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Weimar District Court, decision of April 8th, 2021, Az .: 9 F 148/21
the District Court of Weimar through ...
decided by means of an interim order

I.

The leaders and teachers of the schools for children A, born on ..., and B, born on ..., namely the state regular school X, Weimar, and the Staatlichen Grundschule Y, Weimar, as well as the superiors of the School administrators are forbidden for this and all further to this Schools taught children and pupils to order or to prescribe:

- 1. Face masks of all kinds in class and on school premises, especially mouth and nose covers, so-called qualified masks (surgical Mask or FFP2 mask) or others to wear,**
- 2. Maintain minimum distances from one another or from other people, that go beyond what was known before 2020,**
- 3. to take part in rapid tests to determine the SARS-CoV-2 virus.**

II.

The leaders and teachers of the schools for children A, born on ..., and B, born on ..., namely the state regular school X, Weimar, and the Staatlichen Grundschule Y, Weimar, as well as the superiors of the School management is provided for these and all others at these schools taught children and pupils face-to-face lessons at the school maintain.

III.

The levying of court costs is waived. The parties There are no costs for children. Your extrajudicial costs will be borne by Involved themselves.

IV.

The immediate effectiveness of the decision is ordered.

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reasons

Structure:

A: Facts

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introduction

II.

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III.

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II.

Justification of the suggestion to the family court

1. General

2. The lack of utility in wearing a mask and adhering to

Distance regulations for the children themselves and third parties

**3. The inappropriateness of PCR tests and rapid tests to measure the
Infection process**

4. The violation of the right to informational self-determination by

Rapid tests in schools

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A: Facts

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I. Introduction

For the children named in the tenor, their mother, who with the father of Children has joint custody, with a submission dated March 13, 2021 at the district court - Family Court - Weimar a "child protection procedure according to § 1666 Abs. 1 and 4 BGB" stimulated.

The children attend the state regular school X and the state school in Weimar Elementary school Y, the older son at the age of 14, the eighth grade, the younger son third grade at the age of 8.

Her mother claims that by applying to her children in their schools Forced to wear a face mask and to each other and to other people Keeping minimum distances that the well-being of your children is endangered.

The children would be physically, psychologically and educationally damaged without the one Benefit for the children or third parties. This would also mean numerous Rights of children and their parents under law, constitution and international Violated conventions.

The school administrators and teachers should, according to § 1666 paragraph 4 BGB by the court be expressly instructed to revoke the relevant orders.

Insofar as these orders were based on state regulations such as statutory ordinances, the school administrators and others could not refer to it, as it is unconstitutional be.

The obligation in Article 100 paragraph 1 of the Basic Law, a possibly unconstitutional To submit the law to the Federal Constitutional Court or a state constitutional court, expressly applies only to formal federal and state laws, but not to substantive laws such as ordinances. About their compatibility with the constitution According to the established case law of the Federal Constitutional Court (fundamentally BVerfGE 1, 184 ((195 ff)) each court to decide itself, so also AG Weimar, Judgment of January 11, 2021 - 6 OWi - 523 Js 202518/20 -, juris.

If a decision on the main issue is not possible in the short term, the court should issue an interim order according to §§ 49 ff FamFG.

In addition, the court should take measures to ensure future compliance with the Legal position ensured by the responsible state authorities.

For this purpose, the court should in a separate part of the proceedings pursuant to Article 100 para. 1 Basic Law submit the matter to the Federal Constitutional Court with the proviso that

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To determine the nullity of the Infection Protection Act, which would otherwise be called in the future Authorization basis could create new endangerments for children. The The Federal Constitutional Court may be asked to share this separate part of the procedure with the constitutional complaint of the judge at the regional court Dr. Pieter Schleiter from December 31, 2020, Az.: 1 BvR 21/21, with reference to the detailed justification there connect to.

The court thereupon initiated the preliminary injunction procedure 9 F 148/21 as well as the parallel main proceedings 9 F 147/21 initiated and the children according to § 158 FamFG appointed the lawyer named in the rubrum as legal advisor.

