GIFTIGER LIVE-STREAM

24. Juni 2021
COVID-19-Impfung von Kindern – dürfen, sollen oder müssen?

Endlich – Impfungen für Kinder. Status quo

Karl Zwiauer

KARL LANDSTEINER PRIVATUNIVERSITÄT FÜR GESUNDHEITSWISSENSCHAFTEN

LANDES GESUNDHEITS AGENTUR NIEDERÖSTERREICH

Endlich? - Impfungen für Kinder. Status quo

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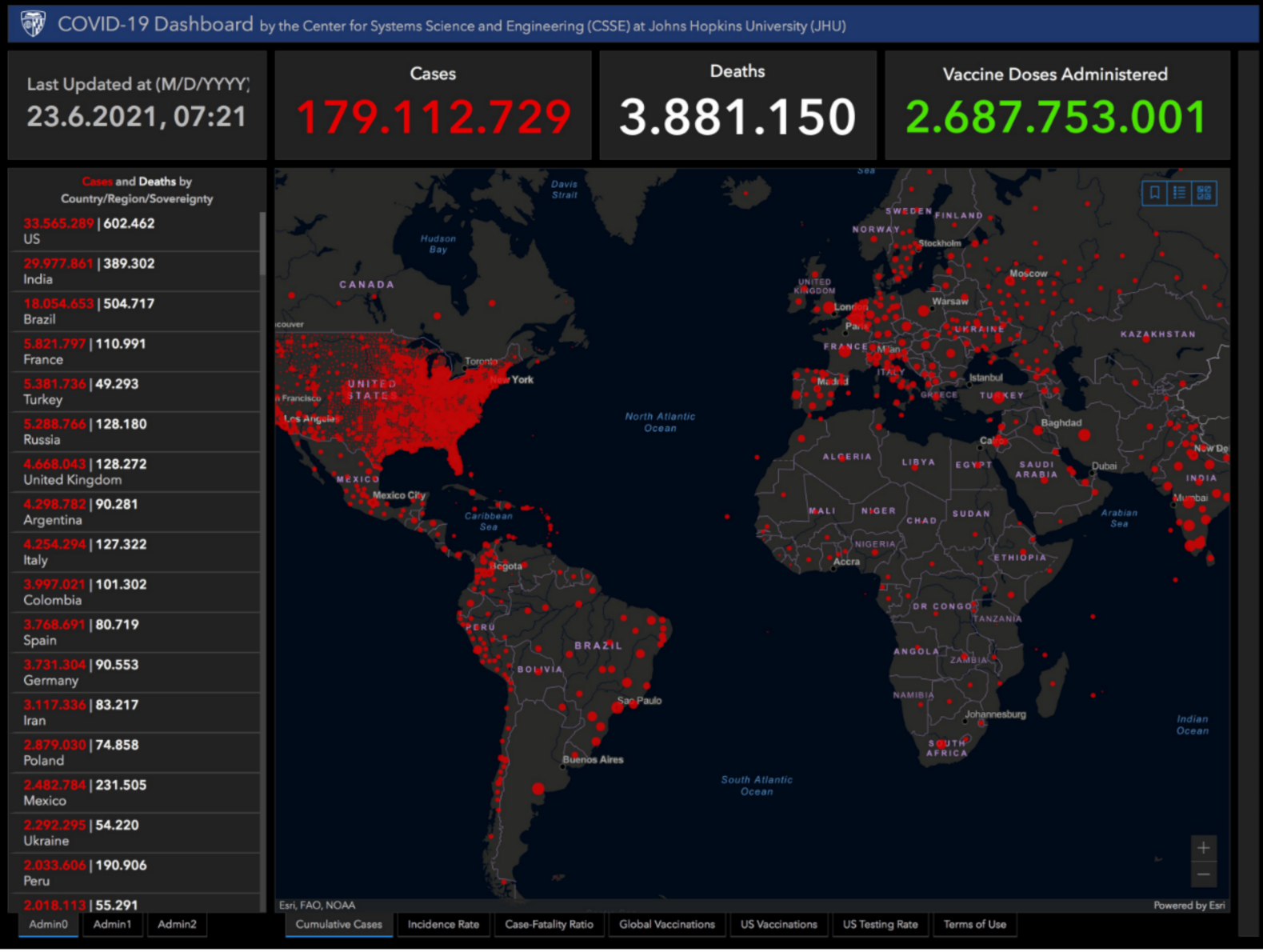
COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)
Last Updated at (M/D/YYYY)
23.6.2021, 07:21
Cases
179.112.729
Deaths
3.881.150
Vaccine Doses Administered
2.687.753.001
Cases and Deaths by Country/Region/Sovereignty
33.565.289 | 602.462 US
29.977.861 | 389.302 India
18.054.653 | 504.717 Brazil
5.821.797 | 110.991 France
5.381.736 | 49.293 Turkey
5.288.766 | 128.180 Russia
4.668.043 | 128.272 United Kingdom
4.298.782 | 90.281 Argentina
4.254.294 | 127.322 Italy
3.997.021 | 101.302 Colombia
3.768.691 | 80.719 Spain
3.731.304 | 90.553 Germany
3.117.336 | 83.217 Iran
2.879.030 | 74.858 Poland
2.482.784 | 231.505 Mexico
2.292.295 | 54.220 Ukraine
2.033.606 | 190.906 Peru
2.018.113 | 55.291
Admin0
Admin1
Admin2
Cumulative Cases
Incidence Rate
Case-Fatality Ratio
Global Vaccinations
US Vaccinations
US Testing Rate
Terms of Use
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COVID-19 Impfung

- Kinder und Jugendliche zeigen meist mildere Verlaufe von COVID-19 als Erwachsene
- Schwere Verläufe sind selten, aber kommen vor
- Jugendliche spielen möglicherweise wichtige Rolle in der SARS-CoV-2 Transmission
- Zunehmende Durchimpfung Erwachsener ⇢ Kinder/Jugendliche gewinnen an Bedeutung für Transmission
- Pandemiemaßnahmen haben Kinder/Jugendliche schwer gestört (Aus)Bildung, geistiges, emotionales, soziales Leben

- **Impfung von Kindern/Jugendlichen könnte vor Krankheit und Infektionsausbreitung schützen**

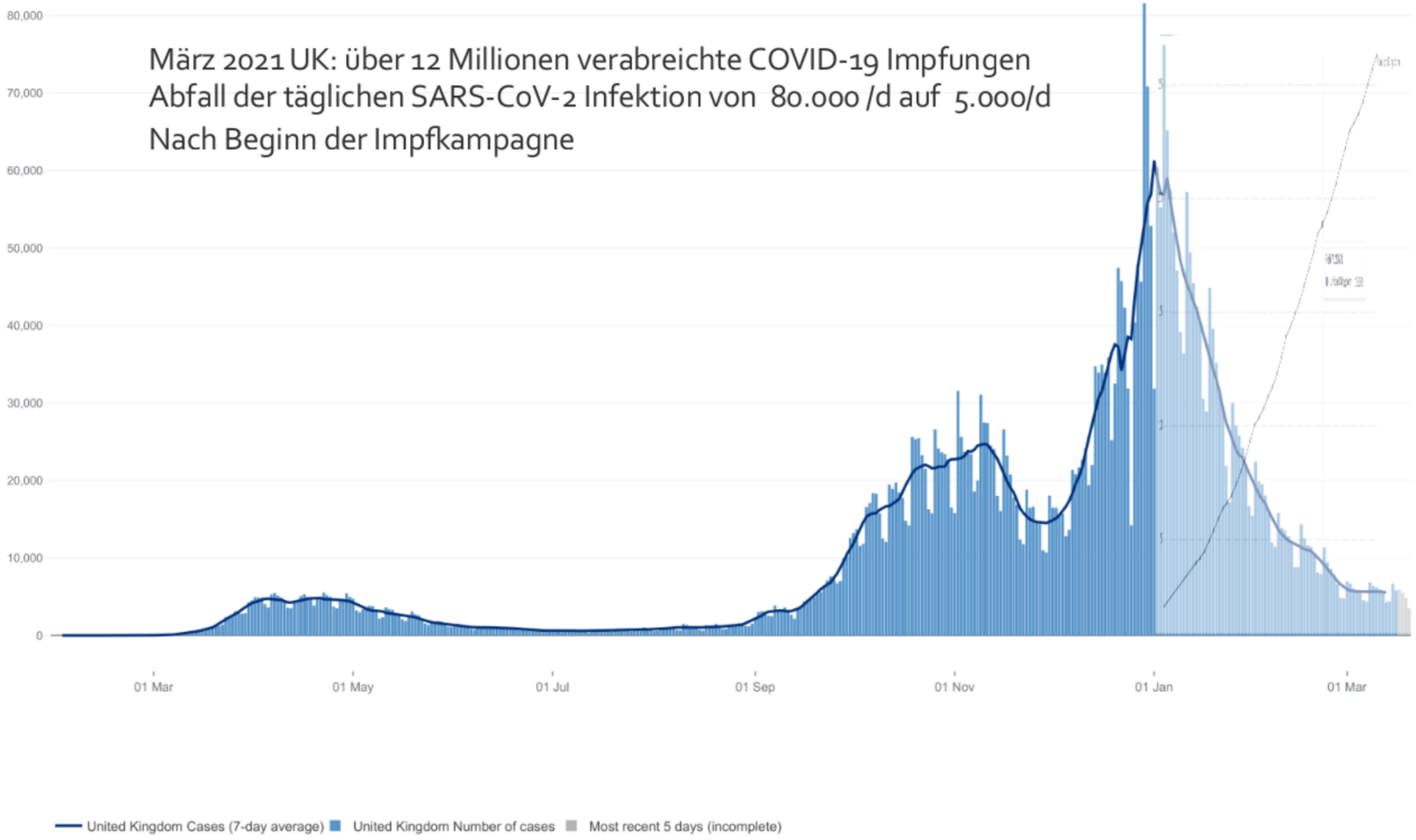

GAME
CHANGER

COVID-19 Impfungen in Israel

Bestätigte COVID-19 Fälle

COVID-19 Impfungen in UK

März 2021 UK: über 12 Millionen verabreichte COVID-19 Impfungen
Abfall der täglichen SARS-CoV-2 Infektion von 80.000 /d auf 5.000/d
Nach Beginn der Impfkampagne



EU Zulassungen

Comirnaty®

21.12.2021
ab 16 Jahre

31.5.2021
12 bis 15 Jahre

Moderna

6.1.2021
ab 18 Jahre

Vaxzevria ®

29.1.2021
ab 18 Jahre

Janssen

11.3.2021
ab 18 Jahre

5

- Zulassung einer COVID-19 Impfung für Kinder ab 12 Jahre
- COVID-19 Impfungen für Kinder in der Pipeline
- (Ir)Rationale für Impfung von Kindern & Jugendlichen
- Risiko/Nutzen Diskussion
- Derzeitige Empfehlungen zur Impfung von Kindern & Jugendlichen

1

COVID-19 Impfung für Kinder & Jugendliche zugelassen

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents

Robert W. Frenck, Jr., M.D., Nicola P. Klein, M.D., Ph.D., Nicholas Kitchin, M.D., Alejandra Gurtman, M.D., Judith Absalon, M.D., Stephen Lockhart, D.M., John L. Perez, M.D., Emmanuel B. Walter, M.D., Shelly Senders, M.D., Ruth Bailey, B.Sc., Kena A. Swanson, Ph.D., Hua Ma, Ph.D., Xia Xu, Ph.D., Kenneth Koury, Ph.D., Warren V. Kalina, Ph.D., David Cooper, Ph.D., Timothy Jennings, D.O., Donald M. Brandon, M.D., Stephen J. Thomas, M.D., Özlem Türeci, M.D., Dina B. Tresnan, D.V.M., Ph.D., Susan Mather, M.D., Philip R. Dormitzer, M.D., Ph.D., Uğur Şahin, M.D., Kathrin U. Jansen, Ph.D., and William C. Gruber, M.D., for the C4591001 Clinical Trial Group*

