



# SARS-CoV-2 & COVID-19 TESTEN UND IMPFEN



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# CORONAVIRUS SARS-CoV-2

## Bilder, Hinweise & Interessenskonflikte



Wertes Auditorium,

die medizinisch-wissenschaftlichen Informationen dieser Präsentation spiegeln ausschließlich meine eigene Meinung und/oder Erfahrung wider.

Der vollständige Einklang der Inhalte mit den jeweiligen Fachinformationen (Austria Codex) kann daher von Seiten des Sponsors (Zulassungsinhabers) dieser Fortbildungsveranstaltung nicht gewährleistet werden.

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### DER DIAS – DANKE !



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Florian Thalhammer



# CORONAVIRUS SARS-CoV-2

## Klinik & Verlauf



Fieber



Halsentzündung



Husten



Kurzatmigkeit



Myalgien

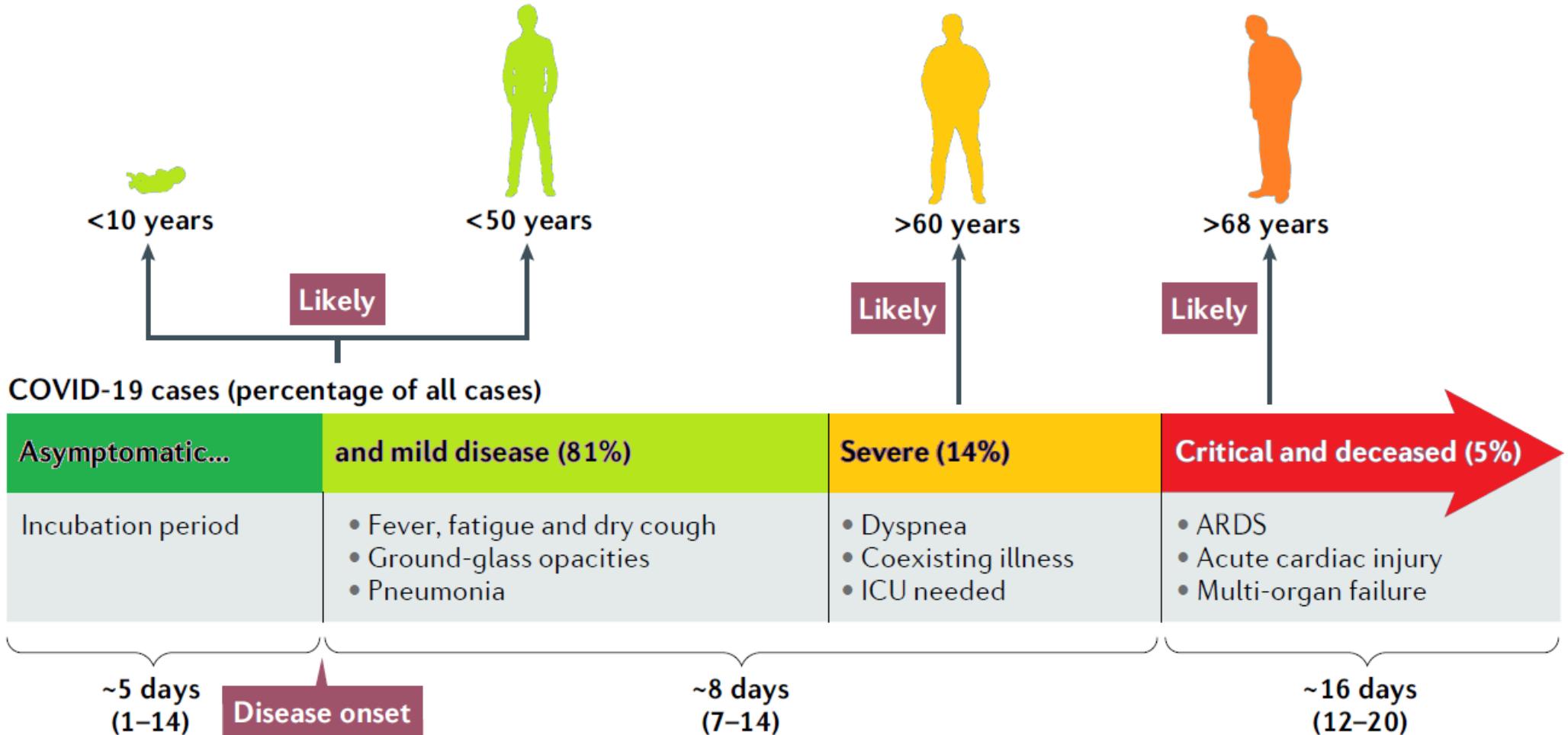


Durchfall



# CORONAVIRUS SARS-CoV-2

## Klinik & Verlauf





CORONAVIRUS SARS-CoV-2

**TESTEN**

**IMPFEN**



CORONAVIRUS SARS-CoV-2

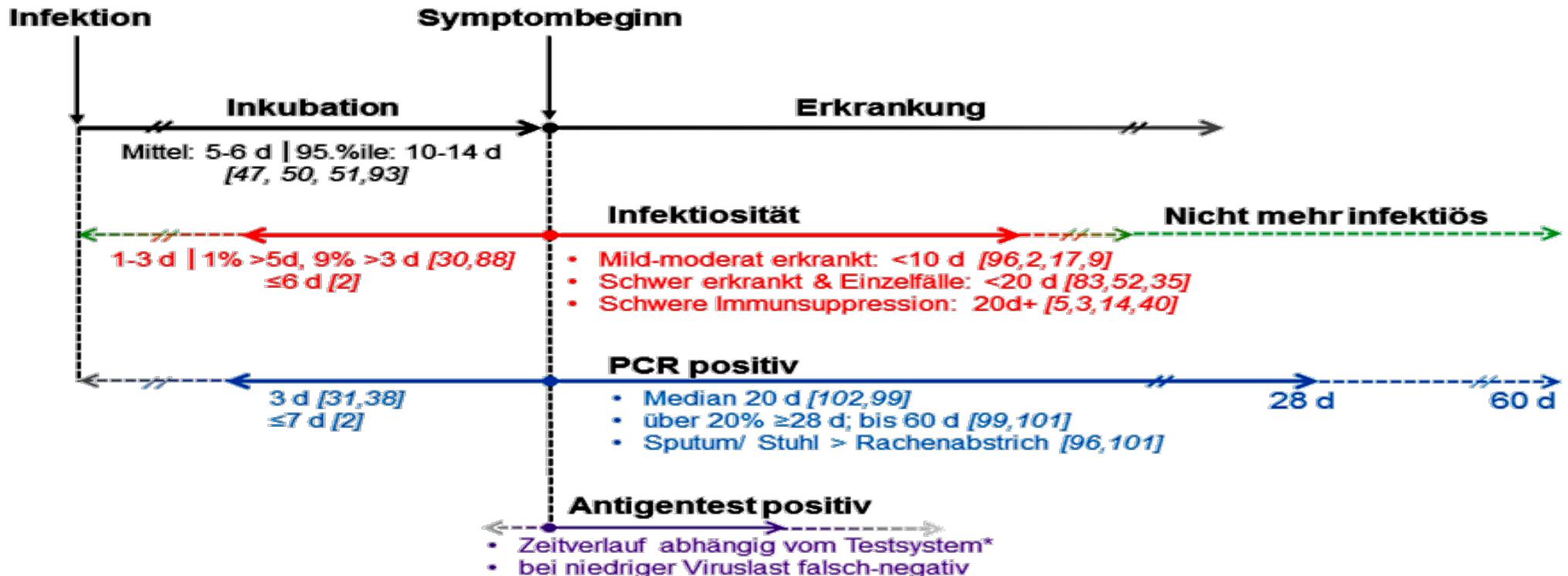
TESTEN

IMPFEN



# CORONAVIRUS SARS-CoV-2

## Infektion & Diagnostik



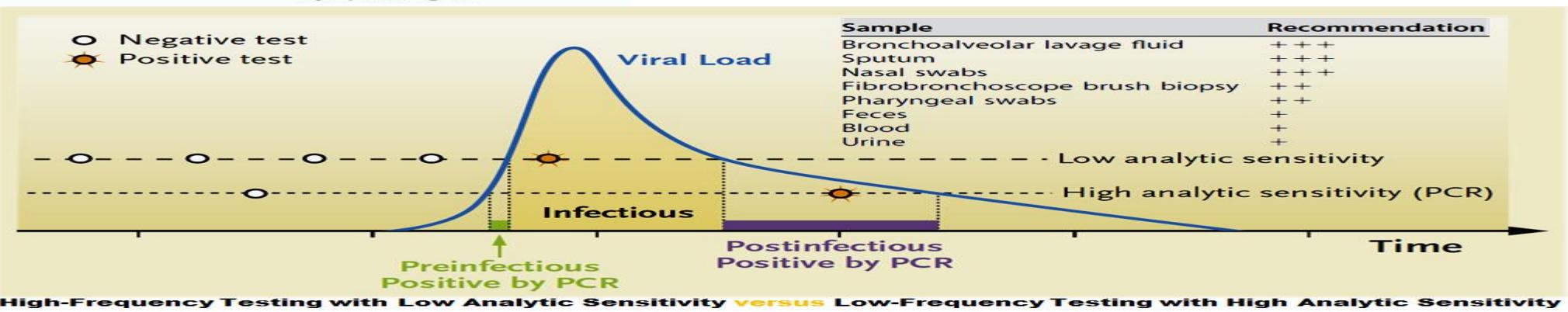
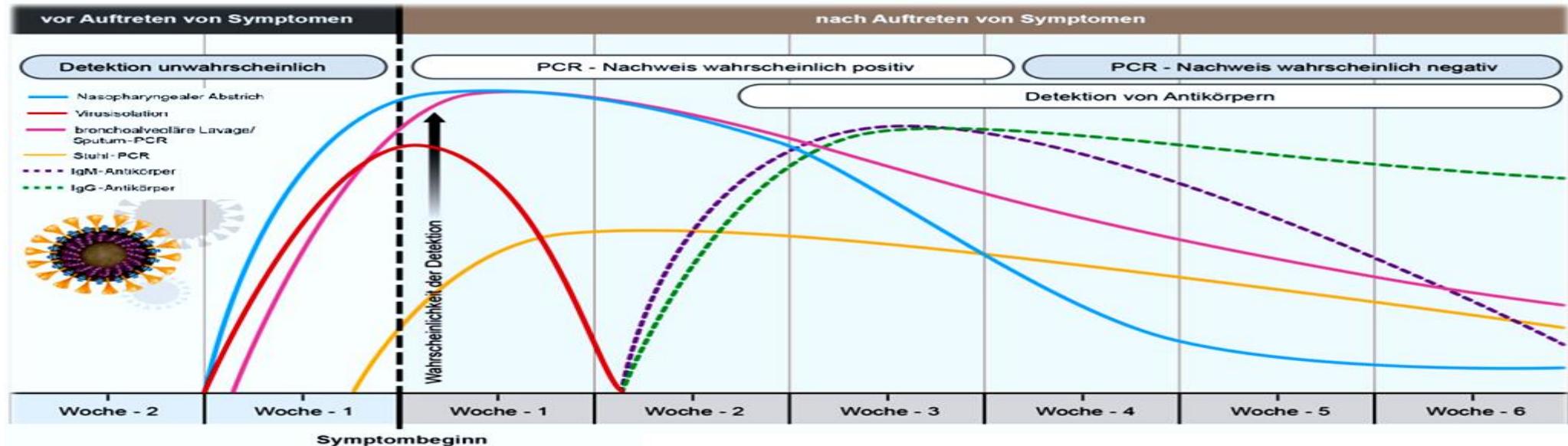
**Ct>30**  
PRAE vs POST  
**COVID-19**

- Serologie positiv
- Serokonversion [53, 77, 100]
    - Median Woche 2 (range, 4-22 d)
    - IgM, IgG mitunter synchron
  - Heterogene Studienlage



# CORONAVIRUS SARS-CoV-2

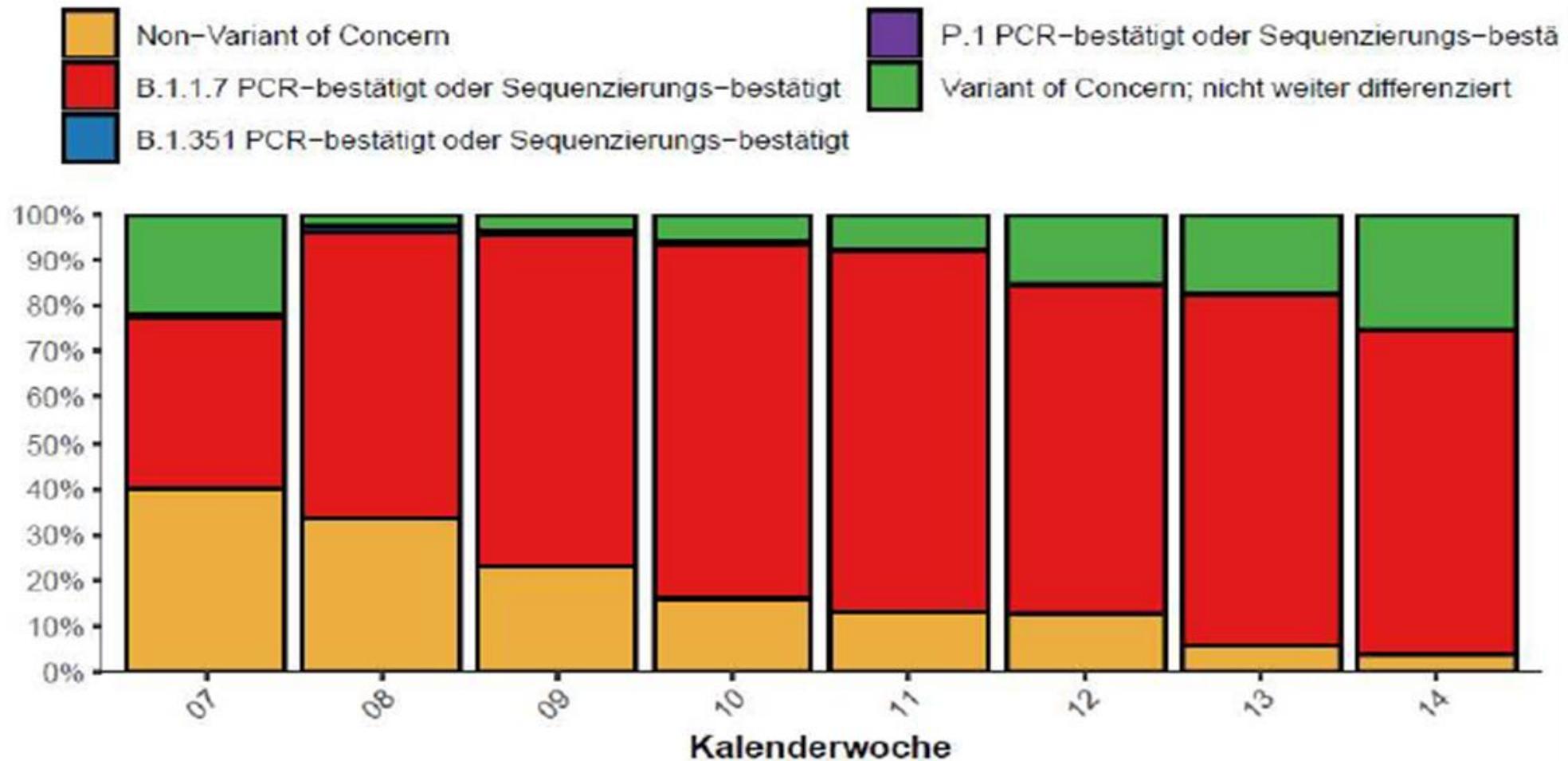
## Virusnachweis & Antikörperverlauf





# CORONAVIRUS SARS-CoV-2

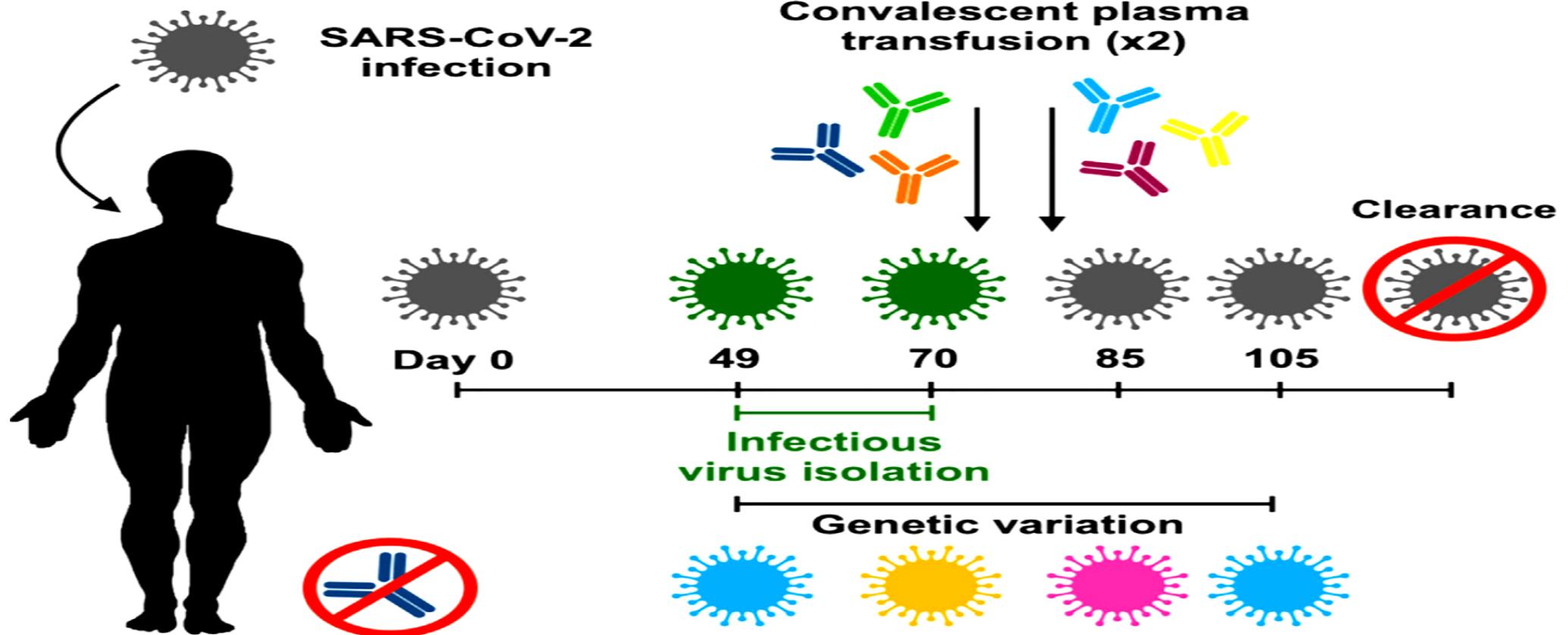
## Mutationsverteilung in Österreich





# CORONAVIRUS SARS-CoV-2

## Immunosuppression & Virusshedding



### Immunocompromised individual

- Cancer (CLL)
- Hypogammaglobulinemia



# CORONAVIRUS SARS-CoV-2

## Schutzrate bei St p COVID-19

- >80% bis zum 65. Lebensjahr
  - <50% ab dem 65. Lebensjahr
- 
- ▶ Re-Infektionen bei älteren eher möglich
  - ▶ St p C19 kein Ausschluss für C19-Vacc