II. The regulations of the Free State of Thuringia that apply to children in schools to mask compulsion

The provisions of the general decree of March 31, 2021 apply to children Implementation of the Thuringian Ordinance on Infection Protection Rules to Curb the Spread of the coronavirus SARS-CoV-2 in day-care centers, the others Youth welfare, schools and for sport (ThürSARS-CoV-2-KiJuSSp-VO), as far as they are in No. 7 orders the wearing of a mouth and nose cover and a qualified face mask, as well as against the ordinances cited by the general decree.

The provisions in question have the following wording as a whole:

1.

General decree of March 31, 2021 for the implementation of the Thuringian Ordinance on the Infection protection rules to contain the spread of the coronavirus SARS-CoV-2 in day-care centers, other youth welfare, schools and for sport (ThürSARS-CoV-2-KiJuSSp-VO)

General decree

According to Section 2, Paragraph 2 in conjunction with Section 15, Clause 1 and Section 37, Clause 1 of the Thuringian Ordinance

on the infection protection rules to contain the spread of the coronavirus SARSCoV-2 in day-care centers, other youth welfare, schools and for the Sport (ThürSARS-CoV-2-KiJuSSp-VO) of February 13, 2021 and according to § 35 sentence 2 Thuringian Administrative Procedure Act of December 1, 2014 (GVBl. P. 685) enacts this Thuringian Ministry for Education, Youth and Sport (TMBJS) in consultation with the Thuringian Ministry of Labor, Social Affairs, Health, Women and Family (TMASGFF)

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for the Free State of Thuringia the following general decree:

...

No. 7.

According to § 38 Abs. 5 ThürSARS-CoV-2-KiJuSSp-VO, pupils from the completed six years of age and the teachers of state schools are obliged to work within the School building a qualified face mask according to § 5 Abs. 3 3. ThürSARS-CoV-2- To carry the special measure regulation. Use is sufficient for students in grades 1 to 6 a mouth and nose covering according to § 6 Abs. 3 to 5 2. ThürSARS-CoV-2- IfS-GrundVO. The obligation to wear a qualified face mask applies to students from Grade 7 and for the teachers of all state schools in every grade level too during class.

The mask requirement for pupils does not apply to physical education. In Periodically, take a break from wearing the face mask respectively Ensure mouth and nose covering, outdoors or during ventilation breaks should take place. When eating, there is no obligation, but compliance with one A minimum distance of 1.50 m must be ensured. About other exceptions to the Obligations in individual cases will be decided by the school management at its due discretion.

2.

Thuringian Ordinance to update the necessary measures for Containment

**the
Spread
of
Coronavirus
SARS-CoV-2
in**

**Day-care centers, other youth welfare services, schools and for sports activities
From February 13, 2021**

On the basis of section 32 sentence 1 of the Infection Protection Act (IfSG) of July 20, 2000 (Federal Law Gazette I p.

1045), last amended by Article 4a of the law of December 21, 2020 (Federal Law Gazette I p. 3136), in conjunction with Section 7 (2) of the Thuringian Ordinance regulating Responsibilities and for the transfer of authorizations according to the Infection Protection Act (ThürIfSGZustVO) of March 2, 2016 (GVBl. P. 155), last amended by Article 3 of Ordinance of September 21, 2020 (GVBl. P. 501), decreed by the Ministry of Education, Youth and Sport in agreement with the Ministry of Labor, Social Affairs, Health, Women and family

and on the basis of § 32 sentence 1 in conjunction with §§ 28, 28a, 29, 30 paragraph 1 sentence 2 and § 31 IfSG in conjunction with Section 7 (1) ThürIfSGZustVO decrees the Ministry of Labor, Social affairs, health, women and family:

....
§ 37

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Changed presence for students during phase "Yellow II"

The ministry may take increased measures nationwide or for specific regions

Order protection against infection in accordance with Sections 38 to 40. These measures change the

Schools operate nationwide or regionally for all pupils and limit the entitlement

Funding according to Section 10, Paragraph 2 of the ThürSchulG. The organizational implementation on site is incumbent

the school administrators as part of their professional responsibility.