Multinationale, placebokontrollierte, geblindete, 1:1 randomisierte Noninferiority Studie – Immunantwort, Reaktogenität und Impfreaktionen/Nebenwirkungen Wirksamkeit (7 Tage nach 2. Impfung mit Comirnaty®)

Frenck RW et al. Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents. May 27, 2021, at NEJM.org. DOI: 10.1056/NEJMoa2107456

Probanden

- 15. Oktober 2020 bis 12. Jänner 2021 Einschlusszeitraum – Ende Studie: 13.3.2021
- 2.260 Probenden im Alter 12-15 Jahre
  1.131 BNT162b2, 1.129 Placebo
- Reaktogenität - Vergleich mit Daten von 16 bis 25-jährigen Probanden
- Immunogenität - SARS-CoV-2 Serum Neutralisations Assay und Rezeptor-Bindungs Domäne oder S1-Bindungs-IgG

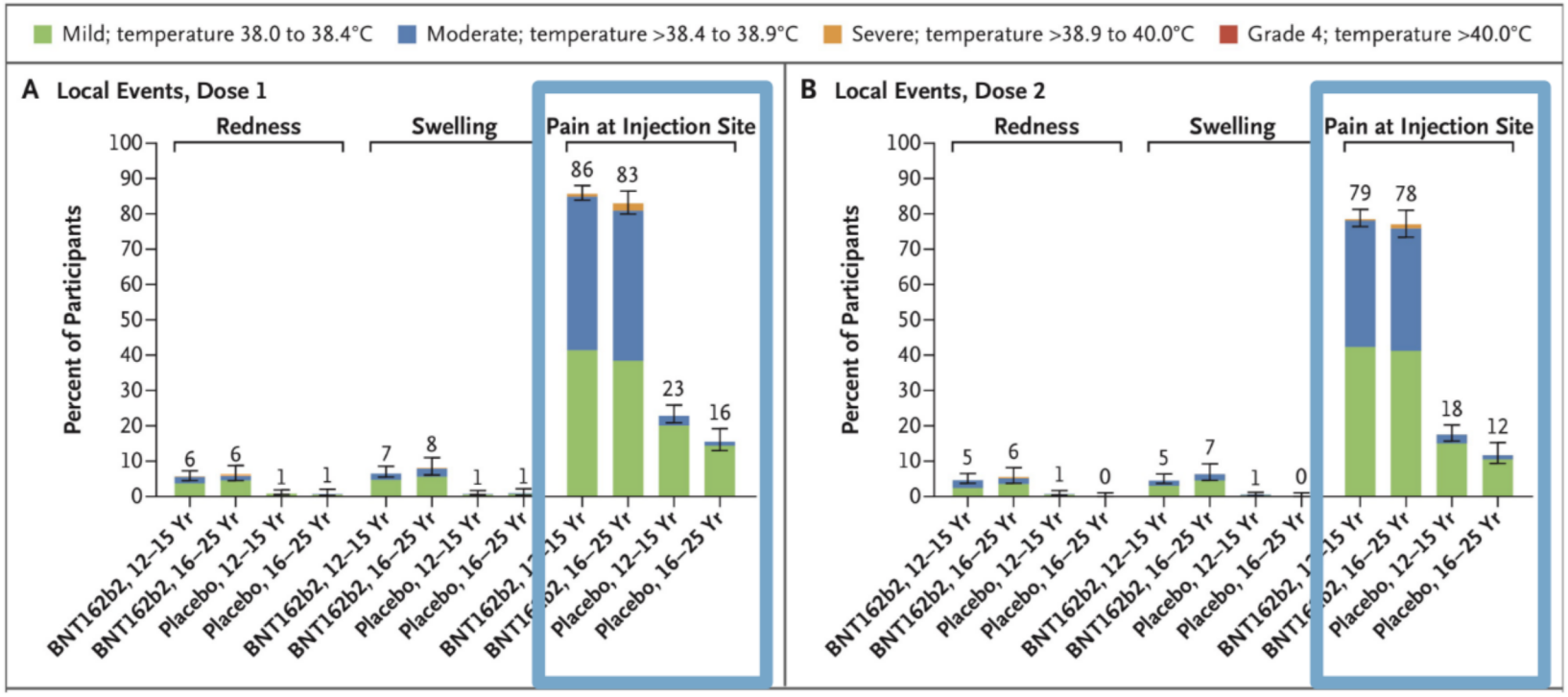
Teilnehmer

Demographic Characteristics of the Participants.*

Characteristic	BNT162b2		Placebo	
	12–15 Yr (N=1131)	16–25 Yr (N=537)	12–15 Yr (N=1129)	16–25 Yr (N=561)
Male sex — no. (%)	567 (50.1)	255 (47.5)	585 (51.8)	269 (48.0)
Race or ethnic group — no. (%)†				
White	971 (85.9)	445 (82.9)	962 (85.2)	466 (83.1)
Country — no. (%)				
United States	1131 (100)	436 (81.2)	1129 (100)	434 (77.4)
Age at vaccination — yr				
Mean	13.6±1.11	19.4±3.26	13.6±1.11	19.6±3.33
Median (range)	14.0 (12–15)	18.0 (16–25)	14.0 (12–15)	19.0 (16–25)
Baseline SARS-CoV-2 status — no. (%)‡				
Positive	46 (4.1)	30 (5.6)	47 (4.2)	34 (6.1)
Negative	1028 (90.9)	497 (92.6)	1023 (90.6)	522 (93.0)
Missing	57 (5.0)	10 (1.9)	59 (5.2)	5 (0.9)

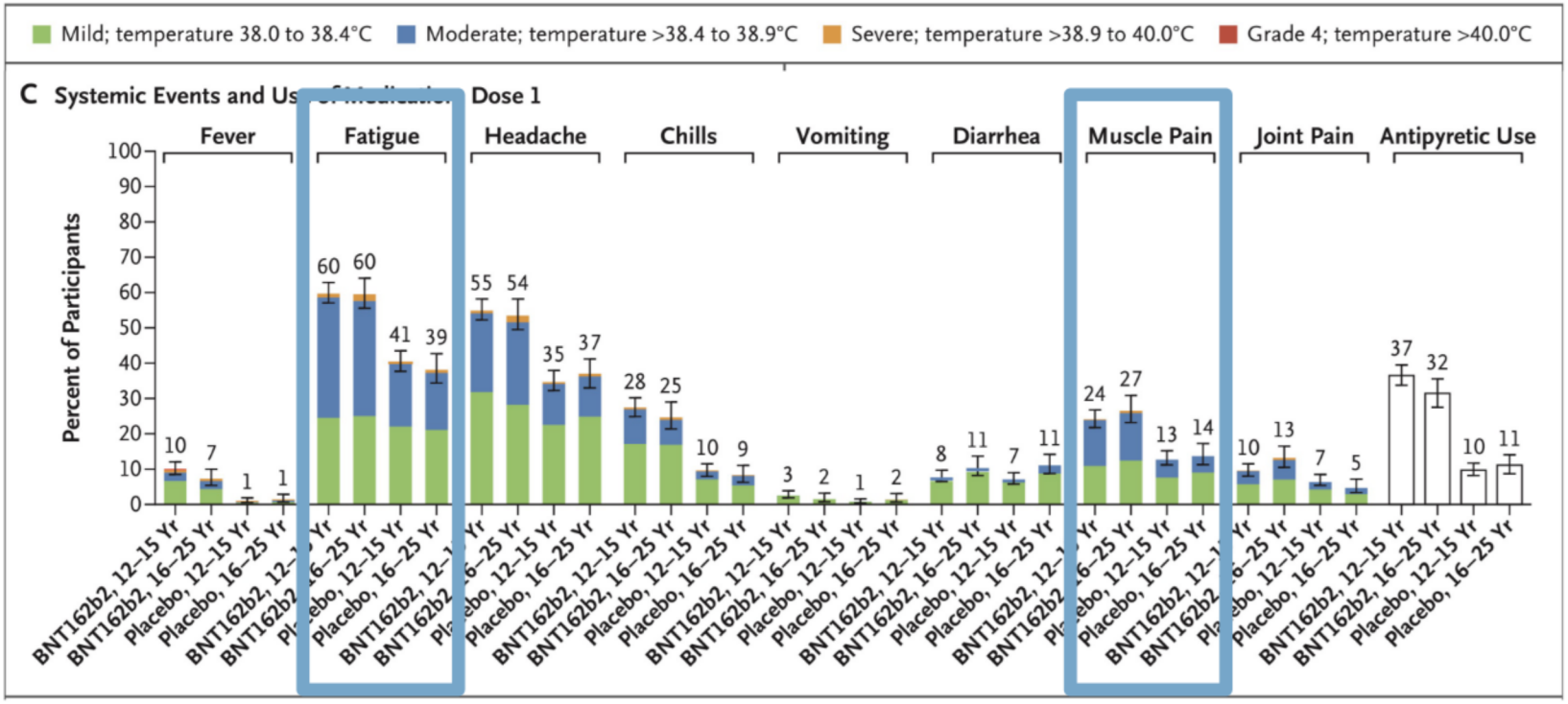
Frenck RW et al. Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents. May 27, 2021, at NEJM.org. DOI: 10.1056/NEJMoa2107456

Lokalreaktionen



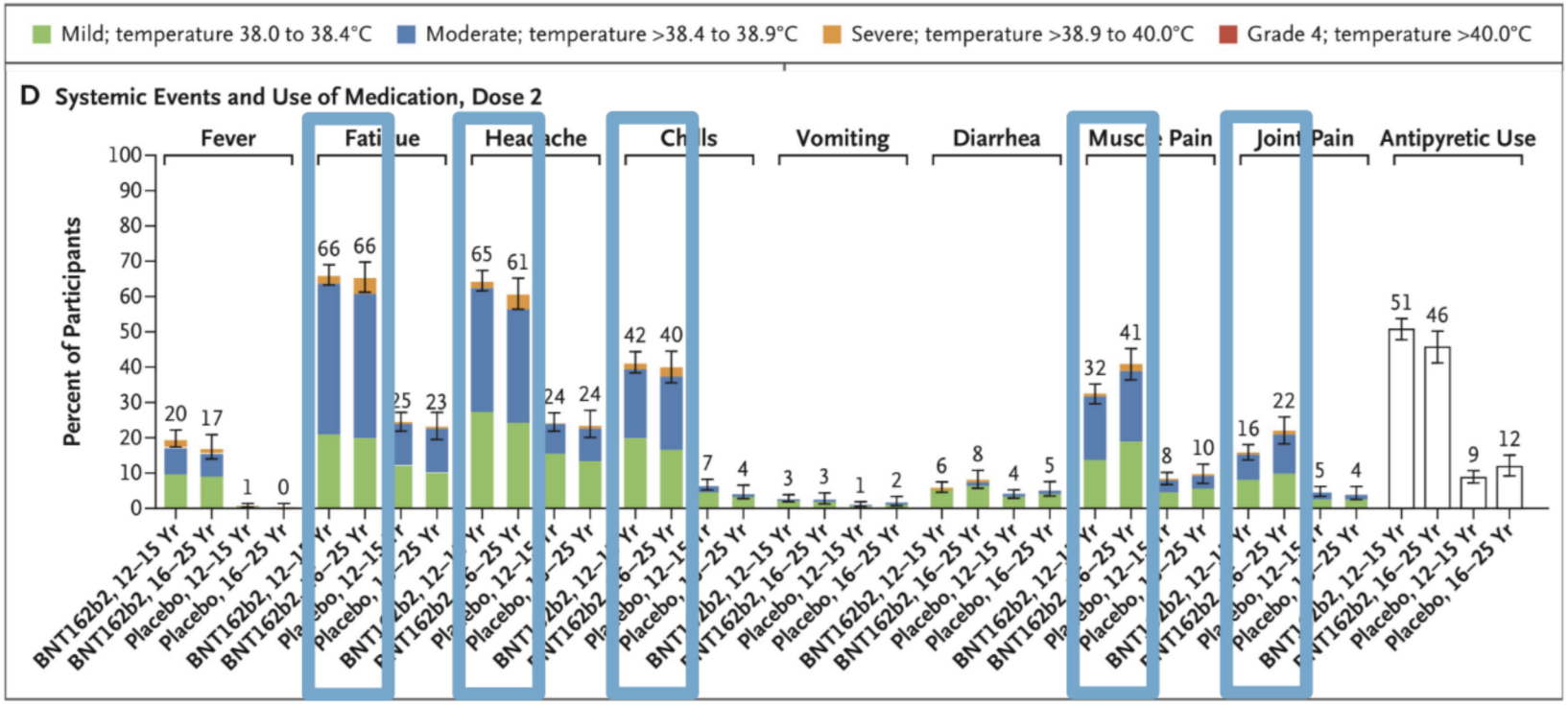
Frenck RW et al. Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents. May 27, 2021, at NEJM.org. DOI: 10.1056/NEJMoa2107456

