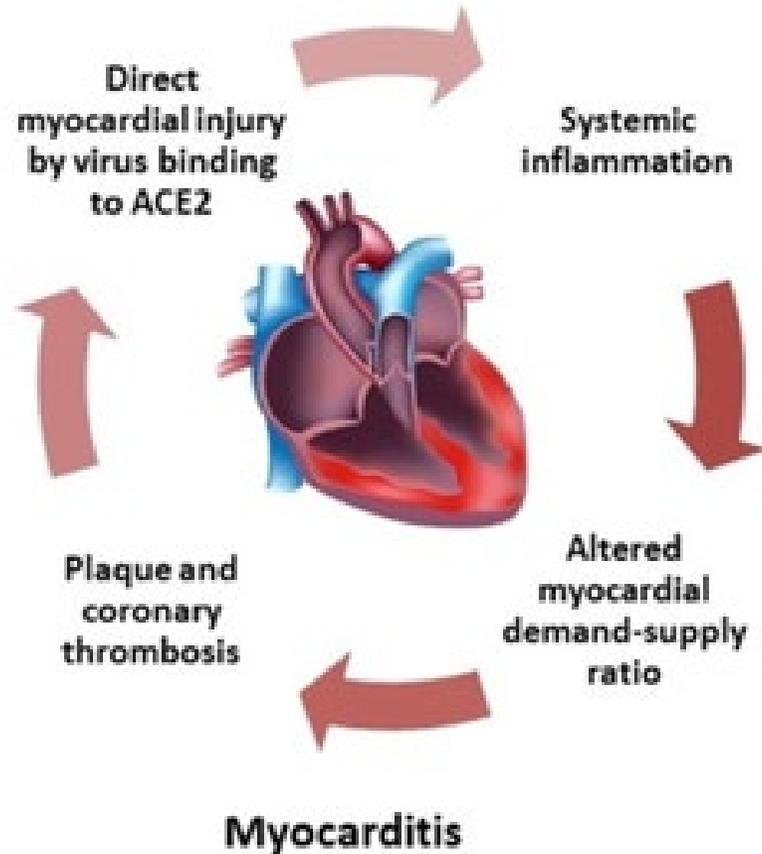
Covid-19 infection

- Direct myocardial infection,
- Respiratory failure or hypoxemia,
- Indirect injury from systemic inflammatory response

Myocarditis

The importance of myocarditis in Covid-19 - Haryalchi - 2022 - Health Science Reports - Wiley Online Library

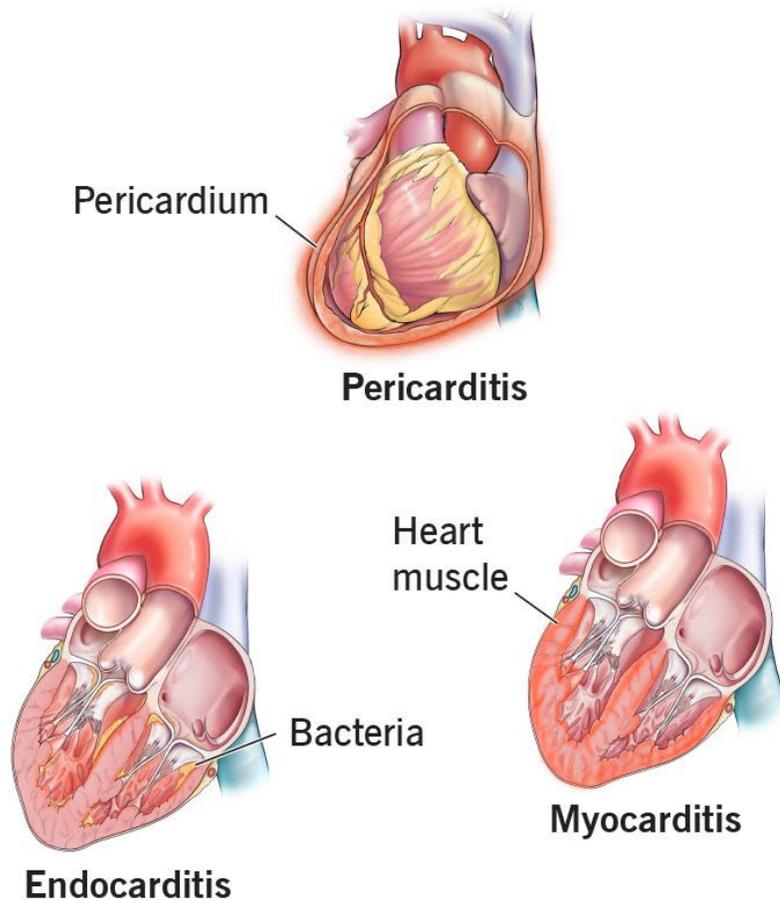
Does the Covid-19 vaccine cause myocarditis (heart muscle inflammation)?