§ 38

Organization of face-to-face teaching during the "Yellow II" phase

...

(5) According to Section 2 (2), the Ministry can impose the obligation to use an oral Nose cover in accordance with the requirements of § 6 Paragraph 3 to 5 2. ThürSARS-CoV-2-IfSGGrundVO or a qualified face mask within the meaning of Section 5 Paragraph 3 3.

ThürSARS-CoV-2-SonderEind MaßnVO for students from grade 7 and for everyone

Extend teachers to teaching; Section 5, Paragraph 2, Clause 2 3. ThürSARS-CoV-2-

SonderEind MaßnVO applies accordingly. Periodically there is a break from that

Use of the mouth and nose cover or the qualified one

Ensure face mask. About exceptions to the obligation according to sentence 1

the school management decides according to its due discretion.

3.

Third Thuringian Ordinance on Extraordinary Special Measures for

Curbing the sudden spread of the coronavirus SARS-CoV-2 (third party

Thuringian SARS-CoV-2 Special Containment Measures Ordinance -3. ThürSARS-

CoV-2-SonderEind MaßnVO-) from March 12th, 2021

first section

Application precedence

§ 1 priority of application

(1) In addition to the provisions of the Second Thuringian SARS-CoV-2-

General Infection Protection Ordinance (2nd ThürSARS-CoV-2-IfS-GrundVO) of 7 July 2020

(GVBl. S. 349) in the currently valid version and the provisions of the Thuringian

Ordinance on infection control rules to curb the spread of

Coronavirus SARS-CoV-2 in day-care centers, other youth welfare services, schools

and for sports operations (ThürSARSCoV-2-KiJuSSp-VO) from February 13, 2021 in the
The current version is subject to the provisions of this ordinance.

(2) In the event of deviations, the provisions of this Ordinance take precedence; to that extent
the provisions of the Second Thuringian SARS-CoV-2 Basic Infection Protection Ordinance

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as well as the Thuringian Ordinance on the infection control rules to curb the
Spread of the coronavirus SARS-CoV-2 in day-care centers, the others
Youth welfare, schools and for the sports business back.

(3) Further orders and measures according to § 13 2. ThürSARS-CoV-2-
IfSGrundVO remain unaffected. For further orders according to sentence 1, refer to
Cases of §§ 6a and 6b the prior approval of the highest health authority
to catch up.

....

§ 5 Extended obligation to use a mouth and nose cover, face mask

(1) In addition to Section 6 Paragraphs 1 and 2 of the 2nd ThürSARS-CoV-2-IfS-GrundVO, the obligation
applies

to use a mouth and nose cover too

1. in all closed rooms that are publicly accessible or where visitors
and customer traffic (public traffic) exists,
2. at all public places specified and marked in accordance with sentence 2 in
Inner cities and in public in the open air, in which people
stay either in a confined space or not just temporarily,
3. in front of retail stores and in parking lots,
4. at meetings according to § 8 para. 1 sentence 1 no. 1 2nd ThürSARS-CoV-2-IfS-GrundVO,
5. at events and gatherings for religious and ideological purposes
according to § 8 Abs. 1 Satz 1 Nr. 2 2. ThürSARS-CoV-2-IfS-GrundVO and
6. at events organized by political parties in accordance with Section 8, Paragraph 1, Clause 1, No. 3 2.
ThürSARSCoV-2-IfS-GrundVO.

The competent authorities according to § 2 para. 3 ThürIfSGZustVO set the locations according to
sentence 1 no.

2 and identify them. Regulations on the use of a mouth and nose covering
remain for the facilities and offers according to Section 1 Paragraph 1 Clause 1 No. 1 to 4
ThürSARSCoV-2-KiJuSSp-VO the separate orders of the person responsible for education
Reserved to the Ministry.