Systemische Reaktionen – 1. Dosis



Frenck RW et al. Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents. May 27, 2021, at NEJM.org. DOI: 10.1056/NEJMoa2107456

Systemische Reaktionen – 2. Dosis



Frenck RW et al. Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents. May 27, 2021, at NEJM.org. DOI: 10.1056/NEJMoa2107456

Impfreaktionen

- Gleiche Frequenz an Impfreaktionen in beiden Altersgruppen (12-15 Jährige vs. 16-25 Jährige)

- Lokalreaktionen und systemische Reaktionen **mild bis moderat**
- Häufigste Lokalreaktion: Schmerzen an der Einstichstelle
  Starke Schmerzen bei 1,5% vs. 3,4%

- Systemische Reaktionen zumeist Kopfschmerzen und Müdigkeit
  Starke Kopfschmerzen und Müdigkeit seltener bei 12-15 Jährigen
- Fieber (≥38° C) nach der 2. Dosis bei **20%** vs. 17%
- Häufiger systemische Impfreaktionen nach der 2. Impfung
- Keine Unterschiede zwischen SARS-CoV-2 positiven / negativen

Frenck RW et al. Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents. May 27, 2021, at NEJM.org. DOI: 10.1056/NEJMoa2107456

Schwere Nebenwirkungen

- 1 Proband BNT162b2 – Fieber über 40° C 1 Tag nach 1. Impfung für 2 Tage – keine 2. Impfung
  14-jähriger Bub, SARS-CoV-2–negativ

- 9 Fälle von Lymphadenopathie bei 1.131 Comirnaty Probanden (0,8% vs. 0,2% Placebo)

Frenck RW et al. Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents. May 27, 2021, at NEJM.org. DOI: 10.1056/NEJMoa2107456

Neutralizing AB/Vaccine efficacy

Table 2. SARS-CoV-2 Serum Neutralization Assay Results 1 Month after Dose 2 of BNT162b2 among Participants without Evidence of Infection.*

Age Group	No. of Participants	Geometric Mean 50% Neutralizing Titer (95% CI)†
12–15 yr	190	1239.5 (1095.5–1402.5)
16–25 yr	170	705.1 (621.4–800.2)

1,76

Table 3. Vaccine Efficacy against Covid-19 in Participants 12 to 15 Years of Age.*

Efficacy End Point†	BNT162b2	Placebo	% Vaccine Efficacy (95% CI)‡
		Surveillance Time (No. at Risk)¶	
Covid-19 occurrence at least 7 days after dose 2 in participants without evidence of previous infection	0	0.147 (972)	100 (75.3–100)
Covid-19 occurrence at least 7 days after dose 2 in participants with or without evidence of previous infection	vs. 16/18	0.163 (1094)	100 (78.1–100)

Frenck RW et al. Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents. May 27, 2021, at NEJM.org. DOI: 10.1056/NEJMoa2107456

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CONCLUSIONS

The BNT162b2 vaccine in 12-to-15-year-old recipients had a favorable safety profile, produced a greater immune response than in young adults, and was highly effective against Covid-19.

2

COVID-19 Impfung für Kinder & Jugendliche in der Pipeline

Study to Evaluate the Safety, Tolerability, and Immunogenicity of an RNA Vaccine Candidate Against COVID-19 in Healthy Children <12 Years of Age

NIH U.S. National Library of Medicine
ClinicalTrials.gov

ClinicalTrials.gov Identifier: NCT04816643

Recruitment Status : Recruiting
First Posted : March 25, 2021
Last Update Posted : June 1, 2021

See Contacts and Locations

Study Description

Go to

Brief Summary:

This is a Phase 1/2/3 study in healthy children <12 years of age.

Dependent upon safety and/or immunogenicity data generated during the course of this study, and the resulting assessment of benefit-risk, the safety, tolerability, and immunogenicity of BNT162b2 in participants <6 months of age may subsequently be evaluated.

Condition or disease	Intervention/treatment	Phase
SARS-CoV-2 Infection, COVID-19	Biological: Biological/Vaccine: BNT162b2 10mcg Biological: BNT162b2 20mcg Biological: BNT162b2 30mcg	Phase 1 Phase 2

Detailed Description:

Phase 1 is the open-label dose-finding portion of the study to evaluate safety, tolerability, and immunogenicity of BNT162b2 on a 2-dose (separated by approximately 21 days) schedule in up to 3 age groups (participants ≥5 to <12 years, ≥2 to <5 years, and ≥6 months to <2 years of age). Dose finding is being initiated in this study in participants ≥5 to <12 years of age based on the acceptable blinded safety assessment of the 30-µg dose in 12- to 15-year-olds in the C4591001 study.

The purpose of Phase 1 is to identify preferred dose level(s) of BNT162b2 from up to 3 different dose levels in each age group.

Phase 2/3 will evaluate the safety, tolerability, and immunogenicity in each age group at the selected dose level from Phase 1. Efficacy will be evaluated across all age groups in which immunobridging is successful, depending on accrual of a sufficient number of cases across those age groups.

All participants will have blood drawn at baseline prior to Dose 1 and 6 months after Dose 2. Immunobridging to participants 16 to 25 years of age in the C4591001 study will be based on immunogenicity data collected at baseline and 1 month after Dose 2. The persistence of the immune response will be based on immunogenicity data collected in participants at baseline and at 1, 6, 12 (original BNT162b2 group only), and 24 months after Dose 2 (original BNT162b2 group only). In addition, efficacy against confirmed COVID-19 and against asymptomatic infection will also be assessed.

At the 6-month follow-up visit, all participants will be unblinded. Participants who originally received placebo will be offered the opportunity to receive BNT162b2 as part of the study.

Kinderstudie Phase 1/2/3

Studien zur Sicherheit und Immunogenität

- Kinder vom 6. Lebensmonat bis 11 Jahre
  - 3 Gruppen: 6 Mo – 2 Jahre, 2 Jahre bis 5 Jahre, 5 bis 11 Jahre
- 2 Dosen im Abstand von 21 Tagen

- Dosisfindungsstudie mit 10µg, 20µg und 30µg

- Primäres Ziel der Studien:
  Verminderung der SARS-CoV-2 Transmission – Marker für asymptomatiche Infektion

BioNTech/Pfizer Kinder unter 12 Jahre

Geplante Studien

- 90 Studienzentren in Finnland, Polen, Spanien, USA …
- Start Juni 2021
- Insgesamt 4.500 Kinder in den Altersgruppen
  - 6 Monate bis 5 Jahre 3 µg
  - 6 Jahre bis 12 Jahre 10 µg
- Sicherheit, Reaktogenität und Immunogenität

- Ergebnisse Oktober/November 2021

Keine Wirksamkeitsstudien

Moderna Kinder 12 bis 17 Jahre

Studie in Abstimmung mit PIP (Paediatric Investigation Plan) und EMA´s Paediatric Committee (PDCO)

- Laufend seit Dezember 2020
- 3.732 Jugendliche im Alter zwischen 12 und 17 Jahren
- Randomisierung 2 : 1 – Impfung : Placebo
- 2 Dosen im Abstand von 28 Tagen – Erwachsenendosierung
- Dauer 13 Monate

- Zulassung in der EU geplant für Juli 2021

Keine Wirksamkeitsstudie

COVID-19 Kinderstudien

European Medicines Agency decision

P/0481/2020

of 30 November 2020

on the agreement of a paediatric investigation plan and on the granting of a deferral for mRNA that encodes for the pre-fusion stabilized spike glycoprotein of SARS-CoV-2 (mRNA-1273) (EMEA-002893-PIP01-20) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

Moderna

Pediatric News

A Step Forward: Moderna Covid19 Vaccine Trials begin in infants and children less than 12 yrs of age

Dr.Reepa Agrawal

More..

22 Mar, 2021

As the global vaccination campaign against COVID-19 is in full swing in adult population, the clinical trials for younger ones have begun earlier this week. Moderna has announced vaccinating healthy infants and children between 6 months – 11 years in U.S and Canada as a part of Phase 2/3 study of mRNA -1273 vaccine (KidCove study).

This study will be conducted by Moderna in collaboration with National Institute of Allergy and Infectious Diseases (NIAID) and Biomedical Advanced Research and Development Authority (BARDA). It will be enrolling 6,750 participants for this particular study which will be conducted in 2 parts to evaluate safety and effectiveness of the vaccine.

Its important to note that in de-escalation Part 1of the study, different dosage of vaccine will be administered according to age. Between 6 months – 2 years either a dose of 25 micrograms, 50 micrograms or 100 micrograms will be given and in 2 -12 years of age 50 micrograms or 100 micrograms will be used. After this an interim analysis will be done to determine the dose . Then post this analysis in part 2 that particular dose will be compared with placebo in participants. A total of 2 doses 28 days apart will be given intramuscularly. Now, unlike adult trials where presence or absence of severe covid infections was a crucial parameter , scientists are of the opinion that in this younger age group as incidence of severe Covid is less as compared to adults, the measurement of neutralising antibodies will be crucial.

Having said that we still don't know the exact protective neutralising antibodies level which prevents disease or infection hence continued evaluation of data from adult population as well is required.

The clinical trials in teens are ongoing. Pfizer had enrolled 2,200 participants between 12-15 years by January 2021, started the same in October 2020. Moderna had enrolled 3,000 teens (12 -18 years) in its TeenCove study by February 2021. Johnson and Johnson may also start trials in pediatric population.

Pediatricians and Infectious Diseases experts are awaiting data of the above trials and some experts believe that by end of 2021 the above 12 years may start getting jabs against COVID-19 once the safety and effectiveness is determined.

This pandemic has taken a big toll on all of us including the kids and these jabs are a ray of hope .