- ▶ The latest research suggests that overall, these rare cases are no more likely to be triggered by a Covid vaccine than any other vaccine.
- ▶ Cases of myocarditis following the vaccine have usually been mild, and those affected have usually quickly felt better with rest and simple treatments.
- ▶ In most cases of myocarditis, heart function returns to normal.

What is the risk of getting myocarditis or pericarditis post vaccine?

Heart Inflammation



Cleveland Clinic ©2021

Pfizer vaccine:

- ▶ Highest-risk age group (18-29): 29 cases of suspected myocarditis or pericarditis for every million second doses of the Pfizer vaccine given in the UK (up until 30 March 2022).
- ▶ Lower following a booster, 16 cases per million in this age group.

Moderna vaccine:

- ▶ Highest-risk age group (18-29): 70 cases of suspected myocarditis or pericarditis for every million second doses given in the UK, in this age group.
- ▶ Lower following a booster, 19 cases per million in this age group.

Other age groups the risk is even lower.

Thrombosis with Thrombocytopenia Syndrome (TTS)

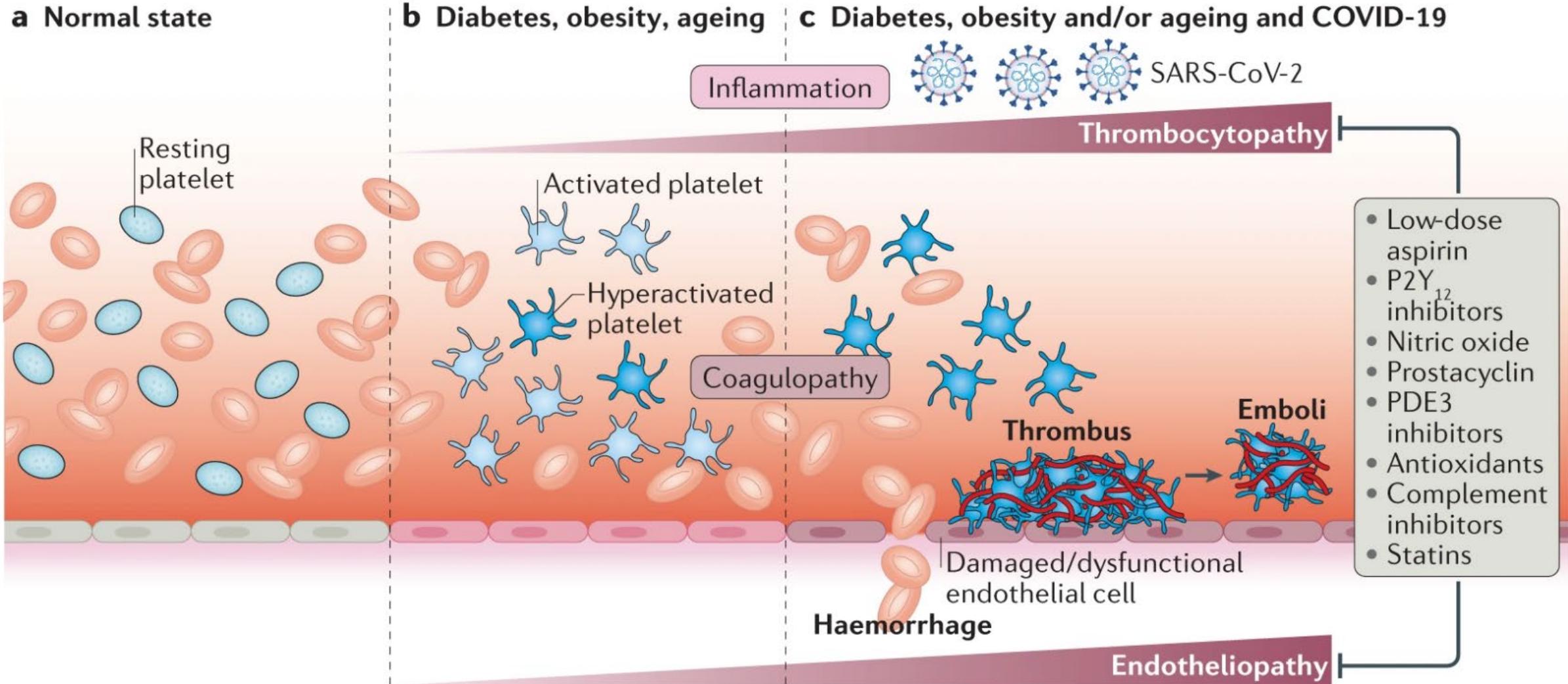


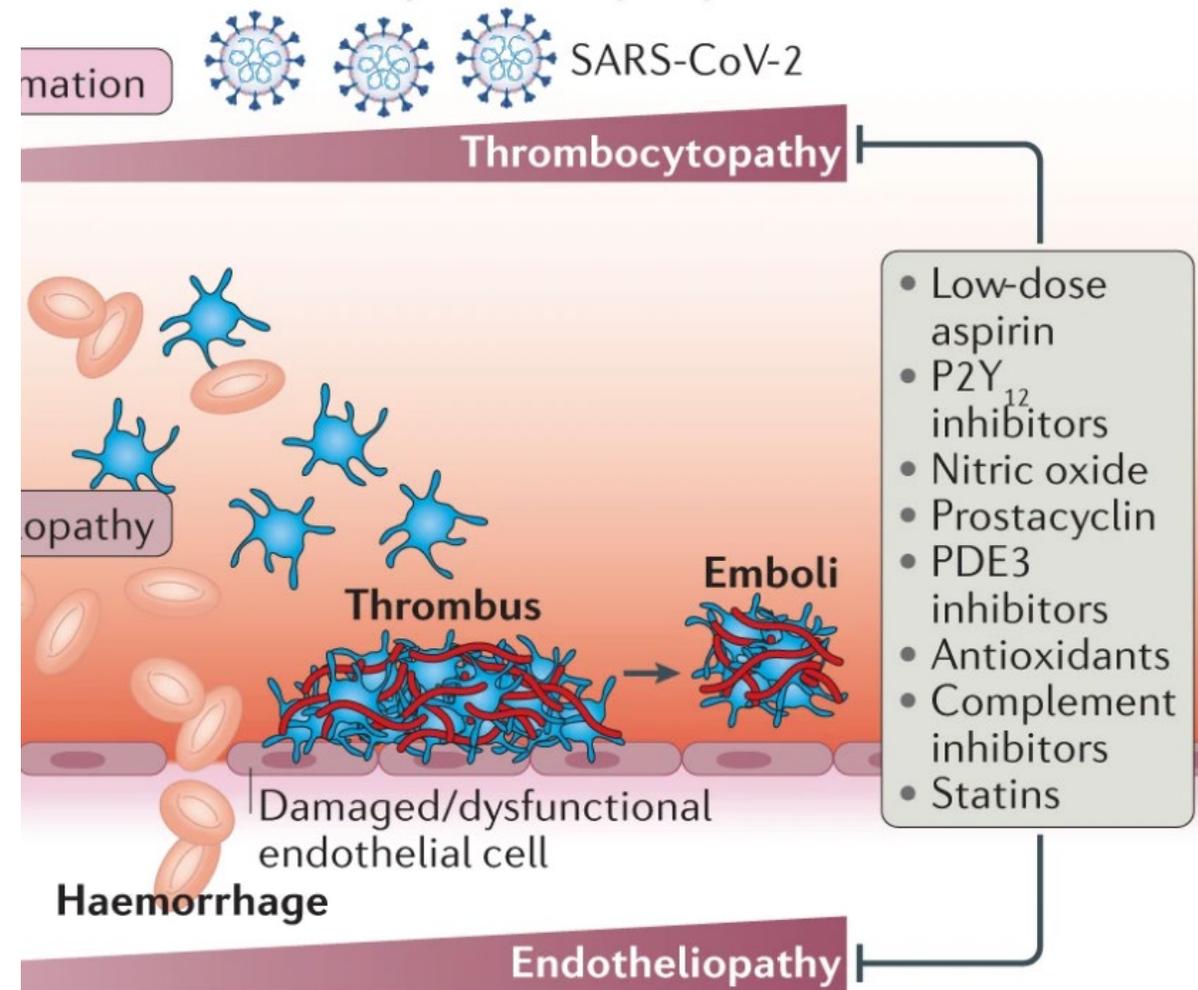
Fig. 1: COVID-19-associated thromboinflammation. | Nature Reviews Cardiology