(2) People over the age of 15 have instead of mouth and nose

Using a qualified face mask cover:

1. at events and gatherings for religious and ideological purposes
according to § 8 Abs. 1 Satz 1 Nr. 2 2. ThürSARS-CoV-2-IfS-GrundVO,
2. as passengers as well as control and service personnel in closed vehicles of the
public transport according to § 6 Abs. 1 2nd ThürSARS-CoV-2-IfS-GrundVO,
3. As customers in shops and service providers with the public or at the
Use of services and offers open to the public,
4. during the theoretical lessons in closed rooms of the driving and
Flight schools, the theoretical driver's and pilot's license test as well as the practical

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Training and practical driver and license test in closed driving and
Aircraft of driving and flight schools,

5. at meetings of municipal bodies, page 5 of 19 6. as doctors or therapists,
each including their staff, as well as patients in medical practices, practices of psychological
and physiotherapists or other medical and therapeutic care providers
serving outpatient facilities, with the exception of treatment rooms, if Art
the performance does not allow this.

Sentence 1 applies to children from the age of six to the age of 15 accordingly, with the proviso that the use of a mouth and nose cover after the requirements of § 6 para. 4 2nd ThürSARS-CoV-2-IfS-GrundVO is sufficient. About that In addition, every person is stopped, especially in closed rooms in situations in which closer or longer contact with other people is unavoidable, a to use qualified mouth and nose covering.

"(3) Qualified face masks within the meaning of this Ordinance are:

1. medical face masks or
2. Protective masks without exhalation valve with a technically higher level of protection, especially FFP2.

Permitted qualified face masks according to sentence 1 are published on the website of the for Public Health Ministry responsible.

(4) In addition, the obligations to provide and use of medical face masks or respiratory protection masks at work according to § 4 of the SARS CoV-2 Occupational Safety and Health Ordinance of January 21, 2021 (BANz AT January 22, 2021 V1) in the currently valid version unaffected.

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Second Thuringian Ordinance on Basic Infection Protection Rules for Containment of the spread of the coronavirus SARS-CoV-2 (Second Thuringian SARS CoV-2 Infection Protection Basic Ordinance -2. ThürSARS-CoV-2-IfS-GrundVO-) from 03/12/2021

...

§ 6 Use of a mouth and nose cover

(1) In closed public transport vehicles, especially in Railways, trams and buses, in taxis, in coaches and in others For public transport, passengers are obliged to have a mouth and nose Use coverage.

(2) In shops with the public, customers are obliged to use a mouth and nose Use coverage.

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(3) Notwithstanding paragraphs 1 and 2, there is an obligation to use a Mouth and nose covering not for:

1. Children up to the age of 6,
2. Individuals who are using a mouth and nose covering because of disability or is not possible or unreasonable for health or other reasons; This is to make credible in a suitable way,
3. Majorities of persons in accordance with Section 1 (2) in coaches and other means of transport according to paragraph 1, provided that they use the means of transport exclusively for themselves and no There is public traffic.

(4) As mouth and nose coverings, you can sew or make yourself Cloth masks, scarves, kerchiefs, hoods and head masks and other coverings of Mouth and nose are used. The mouth and nose covering should be snug and snug to sit.

(5) The prohibition of the use of anti-constitutional symbols and other prohibited symbols, in particular according to Sections 86a and 130 of the Criminal Code and according to the association law regulations, remains unaffected.

III. The specific situation of the children involved in their schools

The older son, the person involved in 1), has to attend school in Thuringia and is at the age of The 8th grade of the state regular school X in Weimar for 14 years. He falls into the Scope of the general ruling.

The procedural adviser submits that the party to 1) must be in the school building and in the Classroom wear a mask to his seat, then he is usually allowed to use the mask drop. Mask must also be worn in the schoolyard if the distance from 1.50 m could not be maintained. The students would be continually asked to do the

to wear a qualified mask in class all day, even though she is not yet 15 Years old.

In the week from March 8th, 2021 to March 12th, 2021 I even had one in physical education qualified mask must be worn. According to the headmaster, the child did wearing the mask all day.