# CORONAVIRUS SARS-CoV-2

## St p Vacc & positive PCR

- **Pat\*in geb. 1980**
  - 18.03. positiv Ct 18.21 symptomatisch
  - 19.03. positiv Ct 24.89 B.1.1.7 nachweisbar
  - 23.03. positiv Ct 30.62
- KEIN 100%-ige Infektionsschutz
- Transmissionsrisiko?
- Procedere?



# CORONAVIRUS SARS-CoV-2

## Ct-Wert & Mutation

- Ct-Wert zwischen 28.5 - <30
  - PCR-Kontrolle 48 Std später (= Kontrolle 1)
- Ct-Wert<28.5
  - Abnahme einer Viruskultur und ad Prof. Indra, AGES IMED WIEN, Währingerstraße 25a, 1090 Wien, Tel.: +43 (0)5 0555-37230
  - Ct-Kontrolle nach 48 Std (= Kontrolle 1)
  - BA für neutralisierende Antikörper
- Ct-Wert<28.5 bei Kontrolle 1
  - Abnahme einer weiteren Viruskultur 72 Std nach Kontrolle I (= Kontrolle 2)
  - Ct-Kontrolle nach 72 Std (= Kontrolle 2)
- Ct-Wert<28.5 bei Kontrolle 2 und folgende Kontrollen
  - selbiges Procedere (PCR, Kultur) alle 72 Std bis Ct-Wert>30 wie bei Ct-Wert<28.5 bei Kontrolle 1
- Indexfälle, die beide mRNA-Impfungen oder eine AstraZeneca-Impfung erhalten haben, unabhängig vom Mutationsstatus
  - zwei PCR-Kontrollen innerhalb von 24 Std
  - Ct-Wert<30 bei Kontrolle 2, dann nach 48 Std neuerliche PCR
  - BA für neutralisierende Antikörper



CORONAVIRUS SARS-CoV-2

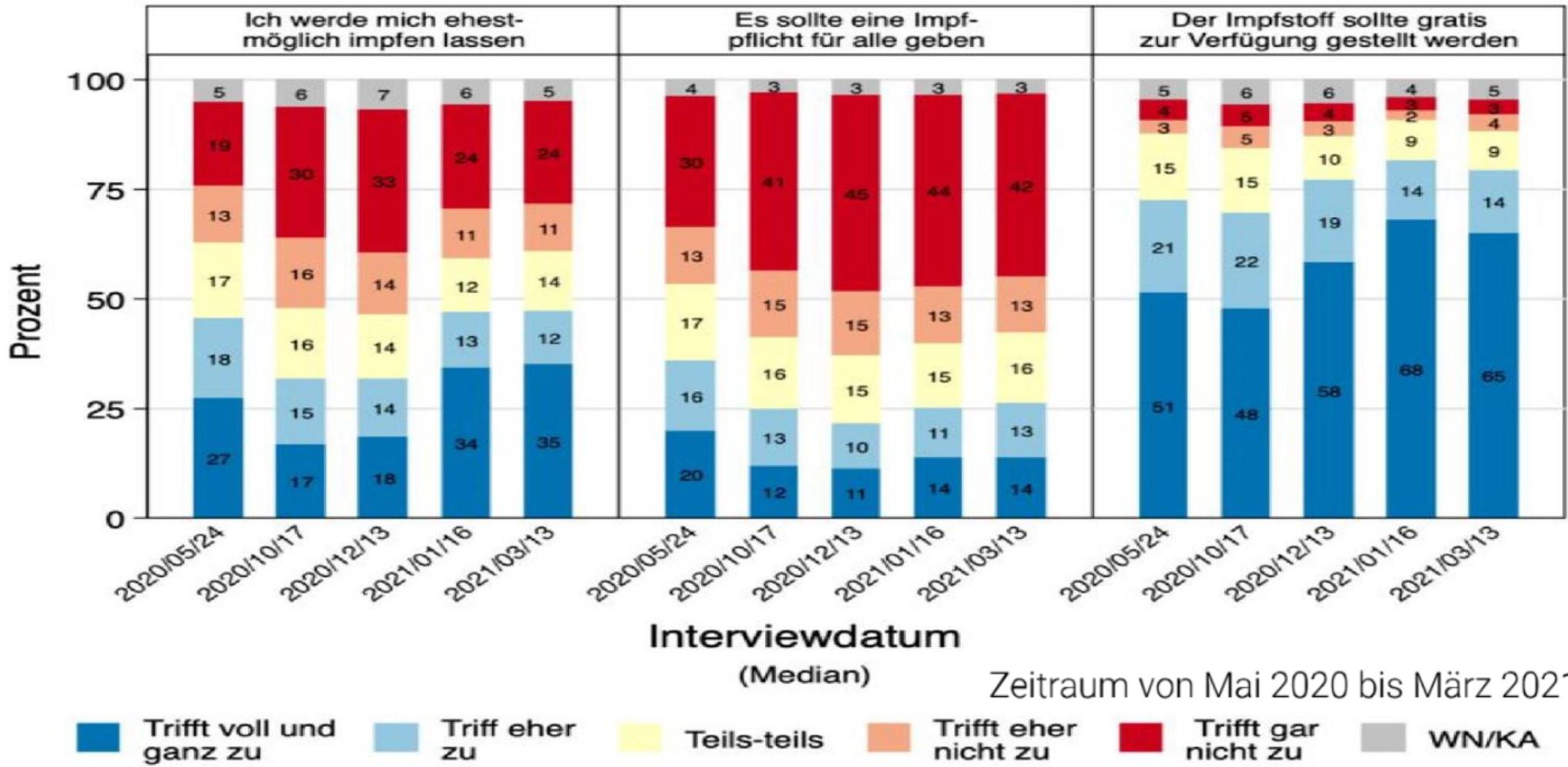
TESTEN

IMPFEN



# CORONAVIRUS SARS-CoV-2

## Impfbereitschaft in Österreich

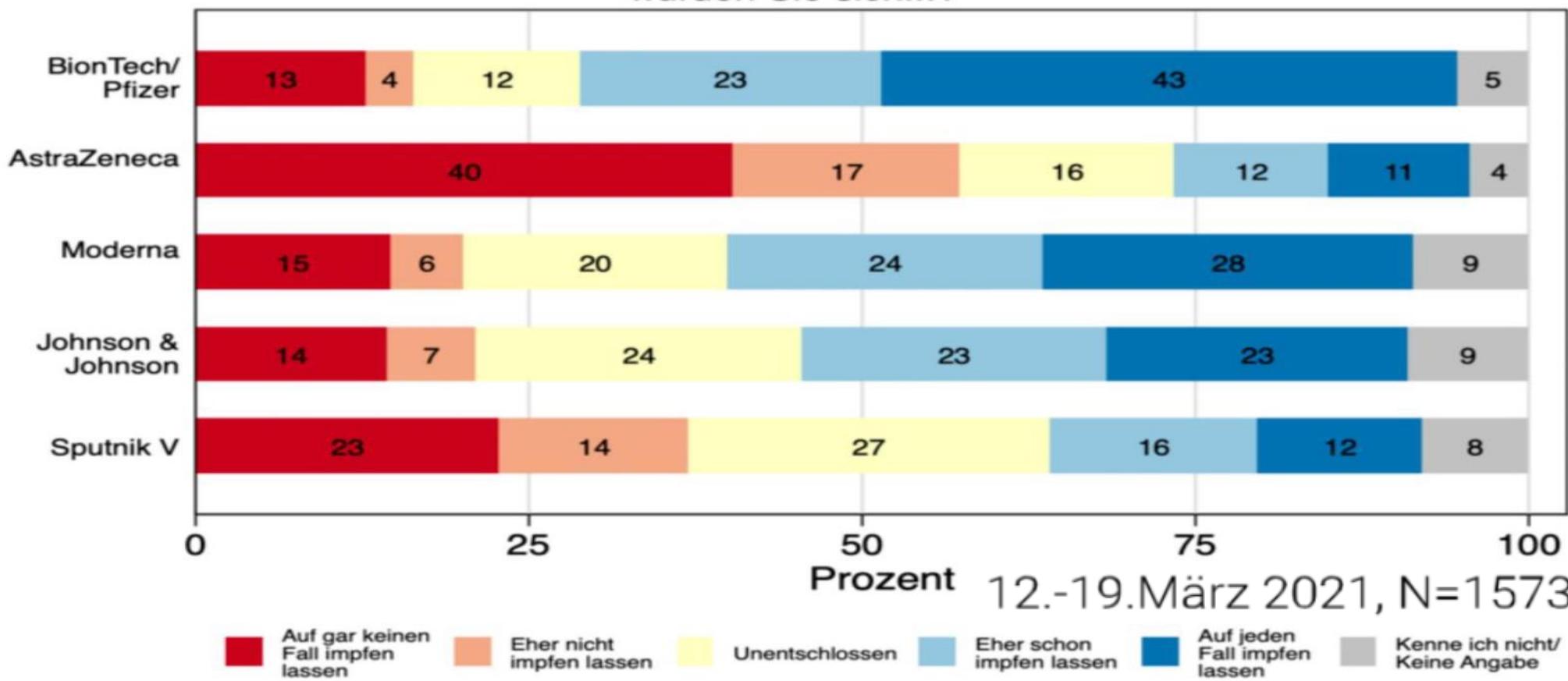




# CORONAVIRUS SARS-CoV-2

## Impfbereitschaft in Österreich

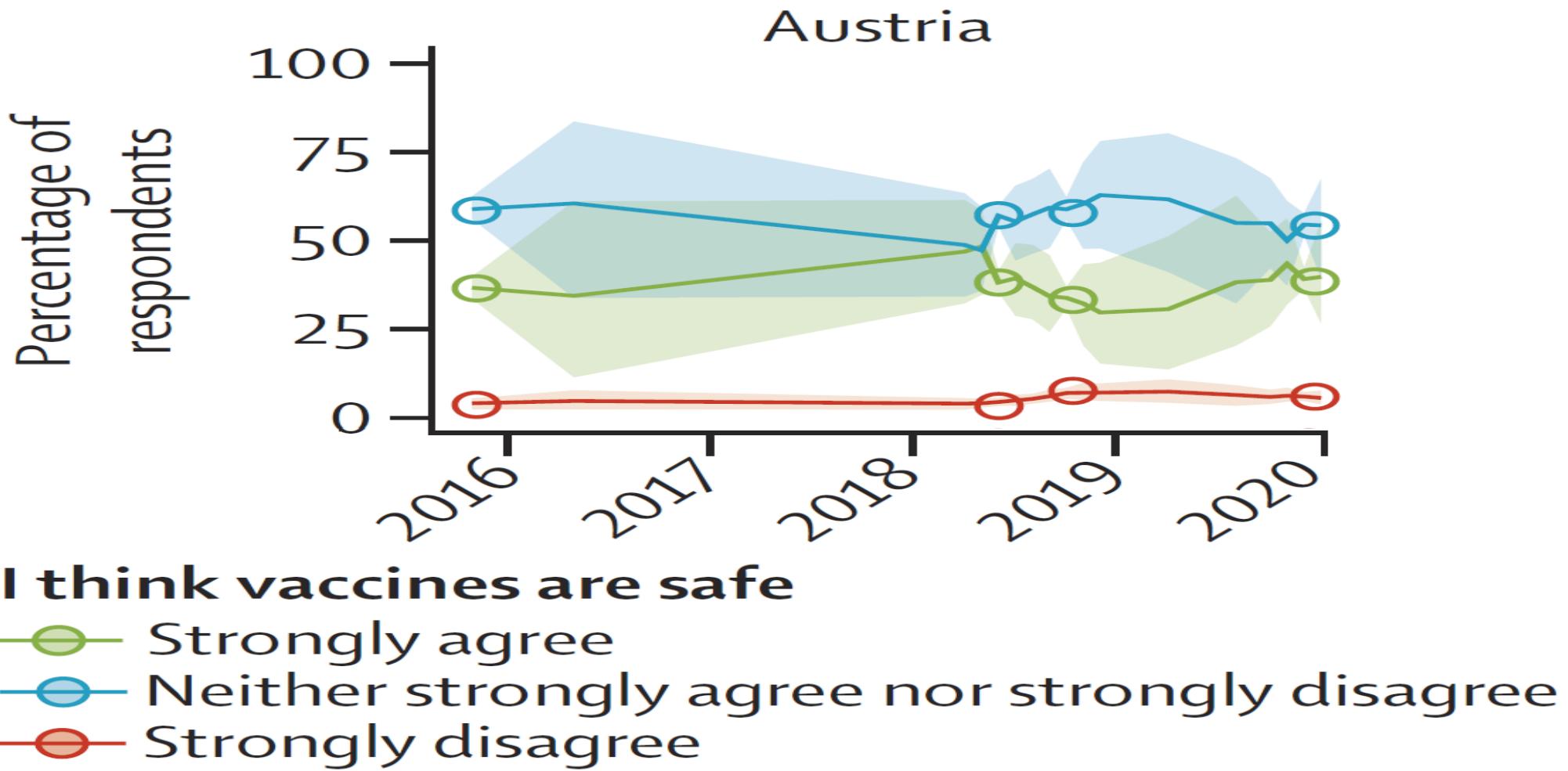
Wenn Sie nächste Woche die Möglichkeit hätten,  
sich mit einem der folgenden Impfstoffe impfen zu lassen,  
würden Sie sich...?