How about Thrombosis with Thrombocytopenia Syndrome (TTS)?

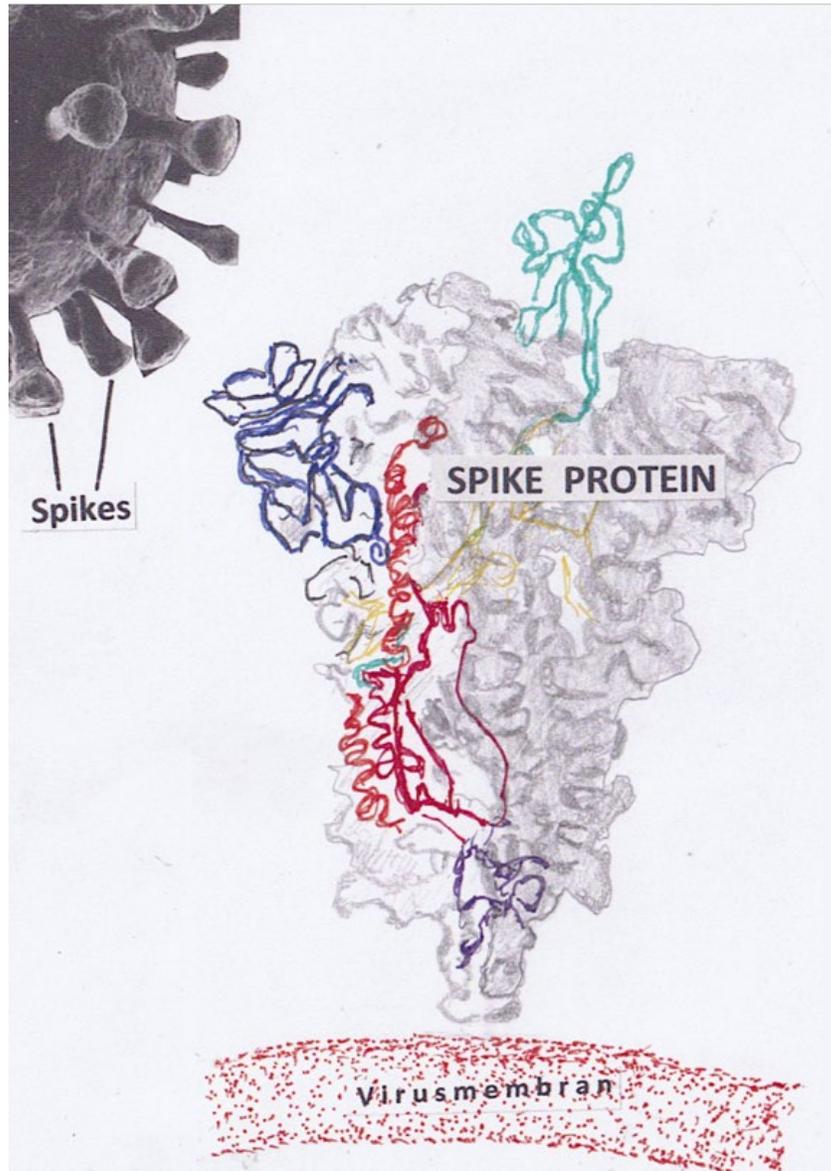
- ▶ Thrombosis with Thrombocytopenia Syndrome (TTS):
 - ▶ unusual and severe blood clotting events associated with low platelet counts,
 - ▶ reported after vaccination with the Astra Zeneca vaccine.
- ▶ In countries with ongoing SARS-CoV-2 transmission, the benefit of vaccination in protecting against COVID-19 far outweighs the risks.