Since it became compulsory to wear a mask, the person involved in 1) no longer likes going to school. He have a severe headache and often feel sick when wearing a mask. Light infections like Cold, slight cough, increased when he wore a mask. These infections would drag on also longer than usual. The participant to 1) is strong two to three times a week bad when he wears a mask. He usually has a headache after school and at the end

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of the day of class, but then so badly that he almost vomited Pain.

The party to 1) submitted a mask certificate on March 22nd, 2021. Then he was from his teacher discriminated against and insulted. He got in the back corner of the Classroom and was no longer addressed by name, but only with "You without a mask". On March 23rd, 2021 the headmaster then announced the Parents of party 1) called. He told them that the certificate of Participants to 1) had been noted, but not by the school the mask requirement exempt. The headmaster is responsible for granting a mask exemption, so the headmaster continues. According to the headmaster, a doctor could inform the participants about 1) not free, only the headmaster is responsible for doing this. According to the headmaster would have to all pupils from the 7th grade onwards wear a so-called qualified mask. In fact but if the masks were often not worn in class, these would be the ones Mask breaks.

The participant to 1) has to wear a mask in the school yard during the break or distance adhere to the fact that there should be no direct contact. He doesn't think that's great because that's the The only time he can talk to his classmates is.

A risk assessment does not take place.

The teachers did not pay attention to correct mask handling or changing Moisturizing the mask. In addition, the teachers did not explain anything about wearing a mask. The younger son, the person involved in 2), has to go to school in Thuringia and visits when he is old from 8 years the 3rd class of the state elementary school Y in Weimar. He falls into the Scope of the general ruling.

The procedural counselor submits that party 2) must have a cloth mask Carry the hose scarf in the school building and in the classroom to its place. On the On the way to lunch and in the dining room, a mask must also be worn until the person involved in 2) sits at the table with his meal. He'll have a meal time of Granted 15 minutes that he was not allowed to eat in peace. In the after-school facilities should the children also wear masks, so the daycare worker goes out a lot to close the mask times reduce.

No masks have to be worn in class at the moment, they are Mask breaks.

The person involved in 2) no longer likes to go into the mask since the obligation to wear the mask School. He had increased headaches, sometimes with nausea. In addition, the party involved to 2) often abdominal pain. Severe headaches and nausea come about one to one twice a week. The person involved in 2) had stomach pain about four times a month, then

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but also with vomiting. The person involved in 2) has a headache and malaise in temporal connection with wearing the mask, he usually had stomach pain at night. He cries in his sleep and sleeps very restlessly. In the school, the person involved dares to 2) not to say something when he is feeling bad.

The school management hadn't spoken about the problems because the parents were afraid against reprisals against their child and would have wanted to protect them.

A risk assessment does not take place. The teachers did not pay attention to a correct one Handling the mask or changing it when the mask is wet. The teachers also did not explain anything about wearing a mask.

The person involved in 2) had also already been snapped at by another teacher, he shouldn't wear a tube scarf, but a real mask. The party to 2) is then so disturbed that he now doesn't like going to school.

IV. Legal statements by the mother of the children involved in relation to her children rights, also from international conventions

In detail, the mother of the children explains that **children are independent of their age Bearers of basic rights** to physical integrity (emotional, spiritual, psychological), free Development of personality, respect for human dignity, i.e. non-violent upbringing, etc. Care and upbringing by their parents, etc.

Interventions in these basic rights - regardless of whether by private individuals or public officials caused - could not be assessed otherwise than an objective endangerment of the "**Child welfare**" within the meaning of §§ 1666 BGB, 157 FamFG.

The internal arrangement of the mask and the maintenance of spatial distance injuring other people as well as the underlying

Containment Ordinance of the Free State of Thuringia specifically basic rights of her and others Children in particular

- Art. 1 GG: respect for human dignity;
- Art 2 GG: on free development of personality and physical integrity;
- Art 6 GG: on upbringing and care by the parents (also with regard to Health care measures and to be borne by children "Objects").