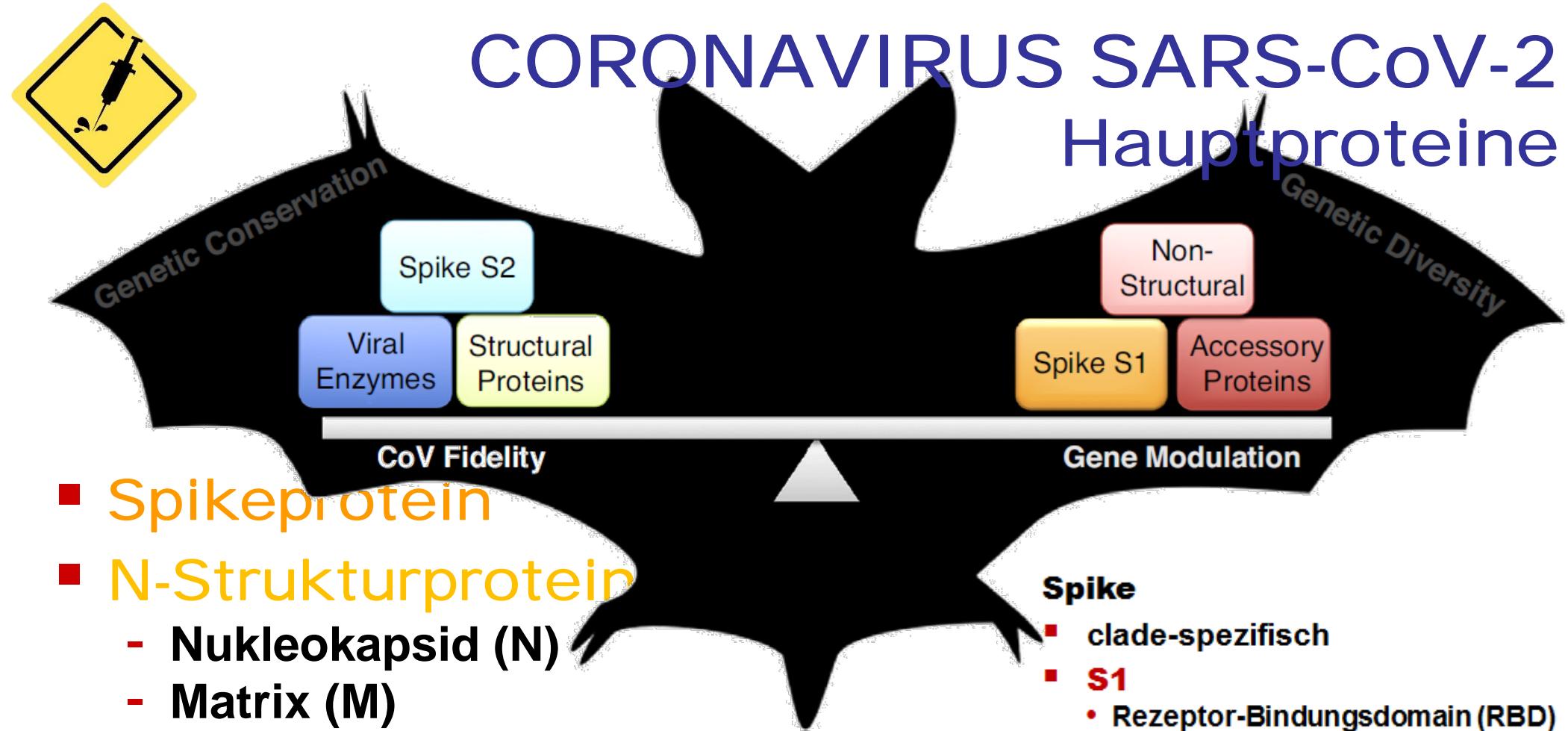


# CORONAVIRUS SARS-CoV-2

## Die Vertrauensfrage



# CORONAVIRUS SARS-CoV-2 Hauptproteine



- **Spikeprotein**
- **N-Strukturprotein**
  - Nukleokapsid (N)
  - Matrix (M)
  - Envelope (E)
- enzymatisch aktive Proteine
  - nsp14
  - nsp16

- Spike**
- clade-spezifisch
  - **S1**
    - Rezeptor-Bindungsdomain (RBD)
    - variabel
    - gut immunogen
  - **S2**
    - mediert Zelleintritt
    - konserviert
    - gut immunogen



# CORONAVIRUS SARS-CoV-2

## Impfstoffplattformen

Impfstofftyp	Beschreibung der Technologieplattform	Zugelassene Impfstoffe
RNA-Impfstoff	Die enzymatisch hergestellten RNA-Moleküle enthalten die genetische Information des Impfantigens; diese RNA wird in Lipid-Nanopartikel eingeschlossen. Die RNA gelangt nach Impfung in Körperzellen, wird dort abgelesen und das Impfantigen vom Körper selbst hergestellt.	COVID-19-Impfstoffe
Vektorimpfstoff, nicht replizierend	Unterschiedliche Vektoren auf Basis von Adenoviren (ChAd, hAd26, hAd5), die gentechnisch modifiziert sind und die genetische Information des Impfantigens enthalten. Das Impfantigen wird vom Körper selbst hergestellt.	COVID-19-Impfstoffe, Ebolaimpfstoffe
Untereinheitenimpfstoffe / Impfstoffe bestehend aus virusartigen Partikeln (VLP; virus-like particles)	Biotechnologisch herstelltes Impfantigen, das mit einem Adjuvans eingesetzt wird.	HPV-Impfstoffe, Hepatitis-B-Impfstoffe, ein Impfstoff gegen Gürtelrose



# CORONAVIRUS SARS-CoV-2 BNT162b2 & mRNA-1273

The NEW ENGLAND JOURNAL of MEDICINE

## RESEARCH SUMMARY

### Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

F.P. Polack, et al. DOI: 10.1056/NEJMoa2034577

#### CLINICAL PROBLEM

Safe and effective vaccines to prevent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and Covid-19 are urgently needed. No vaccines that protect against betacoronaviruses are currently available, and mRNA-based vaccines have not been widely tested.

#### CLINICAL TRIAL

A randomized, double-blind study of an mRNA vaccine encoding the SARS-CoV-2 spike protein.

43,548 participants ≥16 years old were assigned to receive the vaccine or placebo by intramuscular injection on day 0 and day 21. Participants were followed for safety and for the development of symptomatic Covid-19 for a median of 2 months.

#### RESULTS

##### Safety:

Vaccine recipients had local reactions (pain, erythema, swelling) and systemic reactions (e.g., fever, headache, myalgias) at higher rates than placebo recipients, with more reactions following the second dose. Most were mild to moderate and resolved rapidly.

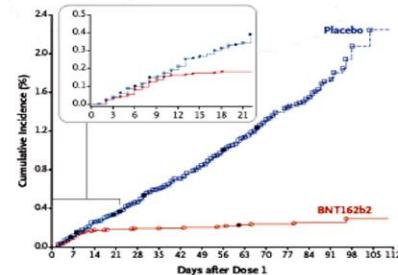
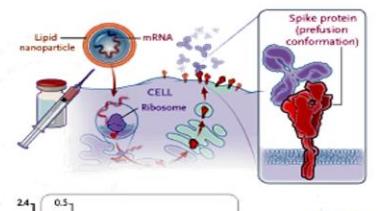
##### Efficacy:

The vaccine showed some early protection 12 days after the first dose; 7 days after the second dose, 95% efficacy was observed.

#### LIMITATIONS AND REMAINING QUESTIONS

Further study is required to understand the following:

- Safety and efficacy beyond 2 months and in groups not included in this trial (e.g., children, pregnant women, and immunocompromised persons).
- Whether the vaccine protects against asymptomatic infection and transmission to unvaccinated persons.
- How to deal with those who miss the second vaccine dose.



	BNT162b2 Vaccine	Placebo
Symptomatic Covid-19	8 N=18198	162 N=18325
Severe Covid-19	1 N=21669	9 N=21686

Vaccine efficacy of 95% (95% credible interval, 90.3–97.6%)

#### CONCLUSIONS

Two doses of an mRNA-based vaccine were safe over a median of two months and provided 95% protection against symptomatic Covid-19 in persons 16 years of age or older.

Links: Full article | NEJM QuickTake | Editorial

The NEW ENGLAND JOURNAL of MEDICINE

## RESEARCH SUMMARY

### Efficacy and Safety of mRNA-1273 SARS-CoV-2 Vaccine

L.R. Baden, et al. DOI: 10.1056/NEJMoa2035389

#### CLINICAL PROBLEM

The Covid-19 pandemic continues and expands. Additional data regarding vaccines to prevent symptomatic severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection are needed. The mRNA-1273 vaccine is a lipid-encapsulated mRNA vaccine encoding the prefusion stabilized spike protein of SARS-CoV-2.

#### CLINICAL TRIAL

A randomized, double-blind trial to evaluate the efficacy and safety of mRNA-1273.

30,420 participants ≥18 years old were assigned to receive either the vaccine or placebo in two intramuscular injections 28 days apart. Participants were followed for safety and the development of laboratory-confirmed, symptomatic Covid-19 over a median of 2 months after the second dose.

#### RESULTS

##### Safety:

Vaccine recipients had higher rates of local reactions (e.g., pain, erythema, swelling) and systemic reactions (e.g., headache, fatigue, myalgia) than placebo recipients. Most reactions were mild to moderate and resolved over 1–3 days.

##### Efficacy:

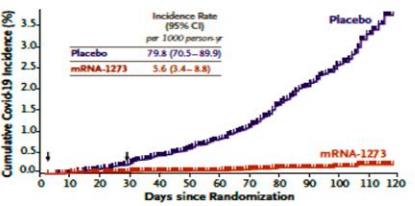
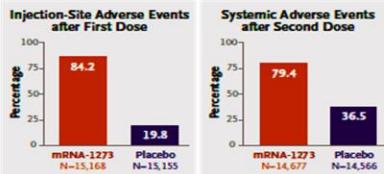
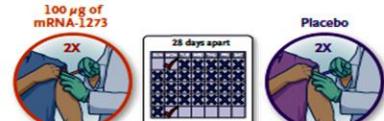
The incidence of Covid-19 was lower among vaccine recipients than among placebo recipients as early as 14 days after the first dose. Protection in the vaccine group persisted for the period of follow-up.

#### LIMITATIONS AND REMAINING QUESTIONS

Further study is required to understand the following:

- Safety and efficacy over a longer period of time, in a larger population, and in pregnant women and children.
- Whether the vaccine protects against asymptomatic infection and transmission to unvaccinated persons.
- How to care for those who miss the second vaccine dose.

Links: Full article | NEJM Quick Take | Editorial



	mRNA-1273 Vaccine N=14,550	Placebo N=14,598
Symptomatic Covid-19	11	185
Severe Covid-19	0	30

Vaccine efficacy of 94.1% (95% CI, 89.3–96.8%; P<0.001)

#### CONCLUSIONS

Two doses of a SARS-CoV-2 mRNA-based vaccine were safe and provided 94% efficacy against symptomatic Covid-19 in persons 18 or older.



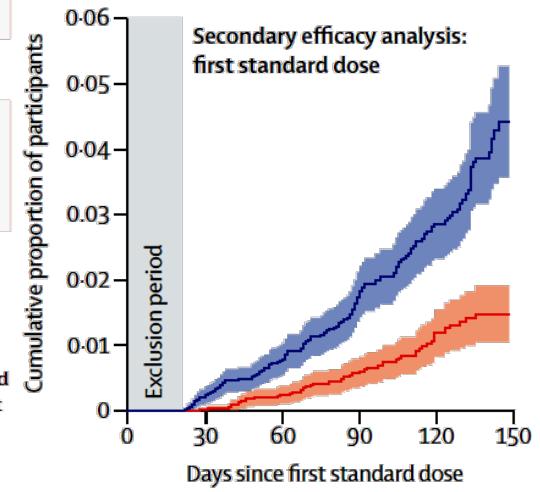
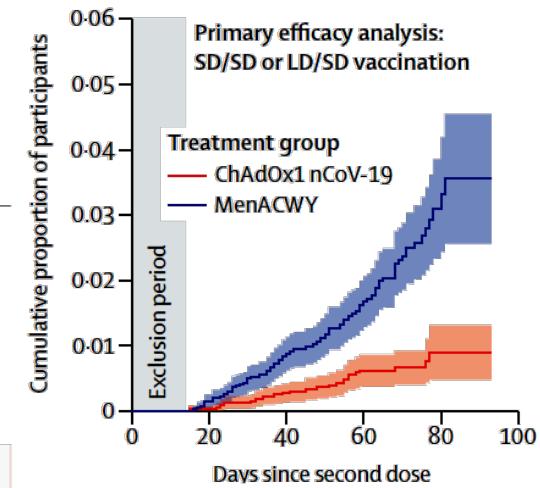
# CORONAVIRUS SARS-CoV-2

## ChAdOx1 nCoV-19

Total number of cases	ChAdOx1 nCoV-19		Control		Vaccine efficacy (CI*)	
	n/N (%)	Incidence rate per 1000 person-years (person-days of follow-up)	n/N (%)	Incidence rate per 1000 person-years (person-days of follow-up)		
All LD/SD and SD/SD recipients	131	30/5807 (0.5%)	44.1 (248 299)	101/5829 (1.7%)	149.2 (247 228)	70.4% (54.8 to 80.6)†
COV002 (UK)	86	18/3744 (0.5%)	38.6 (170 369)	68/3804 (1.8%)	145.7 (170 448)	73.5% (55.5 to 84.2)
LD/SD recipients	33	3/1367 (0.2%)	14.9 (73 313)	30/1374 (2.2%)	150.2 (72 949)	90.0% (67.4 to 97.0)‡§
SD/SD recipients	53	15/2377 (0.6%)	56.4 (97 056)	38/2430 (1.6%)	142.4 (97 499)	60.3% (28.0 to 78.2)
COV003 (Brazil; all SD/SD)	45	12/2063 (0.6%)	56.2 (77 930)	33/2025 (1.6%)	157.0 (76 780)	64.2% (30.7 to 81.5)‡
All SD/SD recipients	98	27/4440 (0.6%)	56.4 (174 986)	71/4455 (1.6%)	148.8 (174 279)	62.1% (41.0 to 75.7)
Other non-primary symptomatic COVID-19 disease¶	18	7/5807 (0.1%)	10.3 (248 299)	11/5829 (0.2%)	16.3 (247 228)	36.4% (-63.8 to 75.3)‡
Any symptomatic COVID-19 disease	149	37/5807 (0.6%)	54.4 (248 299)	112/5829 (1.9%)	165.5 (247 228)	67.1% (52.3 to 77.3)
Asymptomatic or symptoms unknown (COV002)	69	29/3288 (0.9%)	69.8 (151 673)	40/3350 (1.2%)	96.0 (152 138)	27.3% (-17.2 to 54.9)
LD/SD recipients	24	7/1120 (0.6%)	41.4 (61782)	17/1127 (1.5%)	100.6 (61730)	58.9% (1.0 to 82.9)‡
SD/SD recipients	45	22/2168 (1.0%)	89.4 (89 891)	23/2223 (1.0%)	92.9 (90 408)	3.8% (-72.4 to 46.3)
Any NAAT-positive swab	221	68/5807 (1.2%)	100.0 (248 299)	153/5829 (2.6%)	226.0 (247 228)	55.7% (41.1 to 66.7)

Vaccine efficacy was calculated from the robust Poisson model. The primary efficacy population (LD/SD and SD/SD) includes randomly assigned participants who were seronegative at baseline and received LD/SD or SD/SD or were in a corresponding control group, and remained on study more than 14 days after their second dose without having had a previous virologically confirmed SARS-CoV-2 infection. In addition, for groups in COV002, only efficacy groups (ie, groups 4, 6, 9, and 10) are included.

SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. LD/SD=low-dose prime plus standard-dose boost. SD/SD=two standard-dose vaccines given. NAAT=nucleic acid amplification test. \*CIs are 95% unless indicated otherwise. †95.8% CI used for primary analysis. ‡Vaccine efficacy calculated from a reduced robust Poisson model that was not adjusted for age. All other models included an adjustment for age. §*P* value for interaction term comparing LD/SD with SD/SD is *p*=0.010. ¶Other non-primary symptomatic COVID-19 disease includes cases who have symptoms other than the five main symptoms that are required for inclusion in the primary analysis (eg, a participant who has diarrhoea and malaise but no fever, cough, shortness of breath, anosmia, or ageusia).





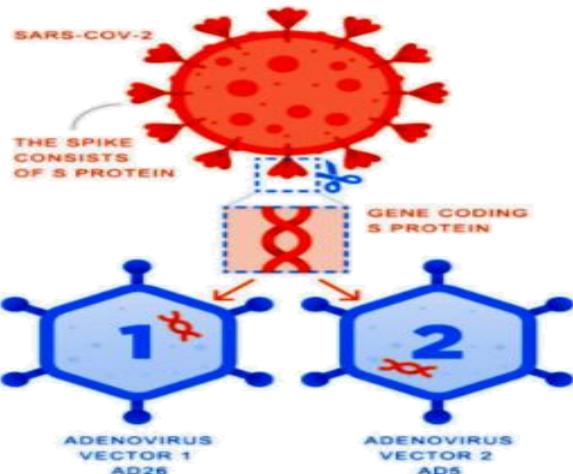
# CORONAVIRUS SARS-CoV-2

## Vektor-Impfstoffe

### Two-vector vaccine against coronavirus

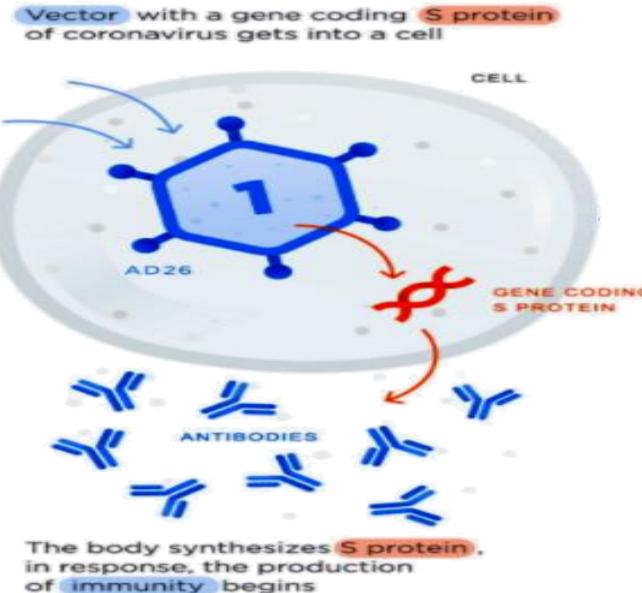
#### Vector creation

A **vector** is a virus that lacks a gene responsible for reproduction and is used to transport genetic material from another virus that is being vaccinated against into a cell. The **vector** does not pose any hazard to the body. The vaccine is based on an adenoviral vector which normally causes acute respiratory viral infections.