Reference :

Clinicaltrials. gov

Moderna Kinder unter 12 Jahre

KidCove STUDY

Geplante Studien in Kooperation mit NIAID/NIH
1. Open-label, dose-escalation (50µg – 100µg), age-de-escalation Study
2. Randomisierte, observer-blind, Placebo-kontrollierte Expansionsstudien

- Studienzentren in USA und Canada
- Insgesamt 6.750 Kinder in den Altersgruppen
  Dosisfindungsstudie mit 25µg – 50µg – 100µg
  Interimsanalyse
  - 6 – 24 Monate
  - 2 Jahre bis 5 Jahre
  - 6 Jahre bis 12 Jahre
- Sicherheit, Reaktogenität und Immunogenität (Neutralisierende Antikörper)

Keine Wirksamkeitsstudie

AZD122 – Ad26.COV2.S

	Vaccine name			
	BNT162b2[42,43)]	mRNA-1273[44,45)]	AZD1222[46)]	Ad26.COV2.S[47)]
Manufacturer	Pfizer	Moderna	AstraZeneca	Janssen (J&J)
Ongoing/completed clinical trials on children	Phase 3: - Adolescents 12–15 yr Phase 3 (finished) summary: N=2,260 Confirmed COVID-19 after last vaccination: Vaccine group: n=18/1,129 Placebo group: n=0/1,131 Phase 1/2/3 (2021.3-): recruiting 6 mo to 11 yr	Phase 2/3 (2021.2-): Recruiting adolescents 12–17 yr Phase 2/3 (2021.3-): Recruiting children 6 mo to 11 yr	Phase 2 (recruiting ing c	Phase - P wborns ents

AZ1222 / Janssen

AstraZeneca

- Noch keine publizierten pädiatrische Studien
- Studie 6-17 Jahre
- Februar 2021 – Studie an 300 britischen Kinder

- Stop der Studie nach thrombo-embolischen Nebenwirkungen bei Erwachsenen

Janssen

- Ankündigung einer Studie für April 2021
- Stop der Studie zur Klärung der Gerinnungsstörungen

BBIBP-CorV – Sinopharm Kinderstudie

ChiCTR 中国临床试验注册中心
Chinese Clinical Trial Registry
世界卫生组织国际临床试验注册平台一级注册机构

Today is 2021-02-08

Description for medicine or protocol of treatment in detail:	
Study design:	Parallel
Inclusion criteria	1. Healthy subjects aged 3 years and above; 2. By asking for a medical history and a physical examination, the researchers determined that the subjects were in good health; 3. From December 2019 to now, the subject has not been to hubei province, outside the country or in a village/community where there has been an outbreak. The subject has not been exposed to a person infected with or suspected of COVID-19; 4. Female subjects with childbearing age are not pregnant at the time of admission (negative reaction in urine pregnancy test), and are not nursing and have not fertility plan within the first 3 months after admission. Effective contraceptive measures shall be taken within 2 weeks before inclusion; 5. Subjects are able and willing to complete the study plan over follow-up period of approximately 14 months; 6. The subject or/and his/her legal guardian or trustee have the ability to understand the study procedures, voluntarily sign informed consent with informed consent, and comply with the requirements of the clinical study protocol.
Exclusion criteria:	1. Confirmed cases, suspected cases or asymptomatic cases with COVID-19 (refer to Information System of China Disease Prevention and Control); 2. Positive in serum antibodies (IgG and IgM) screening of COVID-19; 3. Has a history of SARS virus infection (self-reported, site information); 4. Fever (armpit temperature > 37.0 degree C), dry cough, fatigue, nasal obstruction, runny nose, sore throat, myalgia, diarrhea, shortness of breath and dyspnea within 14 days before administration; 5. Subjects with abnormal indicators, such as blood biochemistry, blood routine and urine routine, which might show clinical meaning, before administration (only refers to Phase I); 6. Armpit temperature > 37.0 degree C before administration; 7. History of severe allergic reactions (such as acute anaphylaxis, urticaria, skin eczema, dyspnea, angioneurotic edema or abdominal pain) or allergy to known composition of COVID-19 vaccine; 8. History of convulsion, epilepsy, encephalopathy or mental illness or family history; 9. with congenital malformations or developmental disorders, genetic defects, severe malnutrition, etc.; 10. with severe liver and kidney diseases, uncontrollable hypertension (systolic pressure >=140 mmHg, diastolic pressure >=90 mmHg), diabetic complications, malignant tumors, various acute diseases or acute onset of chronic diseases; 11. diagnosed with congenital or acquired immune deficiency, HIV infection, lymphoma, leukemia or other autoimmune diseases; 12. with known or suspected diseases include: severe respiratory diseases, severe cardiovascular diseases, liver and kidney diseases, malignant tumors; 13. with history of coagulation dysfunction (e.g. Coagulation factor deficiency, coagulation disease); 14. Receiving anti-TB treatment; 15. Receiving immunotherapy or inhibitor therapy within 3 months (consistently oral or infusion for more than 14 days); 16. vaccinated with live attenuated vaccine within 1 month, or other vaccine within 14 days before vaccination; 17. Receiving blood products within 3 months before administration; 18. Receiving other research drugs within 6 months before vaccination; 19. The investigators determined that other conditions were inappropriate for the study.

http://www.chictr.org.cn/showprojen.aspx?proj=53003

Covaxin

- All India Institute of Medical Sciences (AIIMS) in Patna
- Bharat Biotech Zusammenarbeit mit dem Indian Council of Medical Research
- Inaktivierte Virus-basierte Impfung

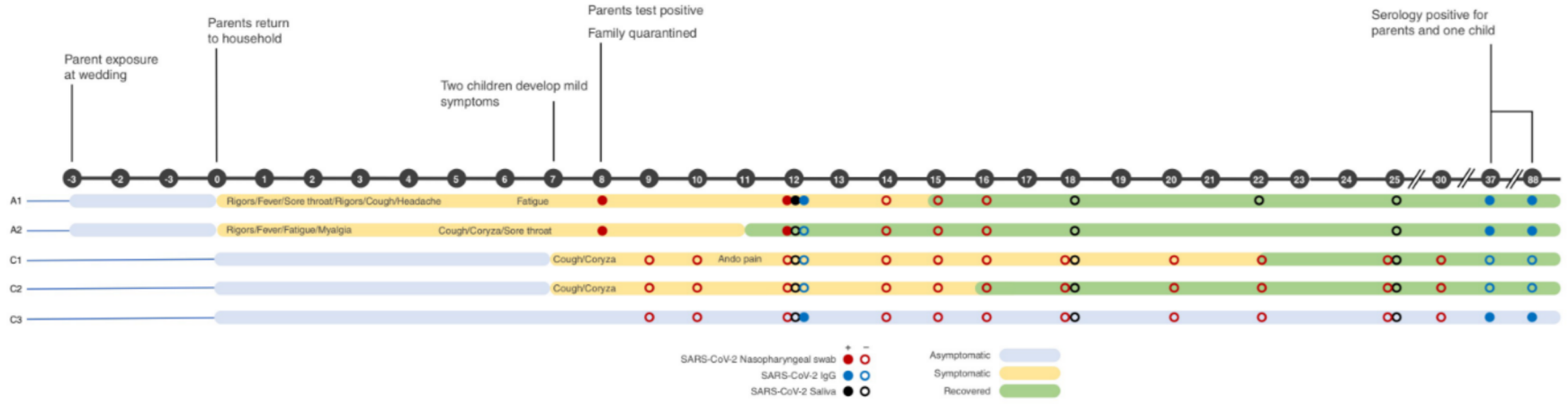
- 525 Kinder und Jugendliche im Alter von 2 bis 18 Jahren
- Phase 2 / 3 Studie in Indien
- 2 Dosen im Abstand von 28 Tagen

3

Warum Kinder & Jugendliche impfen?

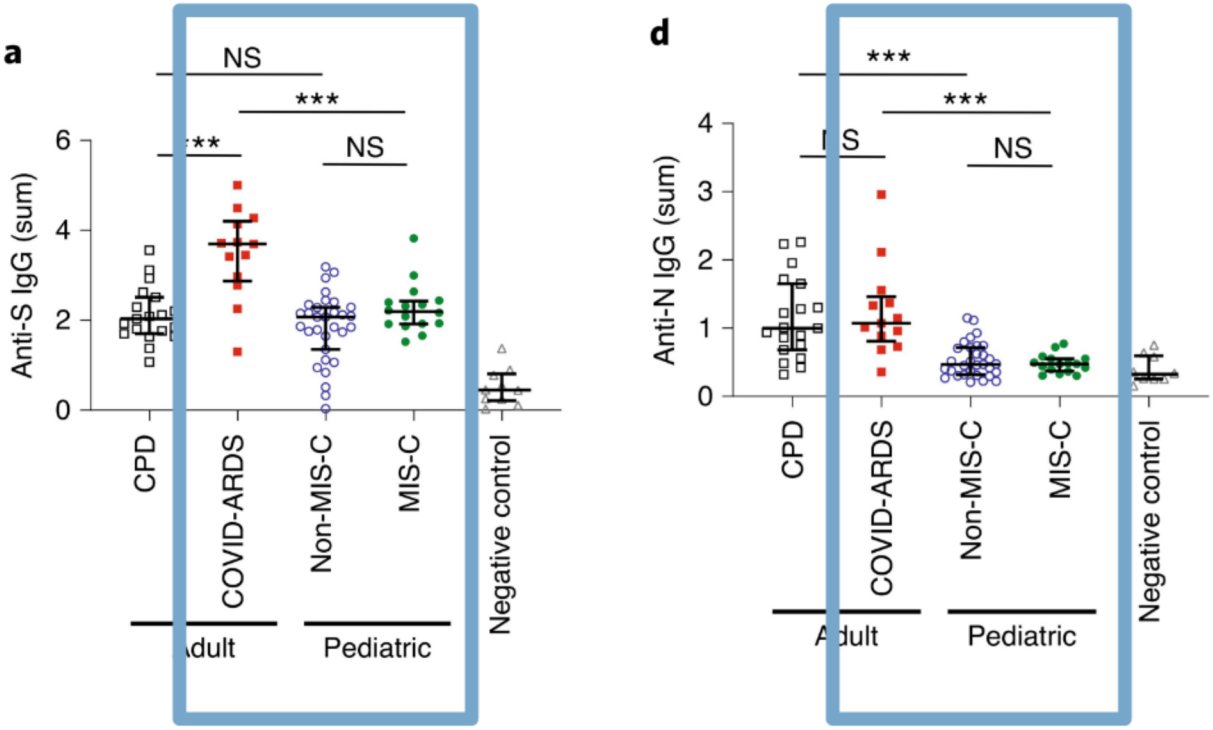
Kinder sind anders …

- Kinder können mit SARS-CoV2 Virus besser umgehen
- Angeborenes Immunsystem potenter mit neuen Pathogenen umzugehen
- Berichte über symptomatische SARS-CoV-2 Infektionen, neutralisierende AK ohne positive PCR-Testung (11 Testungen in 28 Tagen)
  - Rasche immunologische Reaktion auf SARS-CoV-2 verhindert Virusausbreitung



Tosif S et al.: Immune responses to SARS-CoV-2 in three children of parents with symptomatic COVID-19. nature Communications (2020)11:5703 | https://doi.org/10.1038/s41467-020-19545-8

Antikörperantwort Kinder



Unterschiedliche Antikörperantwort auf SARS-CoV-2 Infektion:

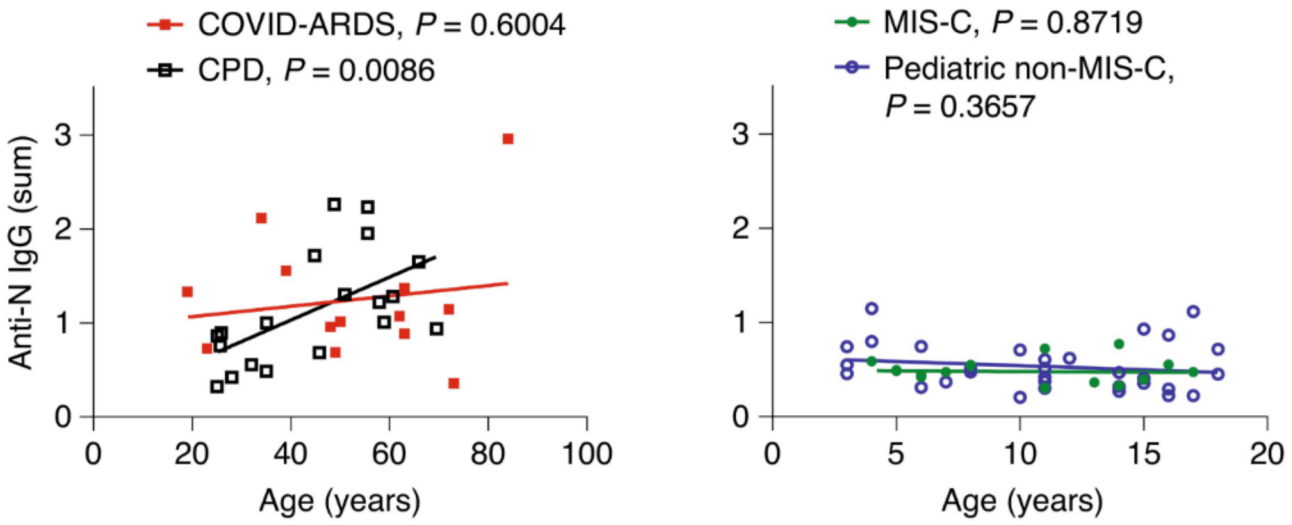
Erwachsene: Anti-S IgG, IgM, IgA und **Anti N IgG positiv**