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In addition, **children's rights and children's rights to protection are excluded** specifically violated **international conventions** ;

from the UN Convention on the Rights of the Child in particular

Art. 3 - The best interests of the child are to be given priority in all measures;

Art 16 - Prohibition of arbitrary or unlawful interference with private life, his Family, his home;

Art 16 para. 2 - to legal protection against assault;

Art 19 - on protection from physical and mental violence;

Art. 28 para. 2, 29 para. 1 - Schooling with respect for the human dignity of the Child,

Adherence to concrete goals of schooling;

Art 37a - Prohibition of torture, degrading treatment;

Art 37 d - special legal protection in the event of deprivation of liberty;

from the **Convention against Torture and Other Cruel, Inhuman or degrading treatment or punishment dated December 10, 1984 (Federal Law Gazette 1990 II p. 246):**

Art. 1

(1) For the purposes of this Convention, the term "torture" means anyone Act by which a person willfully great physical or emotional Pain or suffering are inflicted ...

Art. 2

(1) Each Contracting State shall take effective legislative, administrative, judicial or other measures to avoid torture in all its jurisdiction to prevent subordinate areas.

(2) Exceptional circumstances of any kind, be it war or threat of war, domestic political instability or any other public emergency may not be considered Justification for torture can be asserted.

(3) One issued by a superior or a public authority

Direction may not be used as a justification for torture.

Art. 4

(1) Each State Party shall ensure that, under its criminal law, all Acts of torture are considered criminal offenses. The same goes for attempted torture as well for acts committed by any person that may constitute complicity or Represent participation in torture.

(2) Each State Party shall threaten these offenses with appropriate penalties, which take into account the seriousness of the act.

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Art. 5

(1) Each State Party shall take the necessary measures to maintain its jurisdiction to justify the criminal offenses mentioned in Art. 4 in the following cases; from the **European Convention on Human Rights**

Art. 8

(1) Everyone has the right to respect for their private and family life, for themselves Apartment and their correspondence.

(2) An authority may only intervene in the exercise of this right insofar as the Intervention provided by law and necessary in a democratic society is for national or public security, for the economic good of Landes, to maintain order, to prevent crime, to Protecting health or morals or protecting rights and freedoms another;

by exceeding the limits set out in the **International Covenant on Civil and Political Rights of December 19, 1966 (Federal Law Gazette 1973 II 1553)** defined limits:

Art 4^[SEP]

(1) in the event of a **public emergency threatening the life of the nation** and which is officially promulgated, the contracting states may take measures that their Obligations under this pact **to the extent that the situation is unconditional requires** override, provided that these measures are their do not conflict with other international legal obligations and none Discrimination on the basis of race, skin color, sex, or gender alone Language, religion or social origin.^[SEP]

(2) On the basis of the above provision, Articles 6, 7, 8 (paragraphs 1 and 2), 11, 15, 16 and 18 are not overridden.

(3) Any State Party which has the right to suspend obligations exercises, the other contracting states through the agency of the Secretary General of To notify the United Nations immediately which provisions it shall override and what reasons prompted him to do so. Is on the same path by means of a further communication to indicate the point in time at which such Measure ends.

With regard to personal rights of freedom, see, for example, Art. 9, 12.

Art. 17^[SEP]

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(1) Nobody may arbitrarily or unlawfully interfere with his or her private life, his family, his home and his correspondence or unlawful Be exposed to damage to his honor and reputation.

(2) Everyone has the right to legal protection against such interference or Impairments.

The family court is obliged to take ex officio measures to end further unlawful violation of these rights to be guaranteed to the child.

An encroachment on these children's rights under the Basic Law and international conventions

Regardless of who initiated the intervention, it cannot be assessed differently than

an objective threat to the "best interests of the child" within the meaning of §§ 1666 BGB, 157 FamFG.

If the law is not least due to Art. 2, 1 and 6 GG in § 1631 Abs. 2 BGB parents forbid certain forms of upbringing and this is a punishable offense in §§ 223 ff, 171 StGB place, a similar treatment could not be legitimate just because it was through or im Commissioned by state officials. This will not last too by tightening the threat of punishment for violations of the law by public officials underlined.