(Read the 16 April 2021 statement of the WHO Global Advisory Committee on Vaccine Safety on AstraZeneca COVID-19 vaccine for reports of very rare side effects.)

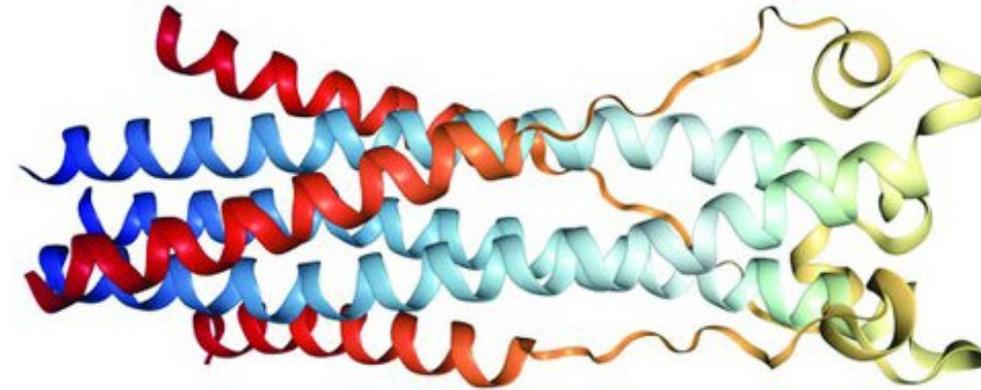
c Diabetes, obesity and/or ageing and COVID-19



Does the COVID-19 Vaccine Affect Fertility?



Syncytin-1



False report surfaced on **social media**, saying that the **spike protein on SARS-CoV-2** was the same as another spike protein **syncytin-1**

“Sterilizing immunity” (good medical language)



**Anti-Vaccination lobby proved right:
101 year old lady infertile after
COVID19-vaccination!**

Der Postillon, 28th December 2020

Trolls and single politicians and „scientists“ use vaccine misinformation to sow political discourse

- Misinformation spanned personal dangers, liberty violations, and conspiracies.
- Tweets about vaccines often referenced side effects or symptoms.
- Engagement with misinformation was low; some intended to correct misinformation.
- Users should be aware of tweets that are characteristic of misinformation.

Trolls use vaccine misinformation to sow political discourse

- ▶ The study discovered several accounts, now known to belong to the same Russian trolls who interfered in the US election, as well as marketing and malware bots, tweeting about vaccines.
- ▶ Russian trolls played both sides, tweeting pro- and anti-vaccine content in a politically charged context.



**DO NOT FEED
THE TROLLS**

Zombiefication



First antivaxx campaign in the 1790s



What we talked about today:

- ▶ COVID-10 update
- ▶ Monkeypox update
- ▶ **AE** following vaccination – versus **SE**
 - ▶ AE / SE: For SE a causal relation to Vx was shown
 - ▶ Package inserts list AE
 - ▶ Risk-Benefit analyses hugely favor vaccination
 - ▶ Plausibility-check of “SE” emerging in social media
 - ▶ Use trusted sources like WHO, CDC, GHP.org your local PH office
- ▶ **Write us: GHC@globalhealthpress.org**

Global Health Cast 9

Sentence of the week:



Dr. Melvin Sanicas



Prof. Dr. Joe Schmitt

„You should not believe everything you are thinking“

Heinz Erhard (1909-1979)