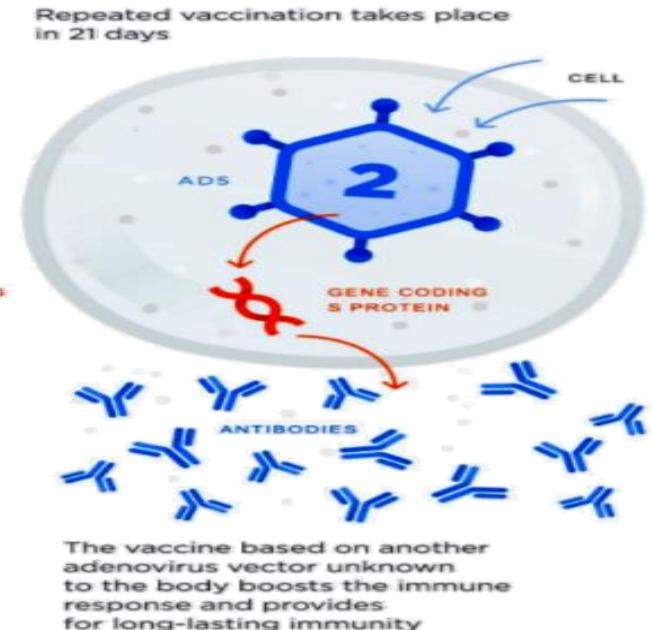


A gene coding **S protein** of SARS-CoV-2 spikes is inserted into each vector. The spikes form the "crown" from which the virus gets its name. The SARS-CoV-2 virus uses spikes to get into a cell

#### First vaccination



#### Second vaccination



The use of two vectors is a unique technology of the Gamaleya Center making the Russian vaccine different from other adenovirus vector-based vaccines being developed globally



# CORONAVIRUS SARS-CoV-2

## Impfstoffeffektivität

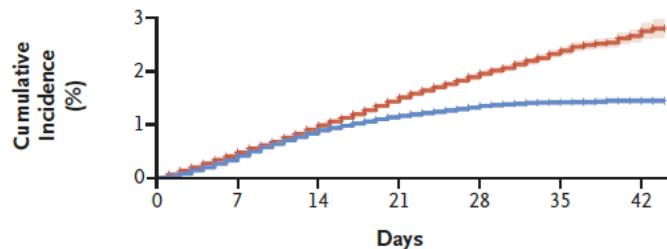
From <a href="http://hildabastian.net/">http://hildabastian.net/</a>	<i>Symptomatic Covid-19</i>		<i>Severe Covid-19</i>	
	<b>Vax vs control</b>	<b>Efficacy (95% CI)</b>	<b>Vax vs control</b>	<b>Efficacy (95% CI)</b>
BNT-Pfizer	8 vs 162	95% (90 to 98)	1 vs 3	66% (-125 to 96)
Moderna	11 vs 185	94% (89 to 97)	1 vs 30 <sup>1</sup>	n.a. (not applicable)
Sputnik V	16 vs 62	92% (86 to 95)	0 vs <20 <sup>2</sup>	n.a.
Oxford-AstraZeneca	72 vs 189	63% <sup>3</sup> (51 to 72)	0 vs 1	n.a.
Novavax <sup>4</sup>	6 vs 56	89% <sup>5</sup> (75 to 95)	0 vs 1	n.a.
Johnson & Johnson	65 to 193	67% <sup>6</sup> (56 to 75)	5 vs 34	85% (54 to 97)

1. One vaccinated person was hospitalized with possibly severe Covid-19 2 months after vaccination was not included by Moderna, but highlighted by the FDA and EMA. The EMA reported Moderna had not yet assessed this person's case. No efficacy rate including this person's illness was calculated. The number of people with severe illness in the control group could change, too, when assessments are completed.
2. Sputnik V's secondary outcome for severity included moderate and severe: 20 in total. Severe proportion not reported.
3. This vaccine efficacy is the one determined by the EMA, based on 2 standard doses of the vaccine.
4. Novavax has only reported some top-line interim results in a press release so far.
5. Overall efficacy: efficacy against the original strain of the coronavirus was 96%. It is the UK phase 3 trial only.
6. This vaccine efficacy is one that was calculated to harmonize with the definitions of symptomatic Covid-19 used by the FDA for the 2 mRNA vaccines (BNT-Pfizer and Moderna). It is an international efficacy rate, and it is a secondary outcome. The primary efficacy outcome for this trial was very similar: 66%. The primary efficacy rate from regions: USA 72%; SA 64%; Latin America 61%.



# CORONAVIRUS SARS-CoV-2 BTN162b2 Vakzine [Pfizer/Biontech]

A Documented SARS-CoV-2 Infection



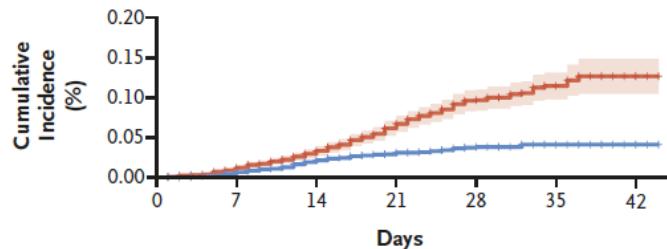
No. at Risk

Unvaccinated	596,618	413,052	261,625	186,553	107,209	37,164	4132
Vaccinated	596,618	413,527	262,180	187,702	108,529	38,029	4262

Cumulative No. of Events

Unvaccinated	0	2362	3971	5104	5775	6053	6100
Vaccinated	0	1965	3533	4124	4405	4456	4460

C Covid-19 Hospitalization



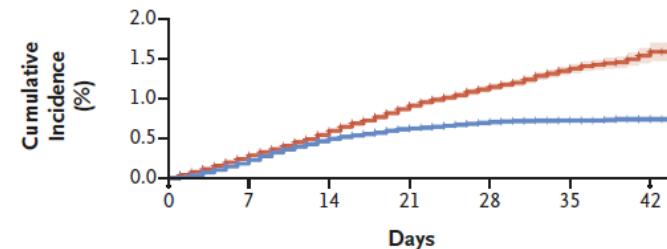
No. at Risk

Unvaccinated	596,618	414,865	264,377	189,808	109,867	38,432	4309
Vaccinated	596,618	414,916	264,482	189,972	110,054	38,561	4321

Cumulative No. of Events

Unvaccinated	0	58	125	198	244	256	259
Vaccinated	0	31	77	98	108	110	110

B Symptomatic Covid-19



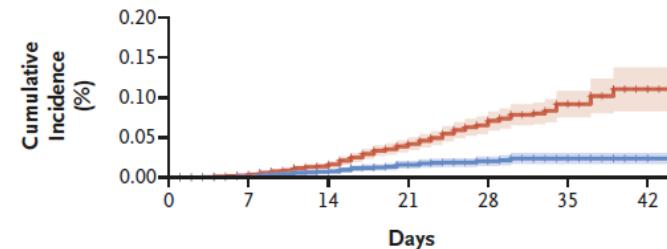
No. at Risk

Unvaccinated	596,618	413,768	262,662	187,784	108,242	37,564	4204
Vaccinated	596,618	414,140	263,179	188,740	109,261	38,299	4288

Cumulative No. of Events

Unvaccinated	0	1419	2393	3079	3433	3582	3607
Vaccinated	0	1103	1967	2250	2373	2387	2389

D Severe Covid-19



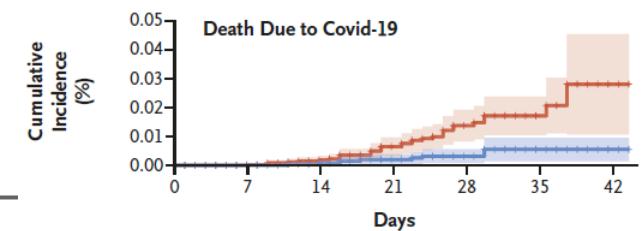
No. at Risk

Unvaccinated	596,618	414,898	264,437	189,874	109,929	38,467	4310
Vaccinated	596,618	414,933	264,516	190,000	110,076	38,571	4322

Cumulative No. of Events

Unvaccinated	0	17	57	114	157	171	174
Vaccinated	0	6	26	45	52	55	55

real life Daten  
aus Israel



No. at Risk

Unvaccinated	596,618	414,909	264,479	189,950	110,008	38,510	4316
Vaccinated	596,618	414,938	264,538	190,032	110,101	38,575	4322

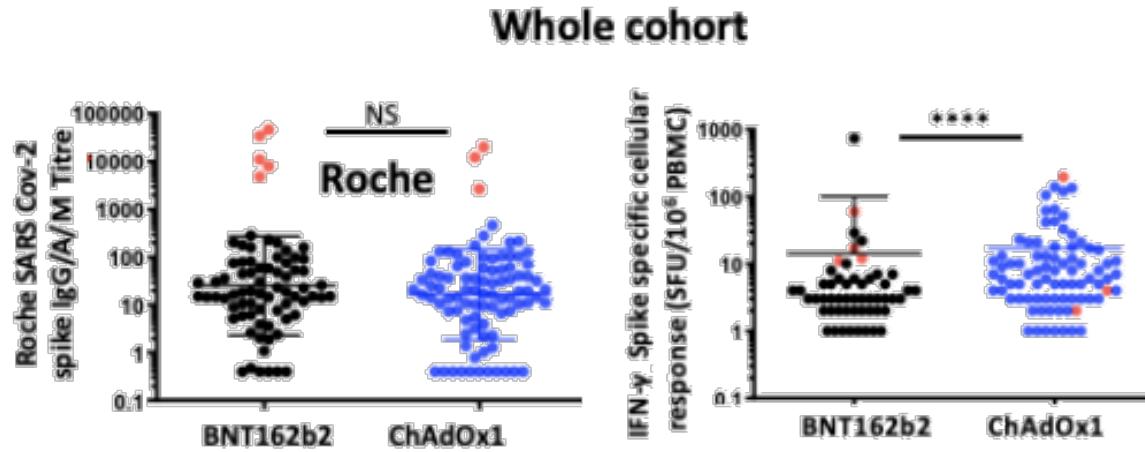
Cumulative No. of Events

Unvaccinated	0	1	6	16	27	30	32
Vaccinated	0	0	2	5	7	9	9



# CORONAVIRUS SARS-CoV-2

## Adaptive Immunantwort



165 TN\*innen  
Alter >80 Jahren  
5 Wo nach EINER Dosis

- Antikörperantworten gegen das Spike-Protein
  - 93% der Empfänger von BNT162b2 – median 19.3 U/ml
  - 87% der Empfänger von AZD1222 – median 19.6 U/ml
- Spike-spezifische T-Zell-Antworten
  - 12% der Empfänger von BNT162b2 – median 2 Spots/Mill
  - 31% der Empfänger von AZD1222 – median 6 Spots/Mill



# CORONAVIRUS SARS-CoV-2 mRNA-Vakzineffektivität

Person-days, SARS-CoV-2 infections, and vaccine effectiveness among health care personnel, first responders, and other essential and frontline workers, by messenger RNA immunization status — eight U.S. locations, December 14, 2020–March 13, 2021

COVID-19 immunization status	Person-days	SARS-CoV-2 infections		Unadjusted vaccine effectiveness*	Adjusted vaccine effectiveness*,†
		No.	Incidence rate per 1,000 person-days	% (95% CI)	% (95% CI)
Unvaccinated	116,657	161	1.38	N/A	N/A
Partially immunized	41,856	8	0.19	82 (62–91)	80 (59–90)
≥14 days after receiving first dose only§	15,868	5	0.32		
≥14 days after first dose through receipt of second dose	25,988	3	0.12		
Fully immunized	78,902	3	0.04	91 (73–97)	90 (68–97)
≥14 days after second dose					

Abbreviations: CI = confidence interval; N/A = not applicable.

\* Vaccine effectiveness was estimated using a Cox proportional hazards model accounting for time-varying immunization status.

† Hazard ratio is adjusted for study site.

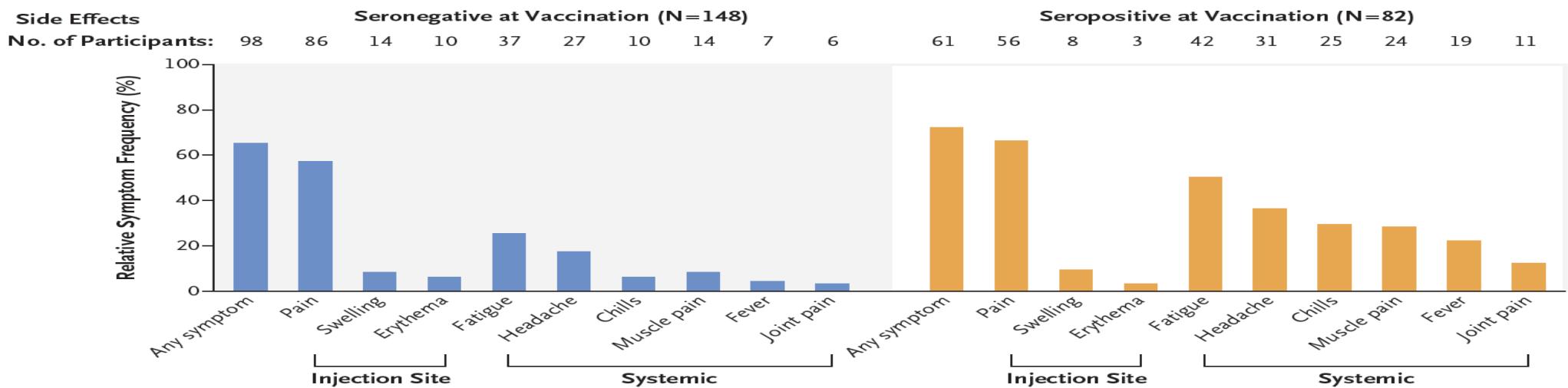
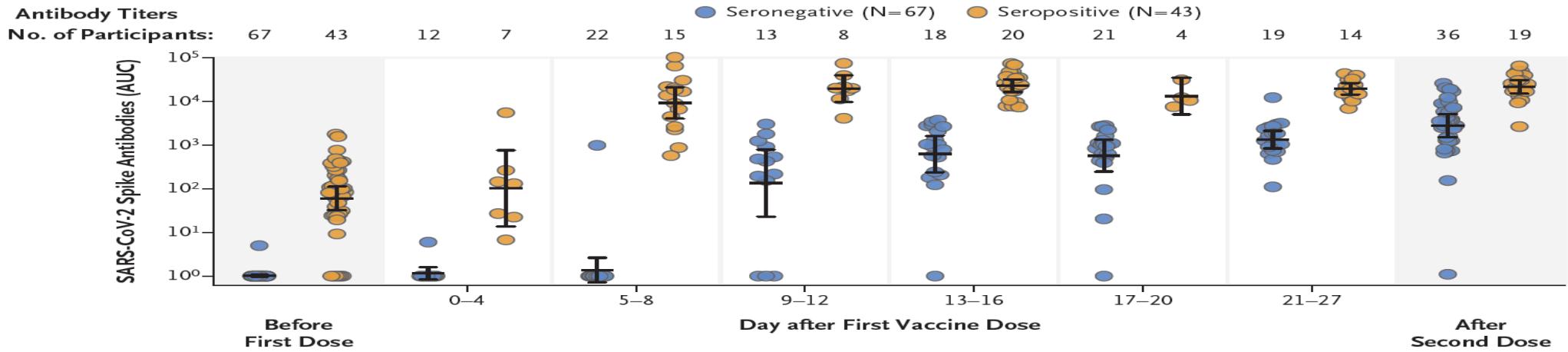
§ Participants received first dose but had not received second dose by the end of the study period.