After that, every restriction of the special rights of the child is required Basic Law or international conventions of special justification, so it is subject to the constitutional requirement of the in every single area Proportionality.

In this respect, what the Federal Constitutional Court and the Federal Court of Justice on the admissibility of a child's separation from their parents would have carried out:

BVerfG v. 24.3.2014 - 1BvR 160/14 - ZKJ 2014, p. 242 ff:

It cannot be ascertained with sufficient certainty that the separation of the Children is suitable to eliminate the dangers assumed by the courts or mitigate. The separation would be suitable in principle, according to the opinion the courts of the mother for the children existing dangers

remove. However, the separation of the child from the parents gets regular independent burdens emerge because the child is under the separation even then can suffer if his well-being was not assured with his parents. A measure

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cannot simply be considered suitable for safeguarding the best interests of the child if it for its part can have negative consequences for the child's best interests. Such negative Consequences of a separation of the child from its parents and out-of-home care are to be taken into account (cf. ...) and would have to be removed by eliminating the Danger to be outweighed, so that the situation of the child in the Overall view would improve (see BGH XII ZB 247/11 of October 26, 2011) (Pp. 244,245)

From the BGH decision v. October 26, 2011 - Az: 12 ZB 247/11 = ZKJ 2012, 107 ff: ... The suitability is not only lacking if the measure poses a risk to the Can not eliminate the best interests of the child. Rather, the measure is even then unsuitable if they are related to other impairments of the child's wellbeing goes hand in hand and does not do this by eliminating the identified hazard outweighed

become unsuitable if they turn to other concerns of the child's best interests

a

Creates a risk situation and therefore none in the overall view Improvement in the situation of the child at risk. (ZKJ p. 109)

According to these principles, an intervention is only permissible if **before a restriction of the Fundamental rights of** the child regardless of the dangers to be averted for the child (or others) a concrete consideration of the possible risks to the child has been made, the specific orders and measures implemented in defense threatened.

Measures would have to be omitted if there were no concrete findings which result in a legally considerable preponderance of the dangers to be averted. According to this, it cannot be assumed that there is an entitlement to restrict fundamental rights become.

There is a lack of a comprehensible determination of existing specific dangers for Higher value legal interests of others through children (see e.g. **Reiss, Bhakdi: Corona False alarm? GOLDEGG 2020**) as well as a specific determination of the by the Measures even for the children concerned to be expected dangers like at one concrete balance between the two.

For further details of the suggestion, reference is made to the brief of March 13, 2021 referenced.

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V. Legal notices from the court to those involved and the decision to take evidence in the parallel main proceedings

The court issued detailed legal information on March 16, 2021 and this on Updated March 25, 2021. The Free State of Thuringia as well as the lines of the children schools visited were involved in the process.

The Free State of Thuringia and the school administrations involved were with the legal Notices encouraged to all raised in the suggestion about this procedure

Questions and in addition to the questions listed below in detail

Comment in the updated version of 25.03.2021 as follows

had:

"In the statement, for all questions for all actual allegations, the scientific evidence and substantiated with the indication of accessible sources become.

1. What goals does the Free State of Thuringia pursue with the measures, in particular the Mask requirement for students and the distance regulations that apply to them exactly?
2. Are the benefits of these measures in relation to the spread of the SARS virus? CoV-2 proven based on evidence?
3. Have the possible physical effects, in particular of the mask requirement, been but also the distance regulations for children checked based on evidence, in particular also with regard to the different tidal volumes of adults and Children? Which results are based on which studies and sources Free State of Thuringia got here?
4. Have the possible psychological effects, in particular of the mask requirement, been but also the distance regulations for children checked based on evidence? Were there the possible consequences due to the possibility of reduced communication, possible dangers through distorted perception of facial expressions and emotions and potential dangers for psychosocial development examined? To which The Free State of Thuringia is included in the results based on which studies and sources got?
5. Has the proportionality of the measures in terms of benefit (both for the schoolchildren themselves as well as for third parties) against the possible negative Has the impact on school children and third parties been checked and assessed in a comprehensible manner?
6. How is the infection rate with the SARS-CoV-2 virus determined?