Kinder: Keine Anti N IgG Antwort, aber Anti-S IgG

SARS-CoV-2 S-Protein - Andocken und Eindringen in die Zelle – Beginn der Infektion

Weisberg, S.P., Connors, T.J., Zhu, Y. et al. Distinct antibody responses to SARS-CoV-2 in children and adults across the COVID-19 clinical spectrum. Nat Immunol 22, 25–31 (2021). https://doi.org/10.1038/s41590-020-00826-9

Antikörperantwort Kinder



Nukleokapsid-spezifische Antikörper werden typischerweise gebildet, wenn große Mengen Virus im Organismus sind

Kinder zeigen keine Anti N IgG Antwort

Weisberg, S.P., Connors, T.J., Zhu, Y. et al. Distinct antibody responses to SARS-CoV-2 in children and adults across the COVID-19 clinical spectrum. Nat Immunol 22, 25–31 (2021). https://doi.org/10.1038/s41590-020-00826-9

SARS-CoV-2 Transmission

- Einige Studien berichten über ähnliche Infektionsaten bei Kindern wie bei Erwachsenen, andere niedrigere bei Kindern verglichen mit Erwachsenen
- Jugendliche wahrscheinlich leichter infiziert als Kinder unter 10 Jahre
  - Daten aus Studien zu Contact tracing, Test Positivität und Seroprävalenzraten
- Sekundäre Transmission von Jugendlichen möglich und real
  - Selten SARS-CoV-2 Transmission bei Studenten selten
    Einige Studen zeigen höheren Transmission in höheren Schulen verglichen mit Volksschulen
- Clusterstudien zeigen effektive Transmission unter Kinder, Jugendlichen und jungen Erwachsenen
- Haushaltstransmission

Bi Q et al. Lancet Infect Dis. 2020;20(8):911-919
CDC Science Brief: Transmission of SARS-CoV-2 in K-12 schools. https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/transmission k 12 schools.html
Larosa E et al. Secondary transmission of COVID-19 in preschool and school settings in northern Italy after their reopening in September 2020. Euro Survei/1. 2020;25(49):2001911.

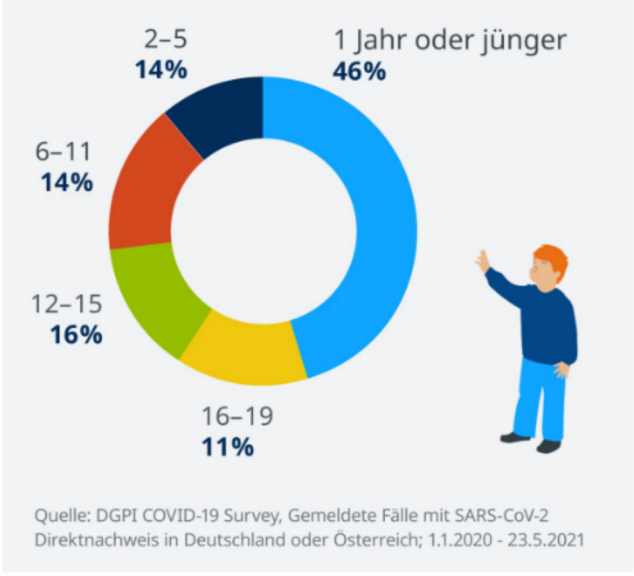
Krankheitslast COVID-19 Kinder

AAP - US

- 3,85 Millionen Kinder positiv auf COVID-19 getestet
- etwa 0,1 bis 1,9 % im Krankenhaus behandelt
- etwa 0,3 Prozent der infizierten Kinder starben

DGPI

- 1548 stationär behandelte Kinder und Jugendliche
- 74 (knapp 5 %) auf der Intensivstation behandelt
- Ca. 1/3 im Alter zwischen 6 und 16 Jahren
- 46 % Säuglinge



Quelle: DGPI COVID-19 Survey, Gemeldete Fälle mit SARS-CoV-2 Direktnachweis in Deutschland oder Österreich; 1.1.2020 - 23.5.2021

Rationale

Klares Ziel für Impfstrategie - ECDC

Primäres Ziel

- **Direkter** Schutz für geimpfte Person –**Indirekter** Schutz für Gesellschaft durch Verminderung der Virustransmission
- Verminderung der Krankheitslast
- Senkung der Inzidenz der COVID-19 (Spitalsaufnahmen, ICU)

Sekundäres Ziel

- Verminderung der Viruszirkulation
- Rücknahme der COVID-19 Schutzmaßnahmen
- Normalisierung des sozialen, gesellschaftlichen, edukativen Lebens

Direkte Vorteile

Verminderung der Transmissionsrate des Virus

- Je mehr Personen geimpft sind, umso mehr wird die Viruszirkulation vermindert
- … umso geringer das Infektionsrisiko für Personen, die nicht geimpft werden können
- … umso geringer das Risiko für das Neuauftreten von Mutationen (VOC)
- … umso ehe ist eine Herdenimmunität zu erreichen

Indirekter Schutz für andere Altersgruppen

- Schutz vulnerabler Personengruppen durch Impfung - Beispiel: Influenza
- CoMix Studie zeigt höhere Kontaktraten von Jüngeren – Dysproportionaler Effekt auf Transmission
- Verminderung des Infektionsrisikos für Lehrpersonal

Indirekte Vorteile

Schutz der Gesundheit

- Akut: COVID-19
- Subakut: Hyperinflammationssyndrom (Synonyme: PIMS, MIS-C)
- Chronisch: Long-COVID

Normalisierung des Lebens von Kindern und Jugendlichen

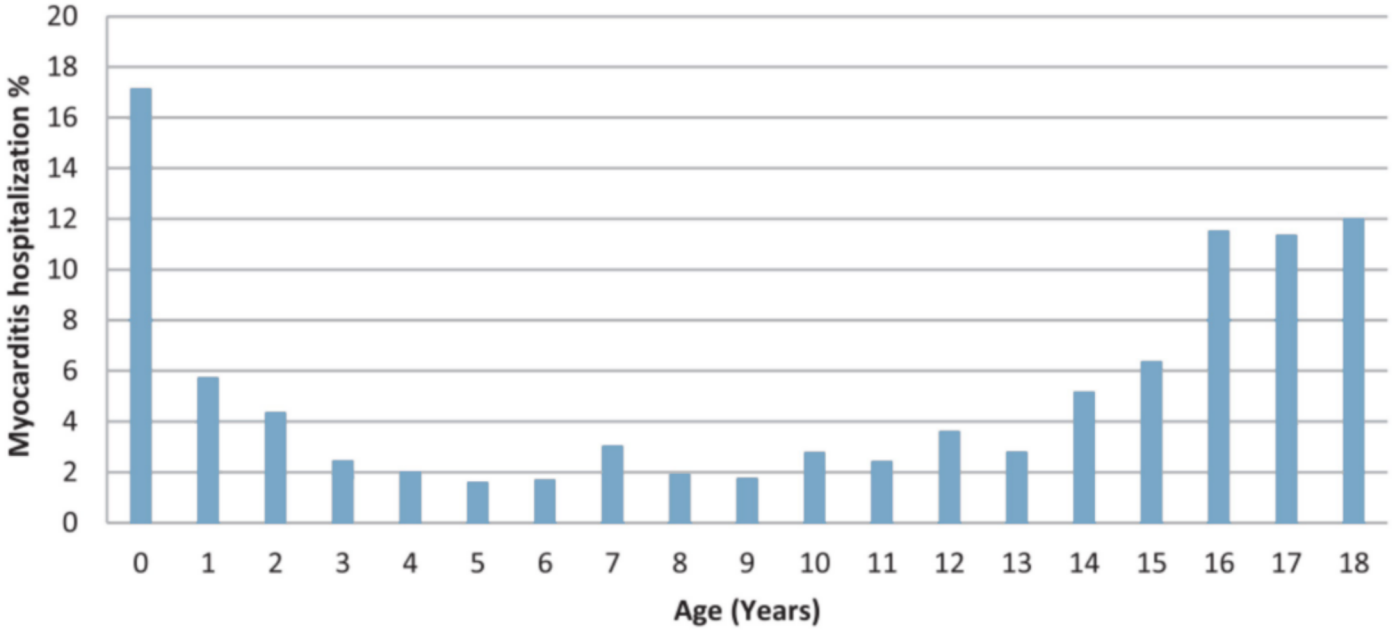
- Dramatische Auswirkungen der Pandemie auf mentale Gesundheit und Wohlbefinden der Kinder/Jugendlichen
- Raschere Normalisierung des Schullebens, Sport, Freizeit andere Aktivitäten

Jarvis CI et al. The impact of local and national restrictions in response to COVID-19 on social contacts in England: a longitudinal natural experiment. BMC Med 19, 52 (2021). doi.org/10.1186/s12916-021-01924-7

4

Risiko/Nutzen Abwägung

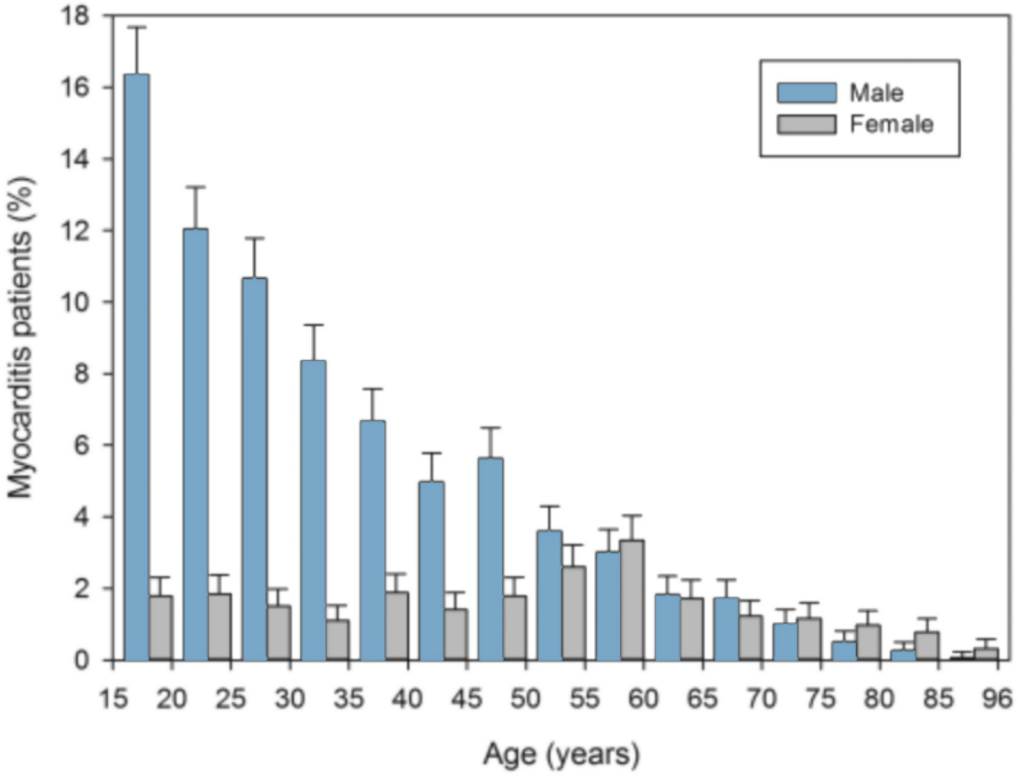
Myokarditis/Perikarditis Kinder



Jährliche Inzidenz 0,8/100.000 - 15-18 Jährige: 1,8/100.000 - 66% männlich

Vasudeva R et al. Trends in Acute Myocarditis Related Pediatric Hospitalizations in the United States, 2007–2016. Am J Cardiol. 2021 Jun 15;149:95-102. doi: 10.1016/j.amjcard.2021.03.019.