H C W 'S



# CORONAVIRUS SARS-CoV-2

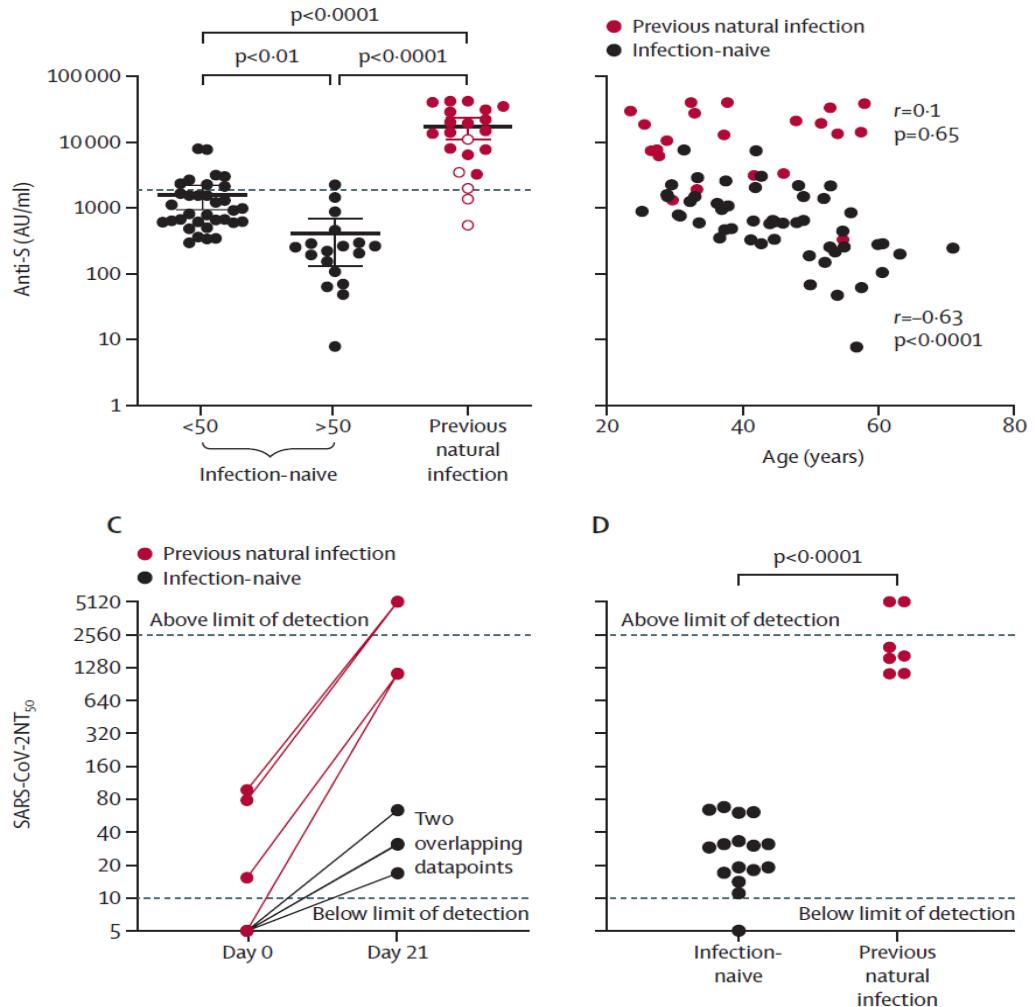
## Vakzineffektivität & COVID-19-Status



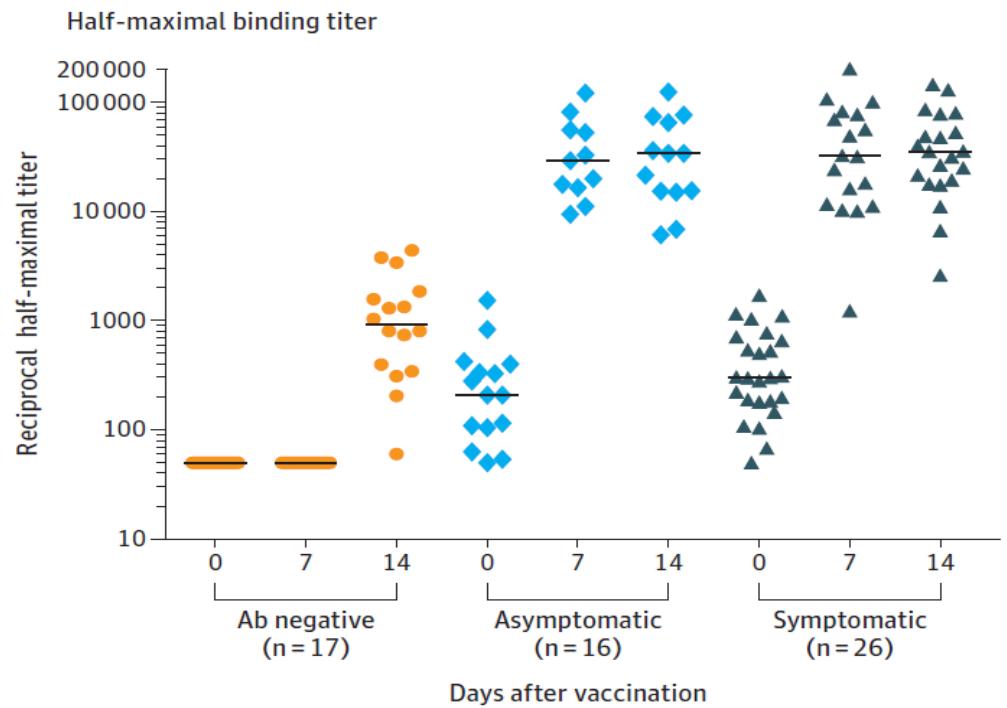


# CORONAVIRUS SARS-CoV-2

## Kombination Infektion & Impfung



## EINE Infektion



## EINE Impfung

Prendekci, Lancet 2021 – Saadat, JAMA 2021



# CORONAVIRUS SARS-CoV-2

## Immunsuppression & Impfantwort

	Antibody, No. (%)		Bivariable IRR (95% CI)	P value	Adjusted multivariable IRR (95% CI)	P value
	Detectable (n = 76)	Undetectable (n = 360)				
Age group, y						
18-39	30 (39)	69 (19)				
40-59	18 (24)	132 (37)	0.81 (0.71-0.93)	.003	0.83 (0.73-0.93)	.002
≥60	28 (37)	159 (44)				
Type of organ transplant						
Kidney	31 (41)	188 (53)	0.68 (0.45-1.04)	.07		
Liver	28 (37)	50 (14)				
Heart	9 (12)	57 (16)				
Lung	4 (5)	45 (13)				
Pancreas	1 (1)	4 (1)				
Other (multiorgan)	2 (3)	12 (3)				
Time since transplant, y						
<3	13 (17)	106 (30)				
3-6	12 (16)	77 (22)				
7-11	19 (25)	82 (23)	1.88 (1.21-2.93)	.005	1.45 (0.96-2.20)	.08
≥12	31 (41)	89 (25)				
Type of regimen						
Includes anti-metabolite maintenance immunosuppression	28 (37)	292 (81)				
Does not include anti-metabolite maintenance immunosuppression	48 (63)	68 (19)	0.21 (0.14-0.32)	<.001	0.22 (0.15-0.34)	<.001
Vaccine						
mRNA-1273 (Moderna)	52 (69)	152 (43)	2.14 (1.24-3.69)	.006	2.15 (1.29-3.57)	.003
BNT162b2 (Pfizer-BioNTech)	23 (31)	200 (57)				

- **436 TX-Pat\*innen**
  - Alter 55.9 Jahre
  - TX-Alter 6.2 (2.7-12.7) a
- **20 Tage post Vacc I**
  - 17% Ak pos
  - Immunsuppression
    - 37% Ak pos mit
    - 63% Ak pos ohne
  - 69% mRNA-1273
  - 31% BNT162b2

immunsuppressive Erhaltungstherapie mit Tacrolimus (83 %), Corticosteroiden (54 %), MycophenolatMofetil (66 %), Azathioprin (9 %), Sirolimus (4 %) und Everolimus (2 %)



# CORONAVIRUS SARS-CoV-2

## Impfdurchbrüche

Case no.	Age, y/sex	Ward	Healthcare sector	Indication for testing	Presumed exposure source	Exposure day	Day of symptom onset†	Day tested	No. days from symptom onset to testing	No. secondary isolations
1	42/F	General surgery	Physician	Symptoms	Unknown	Unknown	-4	+5	Excluded‡	0
2	54/F	Transportation	Secretary	Symptoms	Unknown	Unknown	0	+9	9	1
3	34/M	Geriatrics	Physician	Symptoms	Unknown	Unknown	+1	+1	0	1
4	31/F	Cardiovascular surgery	Nurse	Symptoms	Community	Unknown	+1	+1	0	1
5	49/F	Psychiatry	Cleaning services	Symptoms	Unknown	Unknown	+1	+3	2	0
6	43/F	Laundry	Laundry handler	Symptoms	Community	-3	+2	+3	1	3
7	43/F	Laboratory	Scientist	Exposure	Community	-3	+2	+6	4	0
8	60/F	ED	Nurse assistant	Symptoms	Community	0	+3	+5	2	0
9	50/F	Eye clinic	Technologist	Symptoms	Unknown	Unknown	+4	+6	2	0
10	33/M	Psychiatry	Psychologist	Exposure	Community	+2	+6	+6	0	0
11	36/M	Operating room	Logistics	Symptoms	Community	+4	+7	+8	1	0
12	54/M	Pulmonology	Physician	Symptoms	Community	+4	+7	+7	0	0
13	37/M	ED	Physician	Symptoms	Unknown	+3	+7	+9	2	0
14	32/M	Rehabilitation	Nurse	Symptoms	Unknown	Unknown	+9	+10	1	1
15	40/M	Laboratory	Physician	Symptoms	Unknown	Unknown	+10	+10	0	1
16	52/F	Radiotherapy	Secretary	Exposure	Unknown	Unknown	Asymp	+5	NA	3
17	55/F	General surgery	Phlebotomist	Exposure	Unknown	Unknown	Asymp	+8	NA	4
18	55/F	Kitchen	Food handler	Exposure	Community	-5	Asymp	+2	NA	1
19	61/F	Radiology	Physician	Exposure	Community	+4	Asymp	+11	NA	0
20	40/F	ED	Secretary	Exposure	Community	+6	Asymp	+11	NA	2
21	45/F	Internal medicine	Nurse	Exposure	Unknown	Unknown	Asymp	+8	NA	0
22	39/M	Internal medicine	Nurse	Exposure	Community	+2	Asymp	+8	NA	0

\*All persons with cases were vaccinated during the first week of campaign, December 20–27, 2020. Asymp, asymptomatic; ED, emergency department; NA, not applicable.

†Considering day of vaccination as day 0.

‡Excluded from calculations of mean time from vaccination to symptom onset because symptoms began before vaccination.

0.54%



# CORONAVIRUS SARS-CoV-2

## Impfdurchbrüche

- **77.000.000 vollständig immunisierte Pat\*innen**
- **5.800 Infektionen bei C19-Vacc-Pat\*innen**
- **406 C19-Vacc-Pat\*innen stationär**
- **74 stat-Vacc-Pat\*innen verstorben**

**1:1.040.541**

- **ca 40% im Alter 65+**
- **65% Frauen**
- **29% asymptomatische C19-Vacc-Pat\*innen**



# CORONAVIRUS SARS-CoV-2 BNT162b2 & Mutations-VE

## Durchbruchsinfektionen

- OR 8:1  
**B.1.351 – 1 Wo n Vacc II**
- OR 26:10  
**B.1.1.7 – zw 2 Wo n Vacc I & 1 Wo n Vacc I**



# CORONAVIRUS SARS-CoV-2

## AZD1222 & BNT162b2

### Vakzineffektivität bei Mutationen

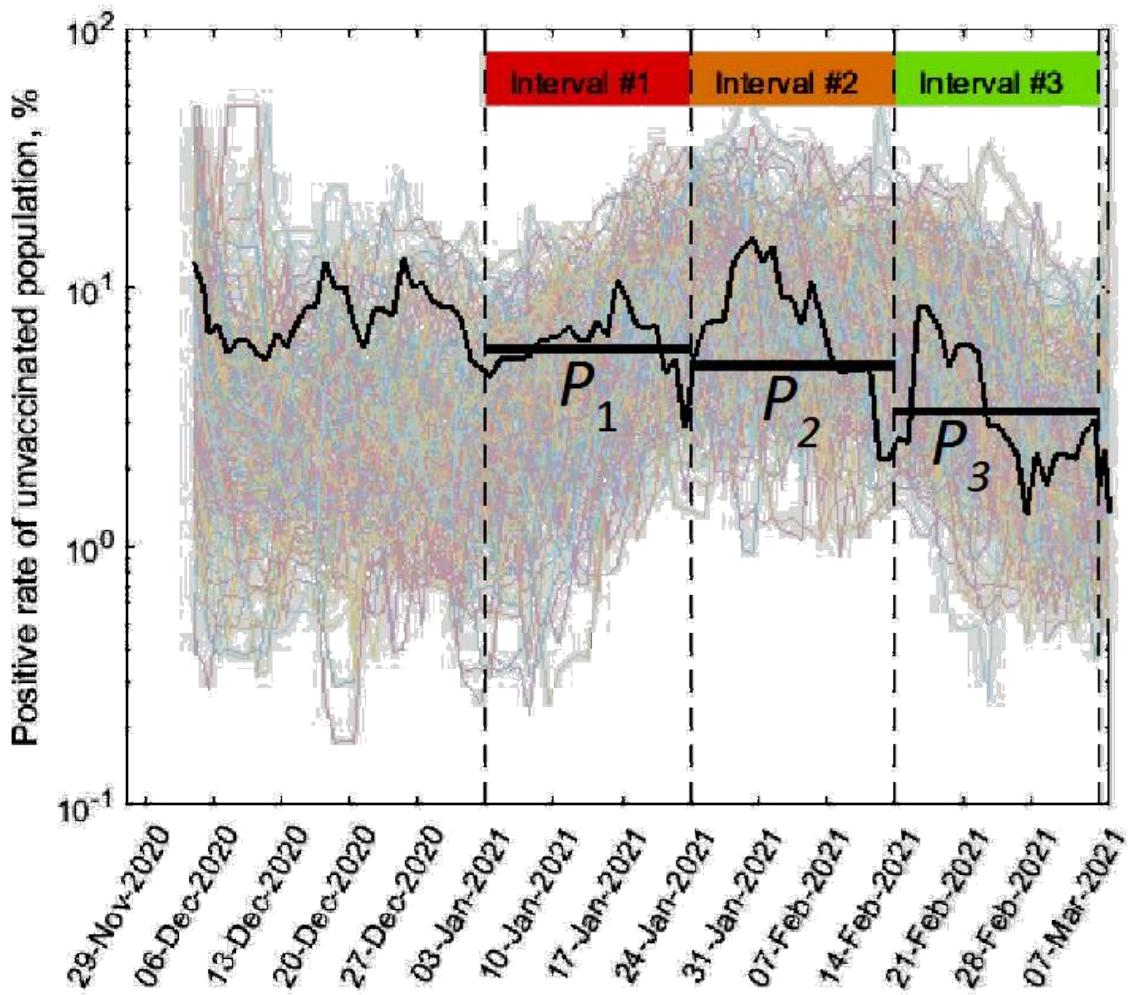
Plasma	rekonvaleszente Patienten <sup>1</sup>	AZD1222	BNT162b2
Varianten	Reduktion neutralisierende Antikörpertiter im Vergleich mit dem frühen Victoria Isolat (x-fach)		
B.1.1.7	2,9x	2,3x	3,3x
P.1	3,1x	2,9x	2,6x
B.1.351	13,3x	9x	7,6x

vor dem Auftreten von B1.1.7



# CORONAVIRUS SARS-CoV-2

## Schutz ungeimpfter Personen



Kreuzprotektion  
für ungeimpfte  
Personen



# CORONAVIRUS SARS-CoV-2

## Mutation & Effektivität

Charakteristika von SARS-CoV-2 Varianten			
	B.1.1.7	B.1.351	P.1
Alternativer Name	501Y.V1 VOC 202012/01	501Y.V2 20C/501Y.V2	501Y.V1 B.1.1.248
Land der Entdeckung	Großbritannien	Südafrika	Brasilien
Erstbeschreibung	Dezember 2020	Dezember 2020	Jänner 2021
Rückverfolgbar bis	September 2020	Oktober 2020	Dezember 2020
Aktuelle Verbreitung in Ö	Dominierend	Wenige Fälle	Einzelfälle?
Zahl Spike Mutationen	8	9	10
Wichtige Spike Mutationen	N501Y, 69–70del, P681H	N501Y, E484K, K417N	N501Y, E484K
Erhöhte Übertragbarkeit	30-70%	Möglich erhöht, nicht etabliert	Möglich erhöht
Reinfektionen	Unwahrscheinlich	Wahrscheinlich	Wahrscheinlich
Sterblichkeit	≈50% erhöht	Keine gesicherten Daten	Keine gesicherten Daten
<u>Wirkung von Antikörpern</u>			
Monoklonale Antikörper			
Lilly®	✓	X	X
Regeneron®	✓	✓	?
Serum v Rekonvaleszenten	Wenig Aktivitätsverlust	Starke Reduktion	?
Serum v mRNA Geimpften	Wenig Aktivitätsverlust	Mäßige Reduktion	Wenig Aktivitätsverlust
<u>Wirkung von Impfungen</u>			
BionTech/Pfizer	Volle Wirkung vermutet	Starke Wirkung vermutet	Starke Wirkung vermutet
Moderna	Volle Wirkung vermutet	Starke Wirkung vermutet	Starke Wirkung vermutet
AstraZeneca	84% → 75%?	Mildes Covid-19: kein Schutz	Keine Daten
Janssen (J&J)	Keine Daten	72% → 57%?	Keine Daten
Novavax	95,6 → 85,6%	90% → 49%, ohne HIV 55%	Keine Daten
CoronaVac (Sinovac)			Wirksam



# CORONAVIRUS SARS-CoV-2

## Nebenwirkungsmeldungen

### Anzahl der Meldungen von vermuteten Nebenwirkungen

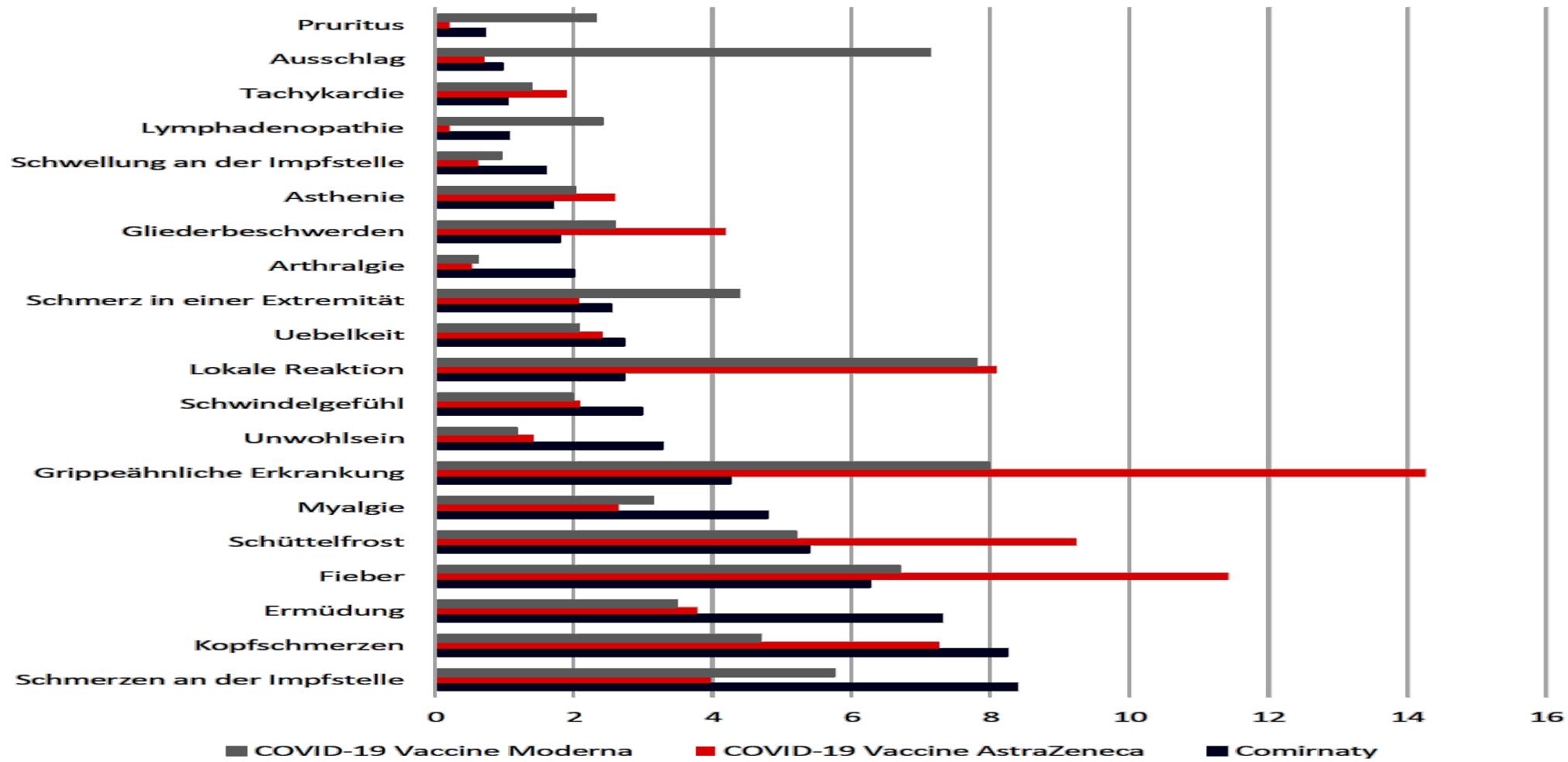
Impfstoff bzw. Zulassungsinhaber	Impfungen laut e-Impfpass	Nebenwirkungs- meldungen	Melderate (Meldungen pro 1.000 Impfungen)
BioNTech/Pfizer	1.384.250	4.619	3,34
Moderna	162.650	585	3,60
AstraZeneca	478.084	13.815	28,90
Gesamt	2.024.984	19.019	9,39

### Die 10 häufigsten gemeldeten Reaktionen

Reaktion	BioNTech/Pfizer	Moderna	AstraZeneca
Fieber	1.521	190	8.292
Kopfweh	1.630	175	7.475
Schmerzen an der Impfstelle	1.134	189	5.229
Müdigkeit	1.188	132	4.039
Gelenkschmerzen	752	80	3.661
Muskelschmerzen	782	77	3.222
Übelkeit	450	56	1.449
Schüttelfrost	521	39	1.154
Erbrechen	113	18	417
Schmerzen in einer Extremität	374	34	398



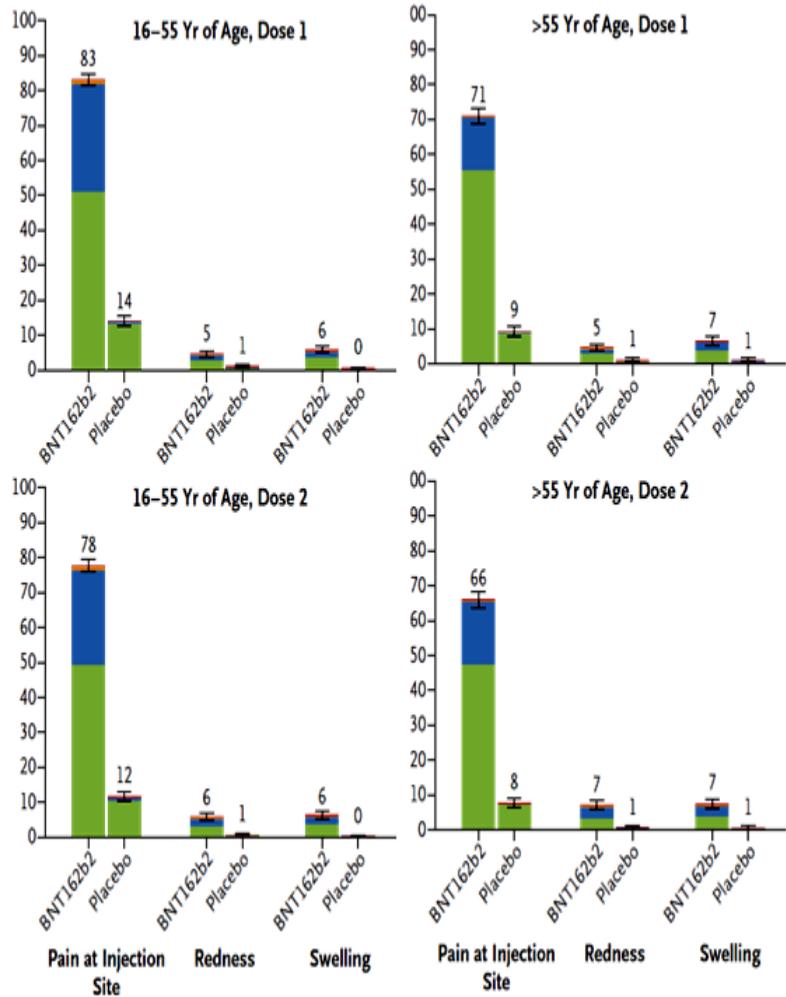
# CORONAVIRUS SARS-CoV-2 mRNA & Vektor im Vergleich



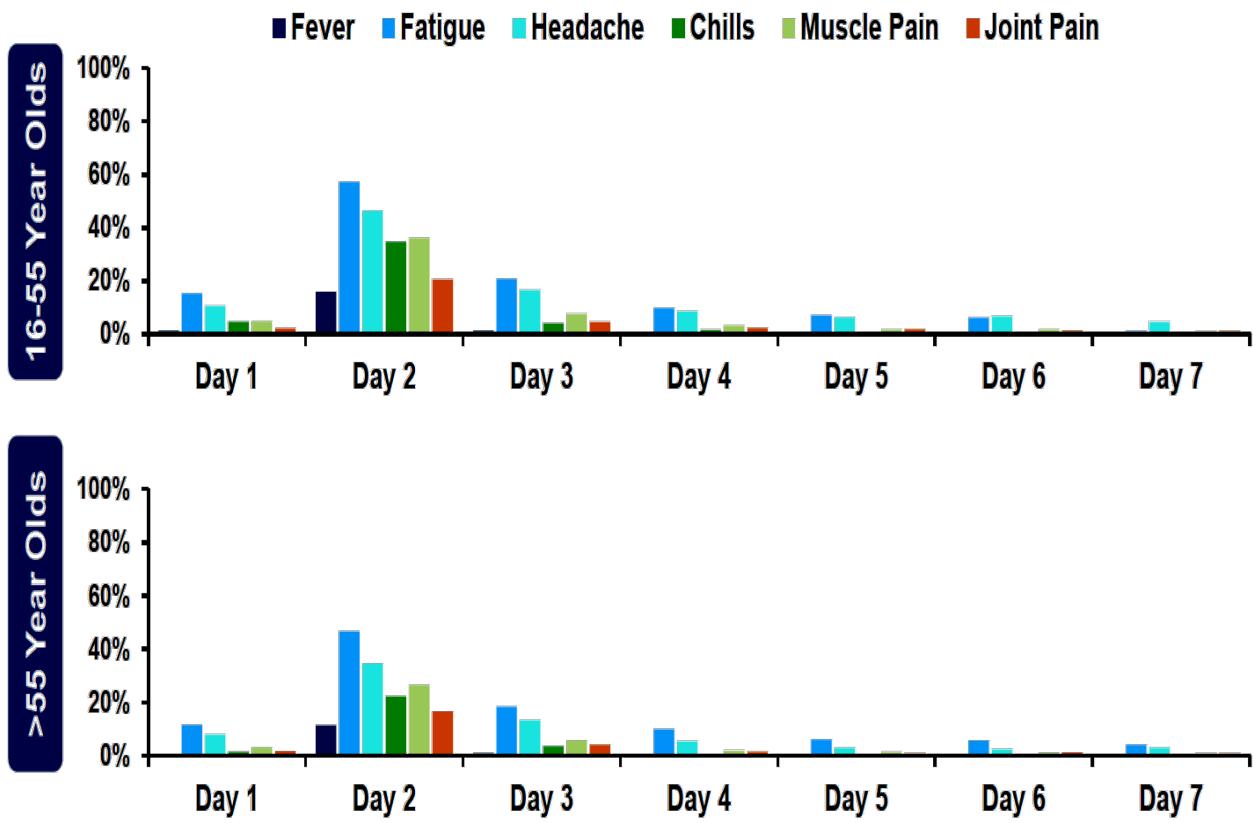


# CORONAVIRUS SARS-CoV-2

## BTN162b2 Vakzine [Pfizer/Biontech]



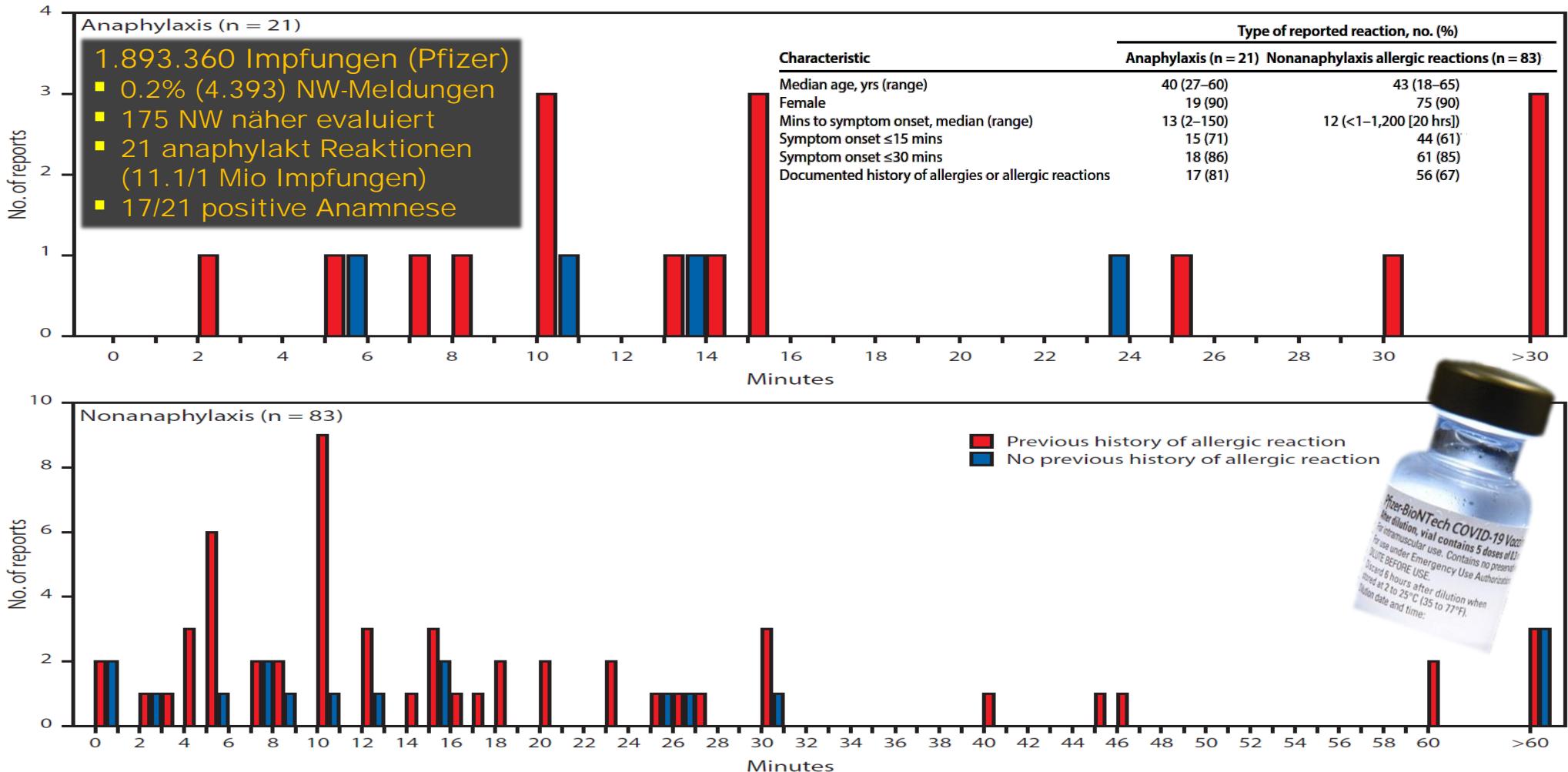
## Dauer reaktogener Symptome





# CORONAVIRUS SARS-CoV-2

## Allergische Reaktionen Pfizer-BioNTech





# CORONAVIRUS SARS-CoV-2

## Lipidnanopartikel

Der Stopfen der Durchstechflaschen des Impfstoffs BNT162b2 der Firma Biontech/Pfizer besteht nach Herstellerangaben nicht aus Naturgummi-Latex, sodass verschleppte Latexspuren als Auslöser einer IgE-vermittelten allergischen Reaktion auf Latex in Zusammenhang mit der Impfstoffverabreichung unwahrscheinlich erscheinen. Neben dem Wirkstoff sind nach publizierten Herstellerangaben als Hilfsstoffe enthalten:

- ALC-0315 = (4-Hydroxybutyl)azandiyil)bis (Hexan-6,1-diyl)bis(2-hexyldecanoat),
- ALC-0159 = 2-[(Polyethylenglykol)-2000]-N,N-ditetradecylacetamid,
- 2-Distearoyl-sn-glycero-3 phosphocholin,
- Cholesterol,
- Kaliumchlorid,
- Kaliumdihydrogenphosphat,
- Natriumchlorid,
- Dinatriumhydrogenphosphat-Dihydrat,
- Saccharose,
- Wasser für Injektionen,

Ein Adjuvans ist nicht enthalten, ebenso wenig ein Konservierungsstoff oder Hühnereiweiß.