Myokarditis/Perikarditis Erwachsene

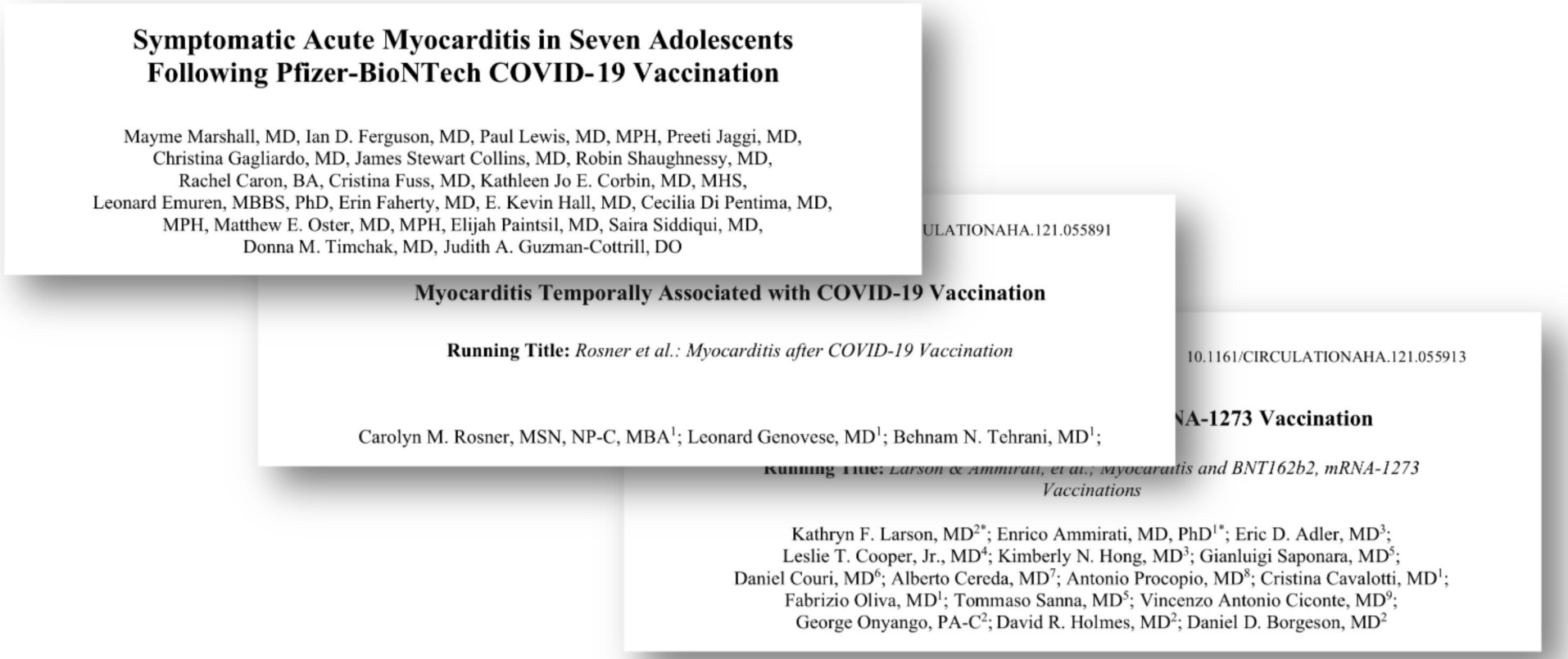


Abnahme der Inzidenz mit dem Alter

74% Männer

Vasudeva R et al. Trends in Acute Myocarditis Related Pediatric Hospitalizations in the United States, 2007–2016. Am J Cardiol. 2021 Jun 15;149:95-102. doi: 10.1016/j.amjcard.2021.03.019.

Myokarditis/Perikarditis – mRNA



Symptomatic Acute Myocarditis in Seven Adolescents Following Pfizer-BioNTech COVID-19 Vaccination

Mayme Marshall, MD, Ian D. Ferguson, MD, Paul Lewis, MD, MPH, Preeti Jaggi, MD, Christina Gagliardo, MD, James Stewart Collins, MD, Robin Shaughnessy, MD, Rachel Caron, BA, Cristina Fuss, MD, Kathleen Jo E. Corbin, MD, MHS, Leonard Emuren, MBBS, PhD, Erin Faherty, MD, E. Kevin Hall, MD, Cecilia Di Pentima, MD, MPH, Matthew E. Oster, MD, MPH, Elijah Paintsil, MD, Saira Siddiqui, MD, Donna M. Timchak, MD, Judith A. Guzman-Cottrill, DO

ULATIONAHA.121.055891

Myocarditis Temporally Associated with COVID-19 Vaccination

Running Title: *Rosner et al.: Myocarditis after COVID-19 Vaccination*

Carolyn M. Rosner, MSN, NP-C, MBA[1]; Leonard Genovese, MD[1]; Behnam N. Tehrani, MD[1];

10.1161/CIRCULATIONAHA.121.055913

NA-1273 Vaccination

Running Title: *Larson & Ammirati, et al.: Myocarditis and BNT162b2, mRNA-1273 Vaccinations*

Kathryn F. Larson, MD[2*]; Enrico Ammirati, MD, PhD[1*]; Eric D. Adler, MD[3]; Leslie T. Cooper, Jr., MD[4]; Kimberly N. Hong, MD[3]; Gianluigi Saponara, MD[5]; Daniel Couri, MD[6]; Alberto Cereda, MD[7]; Antonio Procopio, MD[8]; Cristina Cavalotti, MD[1]; Fabrizio Oliva, MD[1]; Tommaso Sanna, MD[5]; Vincenzo Antonio Ciconte, MD[9]; George Onyango, PA-C[2]; David R. Holmes, MD[2]; Daniel D. Borgeson, MD[2]

Marshall et al. Symptomatic Acute Myocarditis in Seven Adolescents Following Pfizer-BioNTech COVID-19 Vaccination. Pediatrics. 2021 e2021052478. doi: 10.1542/peds.2021-052478

Rosner et al. Myocarditis Temporally Associated with COVID-19 Vaccination. Circulation 2021 Jun 16. doi: 10.1161/CIRCULATIONAHA.121.055891

Larson et al. Myocarditis after BNT162b2 and mRNA-1273 Vaccination. Circulation 2021 Jun 16. doi: 10.1161/CIRCULATIONAHA.121.055913

Myokarditis/Perikarditis – mRNA

- Marshall et al. – 7 männliche Jugendliche im Alter von 14-19 Jahre, 4 Tage nach 2. mRNA Impfung
  - Erhöhtes Troponin, auffälliges EKG und MRI
  - Behandlung mit NSAR, iv Ig/Steroide
  - Entlassung aus Klinik nach 2-6 Tagen

- Rosner et al. – 5 Männer im Alter von 19-39 Jahren, 4 Tage nach 2. mRNA Impfung, 1 24 Jähriger 7 Tage nach 1. Impfung*
  - Erhöhtes Troponin, unterschiedliche EKG Auffälligkeiten, MRI
  - Behandlung mit NSAR,
  - Treatment with NSAIDs or Colchicin, ß-Blocker und Steroiden
  - * Spike protein Antikörper **negativ**

Marshall et al. Symptomatic Acute Myocarditis in Seven Adolescents Following Pfizer-BioNTech COVID-19 Vaccination. Pediatrics. 2021 e2021052478. doi: 10.1542/peds.2021-052478
Rosner et al. Myocarditis Temporally Associated with COVID-19 Vaccination. Circulation 2021 Jun 16. doi: 10.1161/CIRCULATIONAHA.121.055891
*Rosner et al. Berichtete auch über einen 28 Jährigen mit Myokarditis nach einer Johnson & Johnson COVID-19 Impfung

Myokarditis/Perikarditis – mRNA

- Larson et al. – 8 Männer im Alter von 22 bis 56 Jahre, 7 innerhalb von 4 Tagen nach der 2. Impfung, 1 Mann 2 Tage nach der 1. Dosis (St. p. COVID-19)
  - Erhöhtes Troponin bei allen, auffällige EKG und MRI
  - Behandlung mit NSAR, iv Ig/Steroide, rein symptomatische Therapie bei 3 Patienten
  - Entlassung aus Klinik symptomlos und beschwerdefrei

- Gesundheitsministerium Israel - 148 Myokarditis Fälle innerhalt von 30 Tagen nach mRNA Impfung
  - 27 Fälle bei ~5.4 Millionen Erstimpfungen
  - 121 Fälle bei ~5 Millionen Zweitimpfungen
  - Zumeist Männer im Alter von 19 bis 30 Jahre (vor allem im Alter von 16-19 Jahre)
  - 95% milde Fälle

Larson et al. Myocarditis after BNT162b2 and mRNA-1273 Vaccination. Circulation 2021 Jun 16. doi: 10.1161/CIRCULATIONAHA.121.055913
https://www.gov.il/en/departments/news/01062021-03

Myokarditis/Perikarditis

- Seit April 2021 – seltene Berichte über Myokarditis und Perikarditis nach mRNA Impfungen
- Israel, USA, Canada u.a.

- Gutes Ansprechen auf Behandlung
- Rasche Besserung

- Junge männliche Erwachsene über 16 Jahre
- Häufiger nach der 2. Dosis

bu Mouch S, Roguin A, Hellou E, et al. Myocarditis following COVID-19 mRNA vaccination. Vaccine 2021; corrected proof online May 28: https://doi.org/10.1016/j.vaccine.2021.05.087: (Pre-proof accessed June 2, 2021).

Snapiri O, Danziger CR, Shirman N,et al. transient cardiac injury in adolescents receiving the BNT162b2 mRNA COVID-19 Vaccine. Pediatr Infect Dis J 2021;June 2:online ahead of print, doi:10.1097/INF.0000000000003235.

Ministry of Health (Israel). Surveillance of myocarditis (inflammation of the heart muscle) cases between December 2020 and May 2021 (including). Press Release 6/2/2021:https://www.gov.il/en/departments/news/01062021-03 (Accessed June 4, 2021).

Advisory Committee on Immunization Practices. COVID-19 VaST Work Group Technical Report – May 17, 2021: www.cdc.gov/vaccines/acip/work-groups-vast/technical-report-2021-05-17.html (Accessed June 2, 2021).

Public Health Agency of Canada. Reported side effects following COVID-19 vaccination in Canada. Ottawa, Ont.: PHAC, May 28, 2021: https://health-infobase.canada.ca/covid-19/vaccine-safety/ (Accessed June 2, 2021).