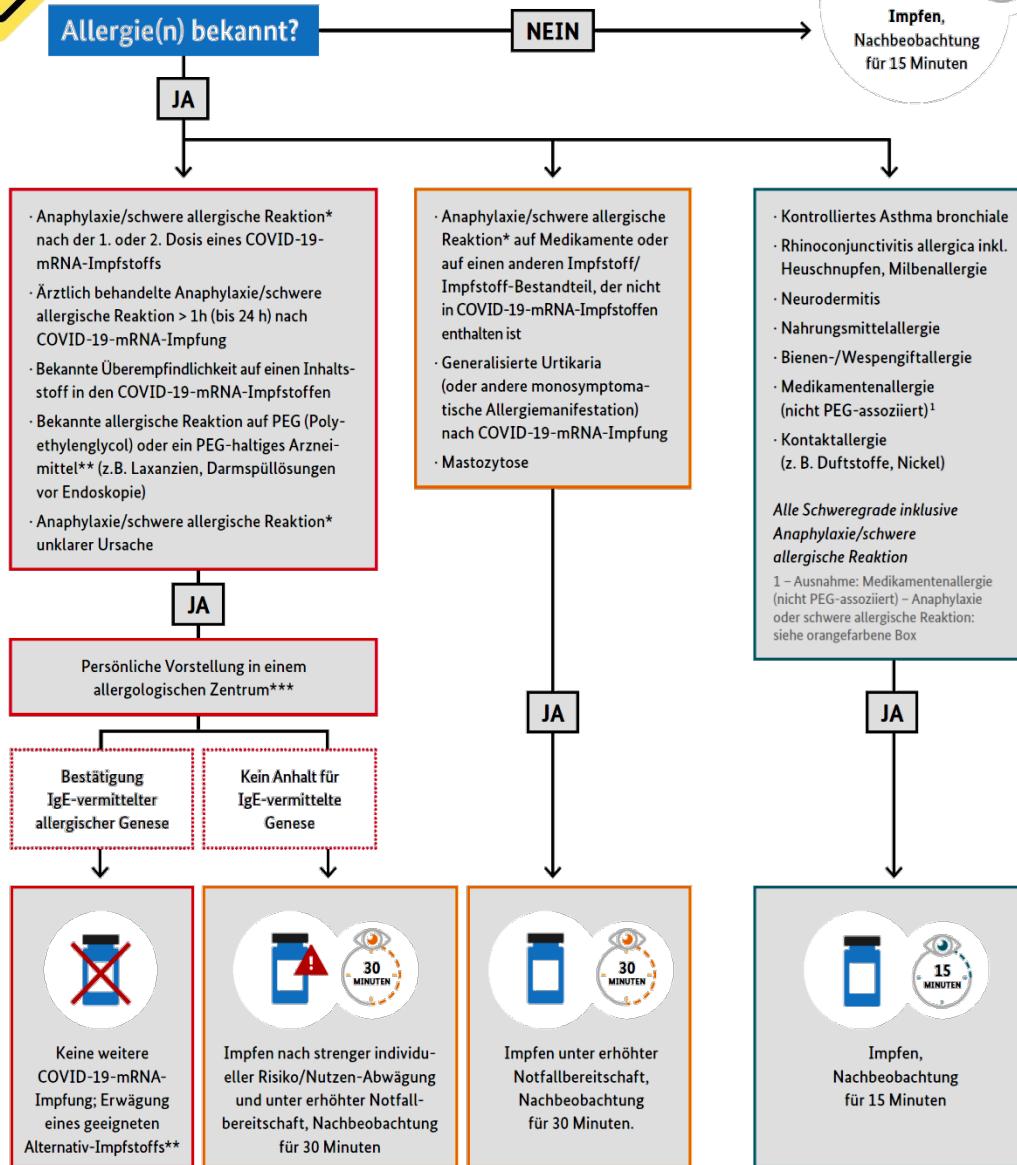
Die vier erstgenannten Lipide bilden die Lipidnanopartikel (LNP) im Impfstoff BNT162b2, die die mRNA einschließen. Es handelt sich um zwei strukturelle Lipide (2-Distearoyl-sn-glycero-3 phosphocholin, Cholesterol) und zwei funktionelle Lipide (ALC-0315, ALC-0159). Eines davon (ALC-0159) ist PEGyliert, d.h., es enthält ein Polyethylenglykol(PEG)-Polymer mit einem Molgewicht von etwa 2000g/mol (PEG 2000). Das entspricht einer mittleren Größe im Vergleich zu den PEG-Längen, die in einer Vielzahl von Kosmetika und Medikamenten als Zusatzstoff oder zur PEGylierung von Arzneistoffen eingesetzt werden (von 300 bis etwa 40.000 g/mol).

Die Lipidnanopartikel ähneln den bereits seit vielen Jahren pharmazeutisch eingesetzten Liposomen, die als Träger für Arzneistoffe dienen.

- **pseudoallergische (nicht-IgE-vermittelte) Reaktionen (CARPA, complement activation-related pseudoallergy) mit Liposomen bekannt**
- **Symptome: Dyspnoe, Tachypnoe, Hypo- und Hypertension kurz nach intravenöser Verabreichung anderer Liposomen-haltiger Medikamente beschrieben**
- **Potenzial unspezifisch Komplement zu aktivieren**
- **Sensibilisierung auf PEG durch vorige Anwendung von Kosmetika oder Medikamenten denkbar**

# CORONAVIRUS SARS-CoV-2

## Allergiealgorithmus



- Anaphylaxie/schwere allergische Reaktion\* nach der 1. oder 2. Dosis eines COVID-19-mRNA-Impfstoffs
- Ärztlich behandelte Anaphylaxie/schwere allergische Reaktion > 1h (bis 24 h) nach COVID-19-mRNA-Impfung
- Bekannte Überempfindlichkeit auf einen Inhaltsstoff in den COVID-19-mRNA-Impfstoffen
- Bekannte allergische Reaktion auf PEG (Polyethylenglycol) oder ein PEG-haltiges Arzneimittel\*\* (z.B. Laxanzien, Darmspülösungen vor Endoskopie)
- Anaphylaxie/schwere allergische Reaktion\* unklarer Ursache



# CORONAVIRUS SARS-CoV-2 Moderna & allergische Reaktion

## **Administration of a Second Dose of the Moderna COVID-19 Vaccine After an Immediate Hypersensitivity Reaction With the First Dose**

### **Protocol for Graded Administration of Second Dose of Moderna COVID-19 Vaccine\***

<b>Sequence</b>	<b>Dose and Concentration</b>
1	0.05 mL of 1:10 vaccine dilution†
2	0.05 mL of full-strength vaccine
3	0.1 mL of full-strength vaccine
4	0.15 mL of full-strength vaccine
5	0.2 mL of full-strength vaccine

\* Given intramuscularly every 15 min.

† Diluted with sterile water.



# CORONAVIRUS SARS-CoV-2

## VITT

Characteristic	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
Age — yr	37	42	32	39	54
Sex	Female	Female	Male	Female	Female
Preeexisting conditions	Pollen allergy	Pollen allergy	Asthma	None	Hypertension
Medication on admission	Contraceptive pill	Contraceptive vaginal ring	None	None	Hormone-replacement therapy, antihypertensive agents
Time from vaccination to admission — days	8	10	7	10	7
Symptoms	Fever, headaches, visual disturbances	Headaches, drowsiness	Back pain	Headaches, abdominal pain	Headaches, hemiparesis
Location of thrombosis	Cortical veins, left transverse sinus, and sigmoid left sinus	Cortical veins, left transverse sinus, and left sigmoid sinus	Portal vein, left hepatic vein, splenic vein, azygos vein, hemiazygos vein, and several basivertebral veins	Inferior sagittal sinus, vein of Galen, straight sinus, right transverse sinus, and right sigmoid sinus	Cortical veins, superior sagittal sinus, both transverse sinuses, and left sigmoid sinus
Platelet count nadir — per mm <sup>3</sup>	22,000	14,000	10,000	70,000	19,000
D-dimer peak — mg/liter	>35	>35	>35	13	>35
INR peak	1.2	1.0	1.1	1.3	1.1
aPTT peak — sec	25	31	25	25	29
Fibrinogen nadir — g/liter†	2.1	0.8	2.3	1.2	1.2
SARS-CoV-2 antibody test results					
Nucleocapsid protein	Negative	Negative	Negative	Negative	Negative
Spike protein	Positive	Positive	Positive	Positive	Positive
Anticoagulation treatment	Initial low dose of LMWH	Reduced dose of LMWH	Reduced dose of LMWH	Reduced dose of LMWH	Heparin (5000 IU)
No. of platelet units transfused	7	19	2	0	2
Other treatment	None	Methylprednisolone (1 mg/kg), IVIG (1 g/kg)	Prednisolone (1 mg/kg), IVIG (1 g/kg)	Prednisolone (1 mg/kg), IVIG (1 g/kg)	Methylprednisolone (1 mg/kg), IVIG (1 g/kg)
Outcome	Fatal	Fatal	Full recovery	Full recovery	Fatal



# CORONAVIRUS SARS-CoV-2

## Risikoabschätzung

Covid-19-Todesfälle in Österreich  
nach Altersgruppe, Letalitätsrate in Prozent

GESAMT 9369 1,8 %

85+ 4249 21,6

75-84 3196 10,8

65-74 1275 3,7

55-64 479 0,67

45-54 130 0,14

35-44 25 0,03

25-34 10 0,01

15-24 4 0,005

6-14 1 0,003

0-5 0 0

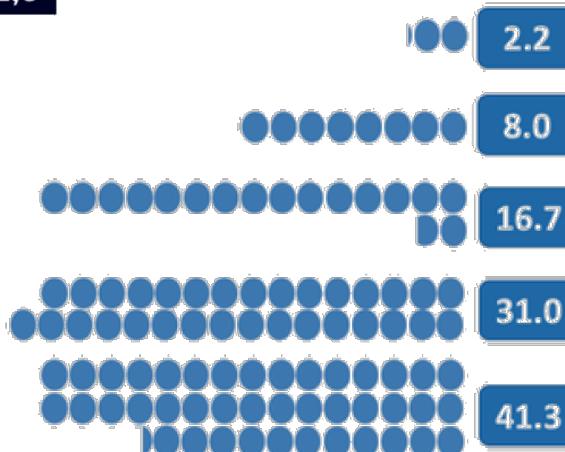
*Weighing up the potential benefits and harms of the Astra-Zeneca COVID-19 vaccine*

For 100,000 people  
with medium exposure risk\*

Potential harms

Potential benefits

ICU admissions due to COVID-19 prevented  
every 16 weeks:



Specific blood clots due to the vaccine:



\* Based on coronavirus incidence of 6 per 10,000 per day: roughly UK in February

Stand: 25. 3. 2021

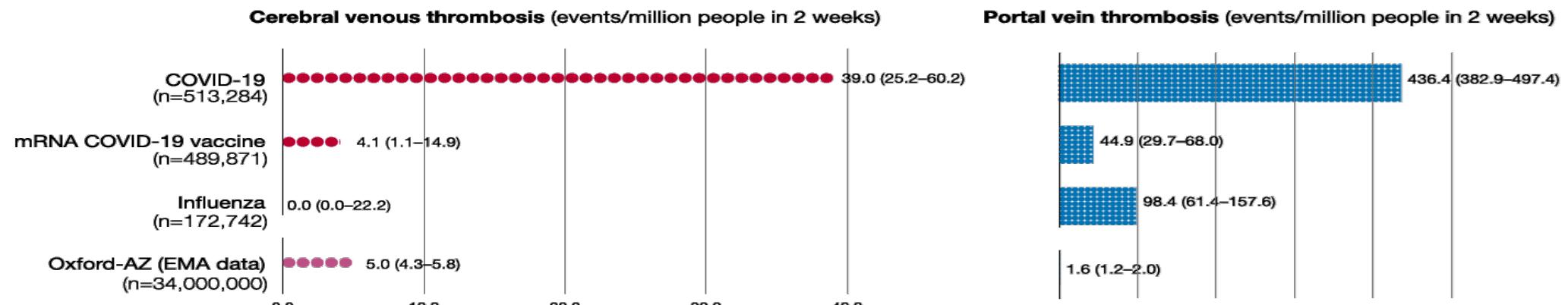
Quelle: Ages  
Grafik: „Die Presse“ - GK



# CORONAVIRUS SARS-CoV-2

## COVID-19, Impfung & Thromboserisiko

Incidence of CVT (A) and PVT (B) per million people in the two weeks after different health events. The numbers in parentheses on the right of each bar represent the 95% confidence intervals. Data for the ChAdOx1 nCoV-19 vaccine are presented for reference and inferred from the European Medicines Agency data (posted 7 April 2021).

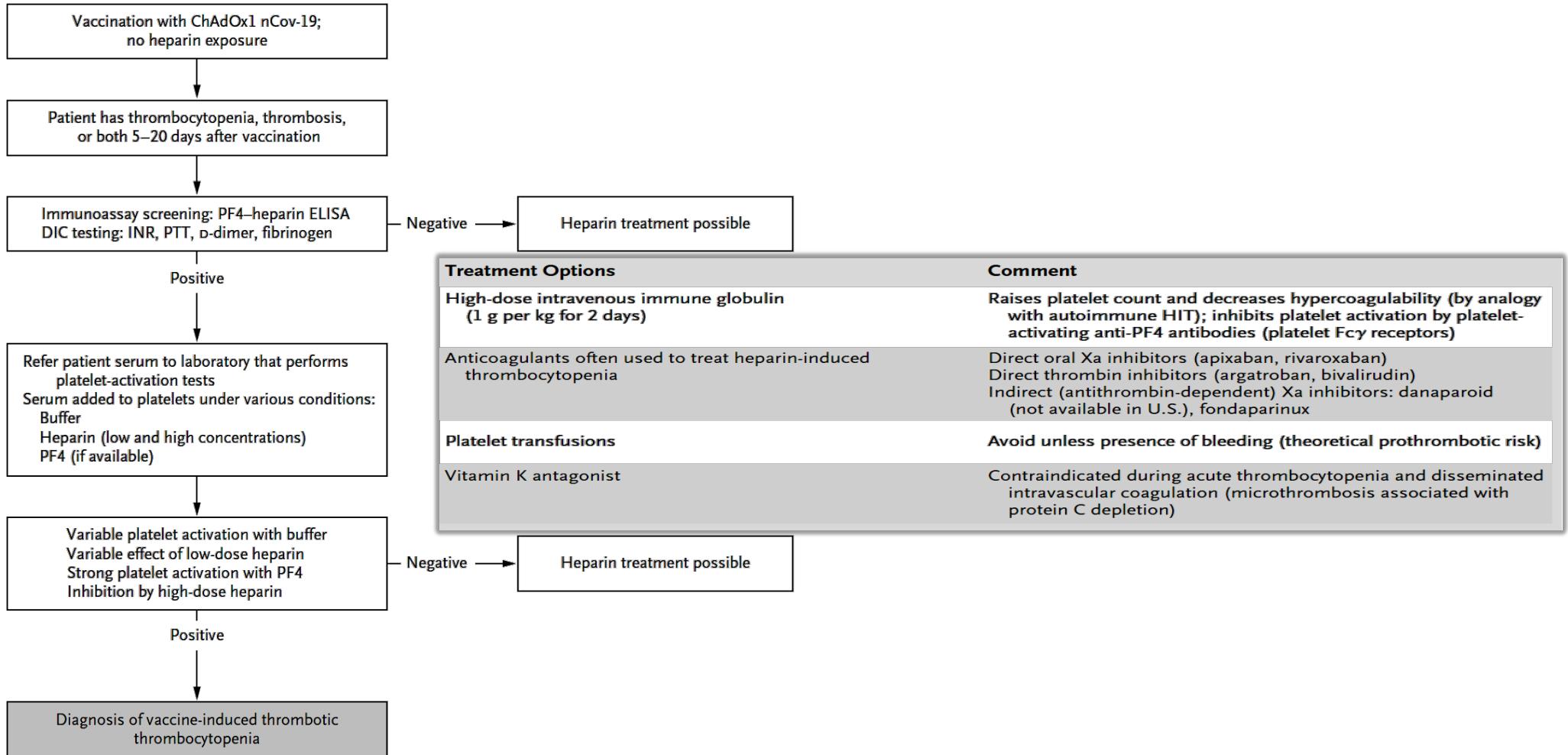


	All patients with COVID-19		Patients with COVID-19 and CVT		Patients with COVID-19 and PVT	
	n (%)	n (%)	n (%)	P	n (%)	P
<b>D-dimer &gt; 5 mg/L n/n with measurement (%)</b>	2035/67212 (3.0)	2/6 (33.3)	0.013		5/74 (6.8)	0.074
<b>Fibrinogen &lt; 200 mg/dL n/n with measurement (%)</b>	1138/19414 (5.9)	1/6 (16.7)	0.3		23/51 (45.1)	<.001
<b>Thrombocytopenia (ICD-10 codes D69.49, D69.59, D69.6)</b>	9323 (1.8)	1 (5.0)	0.31		69 (30.8)	<.001
<b>Death</b>	16091 (3.1)	4 (20.0)	0.0031		41 (18.3)	<.001