Myokarditis/Perikarditis

CDC Meeting 10.6.2021

- USA 172 Millionen verimpfte Dosen
- 475 gemeldete Myo-/Perikarditisfälle
  .
- 226 entsprechend den Definitionen

- Keine Änderung des Nutzen-Risiko Verhältnisses
- Keine Änderung der Empfehlungen zur Impfung

Myokarditis/Perikarditis

AGES Meldungen bis 14.6.2021

- 17 Meldungen
- Keine Meldungen bei Personen unter 18 Jahre
- 1 Meldung: 18-Jähriger nach Comirnaty Impfung
- 3 Meldungen 19-29 Jahr

Alle Fälle werden engmaschig überwacht
Alle Fälle wurden an EudraVigilance weitergeleitet

AGES, Stand 14.6.2021 – persönliche Mitteilung

Myokarditis/Perikarditis Warnsignale

Symptome

- Oft keine Symptome

- Akute Schmerzen in der Brust
- Palpitationen
- Kurzatmigkeit
- inspirationsabhängige Schmerzen, vor allem bei Perikardbeteiligung (Perimyokarditis)
- Müdigkeit
- Leistungsabfall

Meldung an AGES

Myokarditis/Perikarditis Therapie

Bahandlung

- Symptomatische, konservative Therapie
- Körperliche Schonung
- Behandlung ggf. von Rhythmusstörungen
- Ev. Immunsuppressive Therapie

- Häufig Spontanverbesserungen

Myokarditis/Perikarditis

- Laufende Evaluierung durch ECDC, PRAC/EMA, CDC, FDA

- Signal, das nur bei der Menge an verimpften Dosen auffällig geworden ist
- Positive Bestätigung der Überwachungssysteme nach Zulassung der Impfung

- **Derzeit kein sicherer Zusammenhang mit Impfung**

5

COVID-19 Impfung für Kinder & Jugendliche –

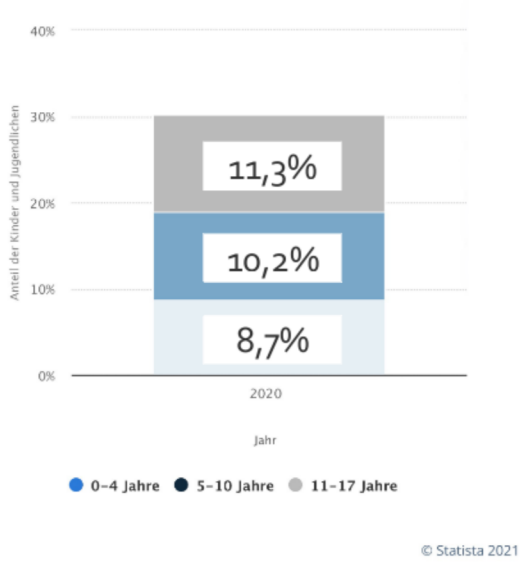
Aktuelle Empfehlungen

Anteil Kinder an der Gesamtbevölkerung

2020 - 30,2 Prozent der Weltbevölkerung sind **Kinder** und Jugendliche im Alter von 0 bis 17 Jahre
2,35 Milliarden Kindern und Jugendlichen weltweit

Österreich:

- Weltweit 30,2%
- Deutschland 16,4%



Anteil Kinder an der Gesamtbevölkerung

Österreich 12-15 Jahre:

- Weltweit 30,2%
- Österreich 17,3%

- Deutschland 16,4%

Bevölkerung am 1.1.2021 nach Alter und Bundesland - Insgesamt

Alter	Österreich	Burgenland	Kärnten	Nieder-österreich	Ober-österreich	Salzburg	Steiermark	Tirol	Vorarlberg	Wien
Insgesamt	**8.932.664**	**296.010**	**562.089**	**1.690.879**	**1.495.608**	**560.710**	**1.247.077**	**760.105**	**399.237**	**1.920.949**
0 Jahre	81.970	2.142	4.469	14.587	14.476	5.622	10.727	7.259	4.203	18.485
1 Jahr	85.449	2.358	4.553	15.222	15.191	5.737	11.073	7.476	4.344	19.495
2 Jahre	87.087	2.483	4.765	15.760	15.540	5.576	11.238	7.687	4.430	19.608
3 Jahre	89.259	2.462	5.019	16.495	15.821	5.793	11.629	7.731	4.354	19.955
4 Jahre	89.990	2.652	5.015	16.804	15.960	5.716	11.499	7.690	4.470	20.184
5 Jahre	87.296	2.612	4.906	16.338	15.356	5.525	11.533	7.652	4.245	19.129
6 Jahre	86.694	2.628	4.948	16.492	15.447	5.580	11.083	7.357	4.323	18.836
7 Jahre	84.656	2.571	4.942	16.430	14.891	5.347	10.935	7.263	4.061	18.216
8 Jahre	85.180	2.700	4.963	16.546	14.988	5.317	11.069	7.282	4.159	18.156
9 Jahre	84.474	2.709	4.998	16.634	14.765	5.249	11.013	7.090	4.127	17.889
10 Jahre	85.657	2.695	5.151	16.706	15.022	5.362	11.213	7.214	4.236	18.058
11 Jahre	83.535	2.661	5.001	16.206	14.661	5.194	11.058	7.090	4.125	17.539
12 Jahre	84.964	2.744	5.197	16.669	14.758	5.333	11.081	7.122	4.148	17.912
13 Jahre	83.778	2.735	5.155	16.250	14.613	5.326	10.999	7.130	4.167	17.403
14 Jahre	85.499	2.704	5.388	17.005	14.849	5.346	11.106	7.284	4.222	17.595
15 Jahre	85.794	2.685	5.346	17.033	14.930	5.541	11.350	7.317	4.334	17.258

0 bis 17 Jahre: 1,543.886 (17,3%)
12 bis 15 Jahre: 340.035 (3,8%)

weltweit

- USA
- Canada
- Japan
- Israel
- Dubai
- Singapur
- ...

- Frankreich
- Italien
- Littauen
- Polen
- Spanien ab Mitte August
- Österreich
- ...

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Home / Diseases / Coronavirus disease (COVID-19) / COVID-19 vaccines / COVID-19 Vaccines Advice

English version last updated on 22 June 2021 to reflect 15 June 2021 SAGE interim recommendations on the Pfizer/BionTech COVID-19 vaccine.

COVID-19 advice for the public: Getting vaccinated

WHO SHOULD GET VACCINATED

The COVID-19 vaccines are safe for most people 18 years and older, including those with pre-existing conditions of any kind, including auto-immune disorders. These conditions include: hypertension, diabetes, asthma, pulmonary, liver and kidney disease, as well as chronic infections that are stable and controlled.

If supplies are limited in your area, discuss your situation with your care provider if you:

- Have a compromised immune system
- Are pregnant (if you are already breastfeeding, you should continue after vaccination)
- Have a history of severe allergies, particularly to a vaccine (or any of the ingredients in the vaccine)
- Are severely frail

Children and adolescents tend to have milder disease compared to adults, so unless they are part of a group at higher risk of severe COVID-19, it is less urgent to vaccinate them than older people, those with chronic health conditions and health workers.

More evidence is needed on the use of the different COVID-19 vaccines in children to be able to make general recommendations on vaccinating children against COVID-19.

WHO's Strategic Advisory Group of Experts (SAGE) has concluded that the Pfizer/BionTech vaccine is suitable for use by people aged 12 years and above. Children aged between 12 and 15 who are at high risk may be offered this vaccine alongside other priority groups for vaccination. Vaccine trials for children are ongoing and WHO will update its recommendations when the evidence or epidemiological situation warrants a change in policy.

It's important for children to continue to have the recommended childhood vaccines.

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines/advice, abgerufen 23.6.2021

COVID-19 vaccine for children

Canadian Paediatric Society

Posted: May 21, 2021

Principal author(s)

Dorothy L. Moore; Canadian Paedatric Society, Infectious Diseases and Immunization Committee

The most substantial effects of the coronavirus disease 2019 (COVID-19) pandemic on children have related more to disruptions in educational, physical, and social activities than direct viral effects. Nonetheless, there have been small numbers of cases of severe COVID-19 and COVID-19-associated multisystem inflammatory syndrome that have caused significant direct morbidity. Vaccination against COVID-19 is now available in Canada for children and adolescents aged 12 years and over. The Canadian Paediatric Society advocates for the vaccination of all children and adolescents aged 12 years and over to begin as soon vaccine supplies permit.

The Canadian Paediatric Society advocates for the vaccination of all children and adolescents aged 12 years and over to begin as soon vaccine supplies permit.

Morbidity and Mortality Weekly Report

The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Adolescents Aged 12–15 Years — United States, May 2021

Megan Wallace, DrPH[1,2]; Kate R. Woodworth, MD[1]; Julia W. Gargano, PhD[1]; Heather M. Scobie, PhD[1]; Amy E. Blain, MPH[1]; Danielle Moulia, MPH[1]; Mary Chamberland, MD[1]; Nicole Reisman, MPH[1]; Stephen C. Hadler, MD[1]; Jessica R. MacNeil, MPH[1]; Doug Campos-Outcalt, MD[3]; Rebecca L. Morgan, PhD[4]; Matthew F. Daley, MD[5]; José R. Romero, MD[6]; H. Keipp Talbot, MD[7]; Grace M. Lee, MD[8]; Beth P. Bell, MD[9]; Sara E. Oliver, MD[1]

The Pfizer-BioNTech COVID-19 vaccine is recommended for persons 12–15 years of age in the U.S. population under the FDA's Emergency Use Authorization.

available data, the Advisory Committee on Immunization Practices made an interim recommendation for use of the Pfizer-BioNTech COVID-19 vaccine in adolescents aged 12–15 years for the prevention of COVID-19.

What are the implications for public health practice?

The Pfizer-BioNTech COVID-19 vaccine is the first COVID-19 vaccine approved for use in adolescents and has high efficacy against symptomatic COVID-19. Vaccination will be important to protect adolescents against symptomatic COVID-19 disease and to reduce community transmission of SARS-CoV-2.

PEDIATRICS

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

COVID-19 Vaccines in Children and Adolescents

Committee on Infectious Diseases

RECOMMENDATIONS

The American Academy of Pediatrics (AAP) recommends the following related to COVID-19 vaccine in children and adolescents:

- The AAP recommends COVID-19 vaccination for all children and adolescents 12 years of age and older who do not have contraindications using a COVID-19 vaccine authorized for use for their age.

HHS.gov U.S. Department of Health & Human Services

"The facts are clear: this is an extremely rare side effect, and only an exceedingly small number of people will experience it after vaccination. Importantly, for the young people who do, most cases are mild, and individuals recover often on their own or with minimal treatment. In addition, we know that myocarditis and pericarditis are much more common *if you get COVID-19*, and the risks to the heart from COVID-19 infection can be more severe.

The following statement has been co-signed by the U.S. Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), American Academy of Family Physicians

"The vaccines are safe and effective, and they prevent COVID-19 illness. They will help protect you and your family and keep your community safe. We strongly encourage everyone age 12 and older who are eligible to receive the vaccine under Emergency Use Authorization to get vaccinated, as the benefits of vaccination far outweigh any harm. Especially with the troubling Delta variant increasingly circulating, and more readily impacting younger people, the risks of being unvaccinated are far greater than any rare side effects from the vaccines. If you get COVID-19, you could get severely ill and be hospitalized or even die. Even if your infection is mild, you or your child could face long-term symptoms following COVID-19 infection such as neurological problems or diminished lung function."

benefits of vaccination far outweigh any harm. Especially with the troubling Delta variant increasingly circulating, and more readily impacting younger people, the risks of being unvaccinated are far greater than any rare side effects from the vaccines. If you get COVID-19, you could get severely ill and be hospitalized or even die. Even if your infection is mild, you or your child could face long-term symptoms following COVID-19 infection such as neurological problems or diminished lung function."

COVID-19 Impfungen 12-15 Jahre

8,465.924 Millionen
1. COVID-19 Impfung

5,822.617 Millionen
Vollständige COVID-19

+ 397.717

COVID Data Tracker

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Total Vaccine Doses

Delivered	378.882.200
Administered	319.872.053

Learn more about the distribution of vaccines.

150.8M
People fully vaccinated

People Vaccinated	At Least One Dose	Fully Vaccinated
Total	177.948.892	150.787.303
% of Total Population	53,6%	45,4%
Population ≥ 12 Years of Age	177.751.325	150.686.259
% of Population ≥ 12 Years of Age	62,7%	53,1%
Population ≥ 18 Years of Age	169.482.968	144.863.642
% of Population ≥ 18 Years of Age	65,6%	56,1%
Population ≥ 65 Years of Age	47.798.400	42.265.434
% of Population ≥ 65 Years of Age	87,4%	77,3%

About these data

CDC | Data as of: June 23, 2021 6:00am ET. Posted: Wednesday, June 23, 2021 3:44 PM ET

COVID-19 Impfung

Ministry of Health

Press Releases

Surveillance of Myocarditis (Inflammation of the Heart Muscle) Cases Between December 2020 and May 2021 (Including)

Secondary topic: Ministry of Health, Updates

Subject: Coronavirus
Publish Date: 02.06.2021

Extended epidemiological team appointed to investigate the possible link between these cases and the vaccine

Ministry of Health

Press Releases

Ministry of Health's Position Regarding the Expansion of the Vaccination Operation to Ages 12-16 Years

Publish Date: 02.06.2021

Yesterday, discussions were held in the Management Team of Epidemics (MTE) and the Vaccination Monitoring Committee headed by the Ministry of Health's Director General

The Ministry of Health's Director General, Prof. Chezy Levy, with the approval of the Health Minister, has drawn the Ministry of Health's position regarding the expansion of the vaccination operation for teenagers aged 12 to 16.

Yesterday, discussions were held in the Management Team of Epidemics (MTE) and the Vaccination Monitoring Committee headed by the Ministry of Health's Director General, Prof. Chezy Levy and with the participation of the Chief COVID-19 Officer, Prof. Nachman Ash, Director of the MTE, Dr. Boaz Lev, representatives from the Israel Pediatric Society and vaccinology and epidemiology experts.

A lengthy discussion was held, during which the various professionals and experts presented their presentations and the work of the multi-disciplinary task force was reviewed, discussing possible complications as a result of expanding the vaccination operation, including myocarditis.

Following our publication from yesterday, it should be noted that the risks for complications of coronavirus diseases outweigh the risks posed by the vaccine's side effects. Myocarditis cases observed among teenagers aged 16 to 19 occurred in low rates and in most cases passed with no complications.

Nevertheless, since the infection rate in Israel is currently very low, it was recommended that people from high-risk groups be vaccinated, including teenagers who are at high-risk for serious coronavirus illness, teenager who live with family members who are at high-risk for serious coronavirus illness, as well as for teenagers in families who plan to travel abroad.
Beyond these high-risk groups, it will be possible to vaccinate anyone who wishes to be vaccinated.

Call Us 1299

The vaccine is effective and safe.

COVID-19 Impfung Kinder - UK

UK approves Pfizer jab for 12 to 15-year-olds

The UK regulator has approved the use of the Pfizer-BioNTech vaccine in children aged 12-15, saying it is safe and effective in this age group and the benefits outweigh any risks.

The MHRA said it had carried out a "rigorous review" of the vaccine in adolescents.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

First COVID-19 vaccine approved for children aged 12 to 15 in EU

News 28/05/2021

EMA's human medicines committee (CHMP) has recommended granting an extension of indication for the COVID-19 vaccine Comirnaty to include use in children aged 12 to 15. The vaccine is already approved for use in adults and adolescents aged 16 and above.

Comirnaty is a vaccine for preventing COVID-19. It contains a molecule called messenger RNA (mRNA) with instructions for producing a protein, known as the spike protein, naturally present in SARS-CoV-2, the virus that causes COVID-19. The vaccine works by preparing the body to defend itself against SARS-CoV-2.

The use of the Comirnaty vaccine in children from 12 to 15 will be the same as it is in people aged 16 and above. It is given as two injections in the muscles of the upper arm, given three weeks apart.

The effects of Comirnaty in children were investigated in 2,260 children aged 12 to 15 years. This study was carried out in accordance with Comirnaty's paediatric investigation plan (PIP), which was agreed by EMA's Paediatric Committee (PDCO).

The trial showed that the immune response to Comirnaty in this group was comparable to the immune response in the 16 to 25 age group (as measured by the level of antibodies against SARS-CoV-2). The efficacy of Comirnaty was calculated in close to 2,000 children from 12 to 15 years of age who had no sign of previous infection. These received either the vaccine or a placebo (a dummy injection), without knowing which one they were given. Of the 1,005 children receiving the vaccine, none developed COVID-19 compared to 16 children out of the 978 who received the dummy injection. This means that, in this study, the vaccine was 100% effective at preventing COVID-19 (although the true rate could be between 75% and 100%).

The most common side effects in children aged 12 to 15 are similar to those in people aged 16 and above. They include pain at the injection site, tiredness, headache, muscle and joint pain, chills and fever. These effects are usually mild or moderate and improve within a few days from the vaccination.

The CHMP concluded that the benefits of Comirnaty in this age group outweigh the risks.

COVID-19 Impfung Kinder

- Indikationsimpfung für Kinder mit erhöhtem Risiko für einen schweren Verlauf von COVID-19
- Zusätzlich: Kinder und Jugendliche, in deren Umfeld sich Angehörige oder andere Kontaktpersonen mit hoher Gefährdung befinden, die nicht geimpft werden können
- Berufliche Gefährdung
- Auf Wunsch und bei Risikoakzeptanz

ROBERT KOCH INSTITUT

Risikofaktoren / Grunderkrankungen

- Adipositas (> 97. Perzentile des Body Mass Index (BMI))
- angeborene oder erworbene Immundefizienz oder relevante Immunsuppression
- angeborene zyanotische Herzfehler (O2-Ruhesättigung <80 %)
- schwere Herzinsuffizienz
- schwere pulmonale Hypertonie
- chronische Lungenerkrankungen mit einer anhaltenden Einschränkung der Lungenfunktion
- chronische Niereninsuffizienz
- chronische neurologische oder neuromuskuläre Erkrankungen
- maligne Tumorerkrankungen
- Trisomie 21
- syndromale Erkrankungen mit schwerer Beeinträchtigung
- nicht ausreichend eingestellter Diabetes mellitus

Warum?

ROBERT KOCH INSTITUT

Die Daten zur Sicherheit der COVID-19-Impfung für Kinder und Jugendliche sind bisher noch begrenzt

- Nur etwa mehr als 1.000 Kinder in der Zulassungsstudie in der Impfgruppe
- Kurzer Beobachtungszeitraum (1-2 Monate)

Limitierte Impfstoffressourcen

Empfehlung

- … der deutsche Berufsverband der Kinder- und Jugendärzte (BVKJ) spricht sich für Impfungen von 12- bis 16-Jährigen aus - auch im Hinblick auf die angestrebte Herdenimmunität

Kinder- & Jugendärzte im Netz

Ihre Haus- & Fachärzte von der Geburt bis zum vollendeten 18. Lebensjahr

Herausgeber: bvkj. Berufsverband der Kinder- und Jugendärzte e.V.

Startseite | Arzt-Suche | Altersgruppen | Krankheiten | Vorsorge | Impfen | Erste Hilfe | Adressen | Mediathek | Suchbegriff

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12.05.2021

Kinder- und Jugendärzte für baldige Impfungen von Jugendlichen ab 12 Jahren bereit

Der Berufsverband der Kinder- und Jugendärzte (BVKJ e.V.) spricht sich für Impfungen von 12- bis 16- Jährigen aus und signalisiert seine Bereitschaft, am Erfolg der Impfkampagne in großem Umfang mitzuwirken.

Verusicherung der Eltern

COSMO
COVID-19 Snapshot Monitoring

- COSMO Befragung (Welle 45, 15.06.21 und 16.06.21, N = 1029 Befragte), deutschlandweite nicht-probabilistische Quotenstichprobe

Interpretation und Empfehlungen

- Möglicherweise ist die Impfbereitschaft teilweise etwas zurückgegangen, da die STIKO die Kinderimpfung nicht allgemein empfiehlt. Dies betrifft vor allem die Eltern von Kindern in dem Alterssegment, in dem die Impfung neu zugelassen wurde und worauf daher besonderes Augenmerk in der öffentlichen Debatte lag. Impfempfehlungen spielen eine große Rolle für die Impfbereitschaft.
- Möglicherweise ist das Vertrauen in die Sicherheit der Kinderimpfung gesunken, weil das Ausbleiben der Empfehlung für alle Kinder v.a. mit fehlenden Daten zur Sicherheit der Impfung begründet wurde.
- Da das Vertrauen in die Sicherheit der Impfung der wichtigste Faktor für die Impfbereitschaft ist, sollte bei der Kommunikation größtmögliche Sorgfalt an den Tag gelegt werden

Verusicherung der Eltern

COSMO
COVID-19 Snapshot Monitoring

- COSMO Befragung (Welle 45, 15.06.21 und 16.06.21, N = 1029 Befragte), deutschlandweite nicht-probabilistische Quotenstichprobe

- Bei Eltern von 12- bis 15- Jährigen ist die Bereitschaft trotz zwischenzeitlicher Zulassung des Impfstoffes für diese Altersgruppe von 66% Ende Mai auf 44% gesunken

Interpretation

- **Kinderimpfung in Deutschland nicht allgemein empfohlen**
- **Vertrauen in die Sicherheit der Kinderimpfung gesunken**

NIG Entscheidungsgrundlagen

EMA Feststellung: … dass der **Nutzen** der Impfung gegenüber dem Risiko auch in dieser Altersgruppe **überwiegt**

- Krankheitslast – Daten der ÖGKJ
- Individualschutz
- Psychosoziale, edukative, medizinische Benachteiligung
- Aspekte der Herdenimmunität

Österreich - NIG

Kinder und Jugendliche

Die EMA hat am 29. Mai 2021 die Zulassung für den Impfstoff Comirnaty® der Firma Pfizer/BioNTech nach Prüfung des Impfstoffes auf Wirksamkeit und Sicherheit für die Verwendung bei Kindern ab dem vollendeten 12. Lebensjahr empfohlen.

Die Studie für die Zulassung des Impfstoffes bei Kindern ab 12 Jahren hat gezeigt, dass die Verwendung von Comirnaty in der Prävention von symptomatischen, im Labor bestätigten COVID-19 bei Personen im Alter von 12-15 Jahren sicher und hoch effektiv ist. Wie bei Erwachsenen können auch bei Personen dieser Altersgruppe nach einer COVID-19-Impfung erwartbare Impfreaktionen auftreten, die gewöhnlich nur wenige Tage anhalten. Die lokalen und systemischen Reaktionen waren ähnlich denen, die bei Personen über 16 Jahre beobachtet wurden.

Der Ausschuss für Humanarzneimittel hat nach der Prüfung des Zulassungsantrages festgestellt, dass der Nutzen der Impfung gegenüber dem Risiko auch in dieser Altersgruppe überwiegt. Sicherheit und Wirksamkeit der Impfung werden bei Kindern und Erwachsenen weiter nicht nur im Rahmen des europäischen Pharmakovigilanzsystems, sondern auch weltweit genau beobachtet. Der Impfstoff wird in dieser Altersgruppe in den USA und Kanada in den vergangenen Wochen schon mehr als 600.000 mal angewendet und es gibt bisher keine Hinweise auf Sicherheitsbedenken.

Kinder und Jugendliche erkranken im Vergleich zu Erwachsenen zwar selten schwer an C OVID-19, dennoch sind schwere Krankheitsverläufe wie ein Multisystem-Inflammationssyndrom (Hyperinflammationssyndrom) auch in Österreich mit einer Häufigkeit von 1:500-1:1000 infizierten Kindern und Jugendlichen beschrieben worden , das jedenfalls zu einer Krankenhausaufnahme führt, oft sogar eine Behandlung auf der Intensivstation erfordert. Zudem mehren sich Hinweise, dass auch Kinder und Jugendliche nach milden und asymptomatischen Verläufen langfristig unter den Folgen einer COVID-19 Erkrankung („long COVID") leiden können. Ein weiterer Faktor ist, dass durch Impfung einschränkende Maßnahmen vermieden werden können.

Zudem ist zu berücksichtigen, dass Kinder nicht nur selbst erkranken können, sondern auch zum allgemeinen Infektionsgeschehen beitragen.