# CORONAVIRUS SARS-CoV-2

## VITT





# CORONAVIRUS SARS-CoV-2

## AstraZeneca

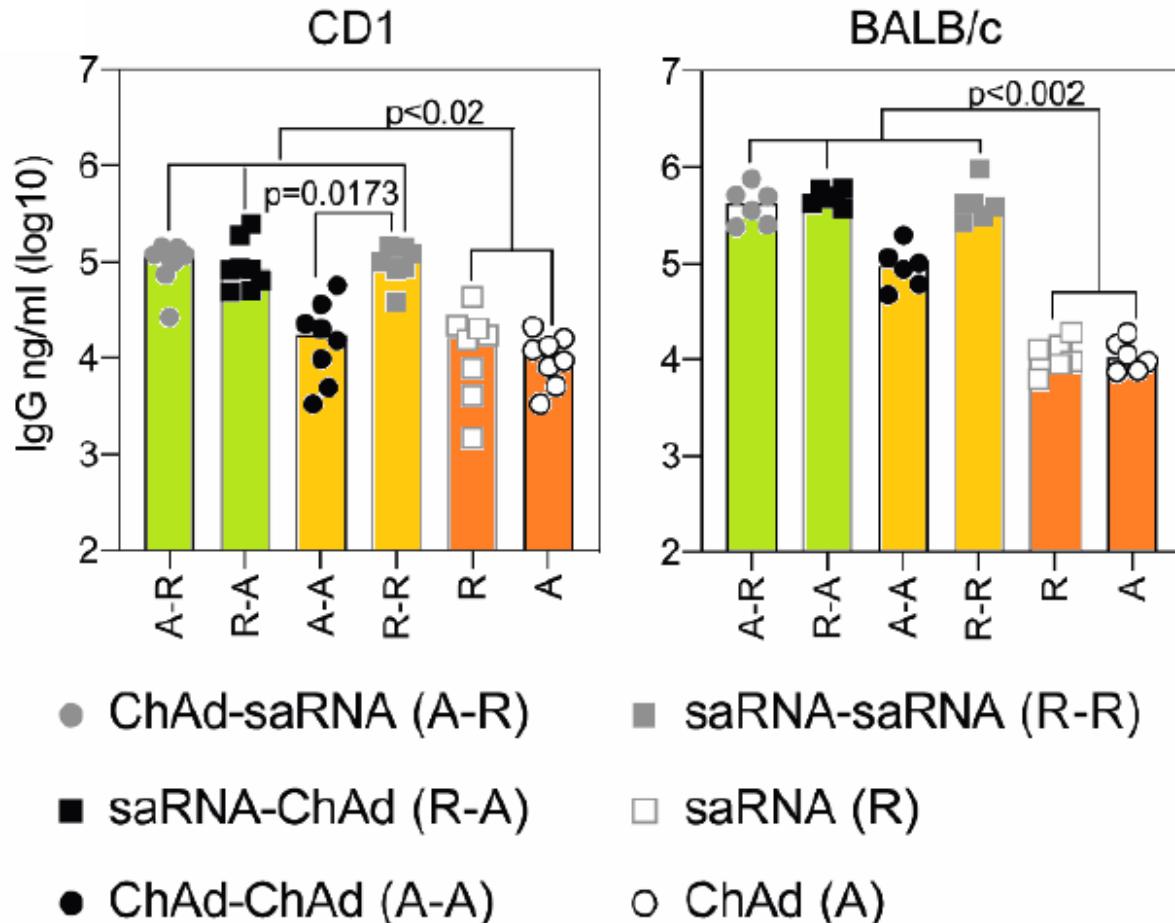
Auf Basis der derzeit verfügbaren, allerdings noch begrenzten Evidenz und unter Berücksichtigung der gegenwärtigen pandemischen Lage empfiehlt die STIKO, die COVID-19 Vaccine AstraZeneca für Personen im Alter  $\geq 60$  Jahren zu verwenden. Der Einsatz der COVID-19 Vaccine AstraZeneca für eine erste oder 2. Impfstoffdosis unterhalb dieser Altersgrenze bleibt indes nach ärztlichem Ermessen und bei individueller Risikoakzeptanz nach sorgfältiger Aufklärung möglich. Bislang liegen keine Daten zum Risiko bei der Zweitimpfung vor. Hinsichtlich der 2. Impfstoffdosis für jüngere Personen, die reits eine 1. Dosis der COVID-19 Vaccine AstraZeneca erhalten haben, gibt es noch keine wissenschaftliche Evidenz zur Sicherheit und Wirksamkeit einer heterologen Impfserie. Bis entsprechende Daten vorliegen, empfiehlt die STIKO, bei Personen im Alter  $< 60$  Jahren anstelle der 2. AstraZeneca-Impfstoffdosis eine Dosis eines mRNA-Impfstoffs 12 Wochen nach der Erstimpfung zu verabreichen.

Vacc II  
mRNA 12 Wo n Vacc I  
Personen  $< 60$  Jahren



# CORONAVIRUS SARS-CoV-2

## Heterologe Impfkombinationen



- **Mäusetierversuch**
- **SARS CoV-2 Spike-spez IgG**
- **höhere Ak-Antwort**



# CORONAVIRUS SARS-CoV-2

## Schwangerschaft & mRNA-Impfung

### Vaccination of pregnant or lactating people

There are currently few data on the safety of COVID-19 vaccines, including mRNA vaccines, in pregnant people. Limited data are currently available from animal developmental and reproductive toxicity studies. No safety concerns were demonstrated in rats that received Moderna COVID-19 vaccine prior to or during gestation in terms of female reproduction, fetal/embryonal development, or postnatal development. Studies in pregnant people are planned and the vaccine manufacturers are following outcomes in people in the clinical trials who became pregnant. Based on current knowledge, experts believe that mRNA vaccines are unlikely to pose a risk to the pregnant person or the fetus because mRNA vaccines are not live vaccines. The mRNA in the vaccine is degraded quickly by normal cellular processes and does not enter the nucleus of the cell. However, the potential risks of mRNA vaccines to the pregnant person and the fetus are unknown because these vaccines have not been studied in pregnant people.

If pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated. A conversation between the patient and their clinical team may assist with decisions regarding the use of a mRNA COVID-19 vaccine, though a conversation with a healthcare provider is not required prior to vaccination. When making a decision, pregnant people and their healthcare providers should consider the level of COVID-19 community transmission, the patient's personal risk of contracting COVID-19, the risks of COVID-19 to the patient and potential risks to the fetus, the efficacy of the vaccine, the side effects of the vaccine, and the lack of data about the vaccine during pregnancy.

Side effects can occur with COVID-19 vaccine use in pregnant people, similar to those expected among non-pregnant people. Pregnant people who experience fever following vaccination may be counseled to take acetaminophen as fever has been associated with adverse pregnancy outcomes. Acetaminophen may be offered as an option for pregnant people experiencing other post-vaccination symptoms as well.

There is no recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after mRNA COVID-19 vaccination.

- **keine Daten**
- **kein Hinweise im Tierversuch**
- **kein Risiko durch mRNA Vacc**
- **keine Erfordernis Schwangerschaft St p Vacc zu vermeiden**
- **keine medizinische Notwendigkeit mRNA Vacc in Schwangerschaft nicht zu geben**



# CORONAVIRUS SARS-CoV-2 Impfung & Schwangerschaft

## C19-Risiko in Schwangerschaft erhöht

Accidental pregnancies in trials for the COVID-19 vaccines approved in the United Kingdom

Vaccine type	Control group			Vaccinated group		
	Participants	Pregnancies	Miscarriages (rate)	Participants	Pregnancies	Miscarriages (rate)
Pfizer/BioNTech	18,846	12	1 (8%)	18,860	11	0 (0%)
Moderna	15,170	7	1 (14%)	15,181	6	0 (0%)
AstraZeneca	5,829	9	3 (33%)	5,807	12	2 (17%)

## niedriges Vacc-Risiko in Schwangerschaft



# CORONAVIRUS SARS-CoV-2

## Stillperiode & mRNA-Impfung

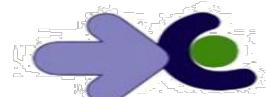
### *Lactating people*

There are no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA COVID-19 vaccines on the breastfed infant or milk production/excretion. mRNA vaccines are not thought to be a risk to the breastfeeding infant. A lactating person who is part of a group recommended to receive a COVID-19 vaccine (e.g., healthcare personnel) may choose to be vaccinated.

- **keine Daten**
- **kein Risiko durch mRNA Vacc für Säugling**
- **keine Erfordernis Stillperiode St p Vacc zu vermeiden**
- **keine medizinische Notwendigkeit mRNA Vacc in Stillperiode nicht zu geben**



# CORONAVIRUS SARS-CoV-2 mRNA-Vakzine & Stillende



DEUTSCHE GESELLSCHAFT  
FÜR PERINATALE MEDIZIN



Deutsche Gesellschaft für  
Gynäkologie und Geburtshilfe e.V.

## Potenzieller Nutzen überwiegt bei Stillenden mit erhöhtem COVID-19-Risiko Bedenken hinsichtlich der Sicherheit der Impfung deutlich

Eine gemeinsame Empfehlung  
der Deutschen Gesellschaft für Perinatale Medizin e. V. (DGPM),  
der Deutschen Gesellschaft für Gynäkologie und Geburtshilfe e. V. (DGGG)  
in Zusammenarbeit mit der Nationalen Stillkommission (NSK)

**Berlin, im Januar 2021** – Nach bisherigem Kenntnisstand ist mit der Verabreichung von Nicht-Lebendimpfstoffen während der Stillzeit kein erhöhtes Risiko für die Stillende oder den Säugling verbunden. Zur Anwendung von mRNA-Impfstoffen in der Stillzeit, wie z. B. den Einfluss auf den gestillten Säugling oder die Muttermilchproduktion/-sekretion, liegen jedoch derzeit keine Daten vor.

Eine grundsätzliche Routineimpfung aller Stillenden wird derzeit auch auf Basis der aktuell limitierten Impfstoffressourcen mehrheitlich von den Fachgesellschaften nicht empfohlen. Die Ständige Impfkommission (STIKO) hält es jedoch für **unwahrscheinlich, dass eine Impfung der Mutter während der Stillzeit ein Risiko für den Säugling darstellt**. Auch die Society for Maternal Fetal Medicine (SMFM) sieht **keinen Grund zu der Annahme, dass der Impfstoff ein Sicherheitsrisiko in der Stillperiode für Mutter und/oder Säugling darstellt**. Ein **biologisch nachvollziehbarer Mechanismus, der Schaden verursachen könnte, ist derzeit nicht bekannt**. Zum jetzigen Zeitpunkt liegen jedoch keine aussagekräftigen Studien zum Übertritt von Impf-Bestandteilen in die Muttermilch vor.



# CORONAVIRUS SARS-CoV-2

## Impfung & Schwangerschaft

Study suggests COVID-19 vaccination in pregnancy leads to effective transplacental antibody transfer

For the study, 20 women with a mean age of 32 years and with a median gestational term of 39 weeks agreed to participation in the study. The median time lapse between the first and second vaccination doses until delivery was 33 and 11 days, respectively. All of the mothers and infants were positive for both anti S and anti-RBD antibodies. The median level of anti S antibodies in maternal sera was 319 AU/ml vs 193 in the newborns and 11,150 vs 3494 (maternal vs newborn) for the anti-RBD antibodies. The authors calculated the median placental transfer ratios as 0.44 (anti S) and 0.34 (anti RBD). In addition, there was a statistically significant and positive correlation between the anti S and anti-RBD antibody levels detected in the mothers and infants. While these results are promising and although based on a small number of women, the data suggest an effective maternal to foetal transfer of antibodies. Nevertheless, the authors also note that the timing of vaccination for optimal antibody transfer remains to be determined.



# CORONAVIRUS SARS-CoV-2

## Blutverdünnung

### Use in patients being treated with warfarin

According to the [Public Health England's Immunisation Against Infectious Disease \(The Green book\)](#), the vaccine can be given intramuscularly to individuals on warfarin who are up-to-date with their scheduled INR testing and whose latest INR is below the upper level of the therapeutic range.

A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the injection site without rubbing for at least two minutes. The patient should be informed of the risk of haematoma from the injection.

If there is any doubt about the level of anticoagulation control, the clinician responsible for prescribing and monitoring the patient's anticoagulant treatment should be consulted.

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### Use in patients being treated with a Direct Oral Anticoagulant or DOAC (i.e. apixaban, dabigatran, edoxaban or rivaroxaban)

According to the [Green Book](#) the vaccine can be given intramuscularly to individuals who are stabilised on a DOAC.

Advice on reducing the risks of vaccination leading to a haematoma are as described for warfarin above.

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### Use in patients with bleeding disorders

According to the [Green Book](#) the vaccine can be given intramuscularly to individuals with a bleeding disorder. If the patient is receiving regular treatment to reduce bleeding (e.g. patients with haemophilia) vaccine administration can be scheduled to occur shortly after this treatment is given.

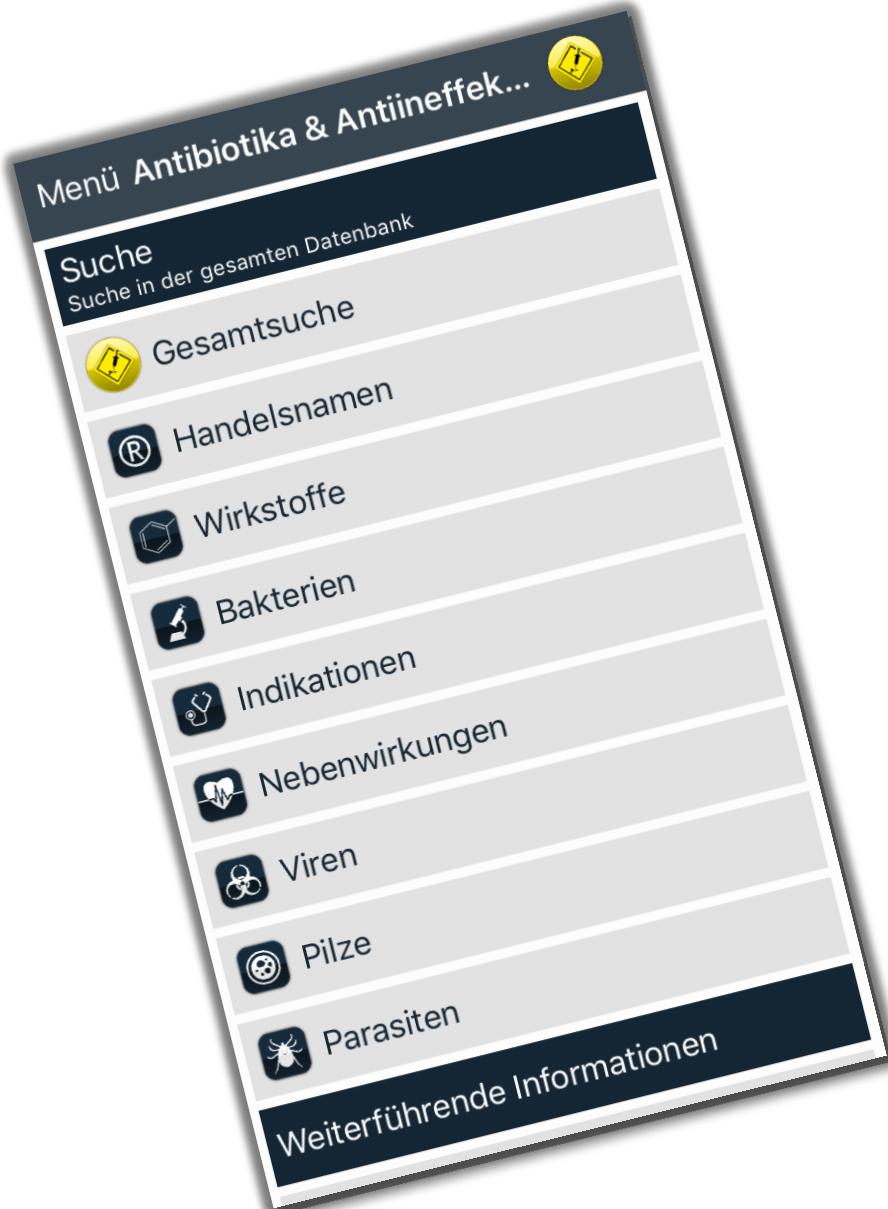
JA  
IMPFUNG  
MÖGLICH



# CORONAVIRUS SARS-CoV-2 geimpft – alles paletti?

Vaccines are not yet a silver bullet: The imperative of continued communication about the importance of COVID-19 safety measures

COVID-19 vaccines are by no means a silver bullet. With more COVID-19 vaccines expecting approval in the coming months, it is necessary to note that vaccine availability does not equate to vaccine accessibility, nor vaccine efficacy. Some research suggests that approximately 9 out of 10 individuals living in lower-income countries will not have access to COVID-19 vaccines until 2023 or later. For higher-income countries, such as the United States, the prevalence of vaccine hesitancy may further compound the situation. These insights combined, in turn, emphasize the fact that even though COVID-19 vaccines are becoming more available, safety measures (e.g., face masks, personal hygiene, and social distancing) are still of pivotal importance in protecting personal and public health against COVID-19. Furthermore, this paper argues for the continued imperative for health experts and government officials to communicate and emphasize the importance of COVID-19 safety measures with the public, to make sure people are protected against COVID-19 till the pandemic ceases to pose a threat to personal or public health.



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