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7. If the RT-q-PCR test is used for this purpose: which test or tests (Manufacturer / test name) is / are carried out in the laboratories in Thuringia? How are the laboratories that carry out the test accredited? What test controls are used? How do the authorities monitor the reliability of the Test execution? Are independent round robin tests carried out on a regular basis?
8. How many gene segments and which were and will be in the RT-q-PCR test in Thuringia examined? Up to which amplification / doubling steps (ct-Value) was and is the test in Thuringia assessed as "positive"?
9. Is the RT-q-PCR test capable of producing and disseminating a To detect the SARS-CoV-2 virus?
10. What is the sensitivity and specificity of the RT-q-PCR tests used? on? As far as is known, these parameters were in practice by a German Institution only once based on a test design recognized for an interlaboratory test determined, namely by INSTAND, a society for the promotion of Quality assurance in medical laboratories eV, among others with the WHO cooperates. This comes in her 51-page "Comment on Extra

Interlaboratory comparison group 340 Virus Genome Detection SARS-CoV-2 “by Prof. Dr. Heinz Konstruhardt, Charité - Universitätsmedizin Berlin, and Dr. Martin Kammel - in Cooperation with the Charité, Universitätsmedizin Berlin, Institute for Virology, the National consulting laboratory for coronaviruses Prof. Dr. Christian Drosten, Dr. Victor M. Corman et al. - from 2.5.2020, updated on 3.6.2020, with regard to the Specificity of the PCR test for a **false positive rate between 1.4% and 2.2%**; the “outliers” have already been eliminated by interchanging them. Becomes this false positive rate taken into account when calculating the "incidences"? (Note on this: There is another round-robin test by instant eV, which is carried out in June / July 2020, but the results are not publicly available are.)

What remains when including this false-positive rate between 1.4 and 2.2% - this should be presented verbally and mathematically - assuming more realistic Are prevalences of the "incidences" currently reported for Thuringia still left? <https://www.instand-ev.de/ringversuche-online/ringversuche-service.html#rvp//340/-2020/>

11. What exactly is meant by “incidence”? As far as the court knows, this means Term the occurrence of new diseases in a (repeatedly tested) defined group of people in a defined period of time, while after the The court actually provided information about the tests carried out

18th are based on undefined groups of people in undefined periods of time, with which the so-called “incidences” would only be simple reporting rates. If so: how does it work this affects the informative value of the tests with regard to the infection process out?

12. Is the WHO Information Notice for IVD Users 2020/05 noticed? Then, if the test result does not match the clinical findings of an examined match, a new sample is taken and carried out a further examination and carried out differential diagnostics become; only then can a positive test be counted according to these specifications. <https://www.who.int/news/item/20-01-2021-who-information-notice-for-ivd-users-2020-05>

13. Ensures that people tested multiple times are not considered newer each time "Fall" are counted? How does this happen?
14. How does the additional introduction of rapid tests affect the determination of the Infection process? Become the ones who tested negative in the rapid tests also recorded in figures? How to ensure that the combination of positive rapid test and negative RT-q-PCR test are then not considered "positive" in the Statistics appears or rated “positive” only once as “positive” in both tests will (analogous to question 13)? Be for finding a realistic one Infection rate also included those who tested negative in the rapid test?

15. Does the other party assume that the person tested positive asymptotically be contagious, i.e. can pass on the SARS-CoV-2 virus? If so is asked to quantify this and provide the scientific evidence to support it to name. The study published on November 20, 2020 from Wuhan, China, will also be noticed with around 10 million participants? The researchers for this study came to the result that the detection rate of asymptomatic positive cases in Wuhan after the previous lockdown it was very low at 0.303 / 10,000 and it there is no evidence that the identified asymptomatic positive cases were infectious at all. <https://www.nature.com/articles/s41467-020-19802-w>

16. Does the other party assume that the person tested positive presymptomatically be contagious, i.e. can pass on the SARS-CoV-2 virus? If so is asked to quantify this.

17. How high is the infectivity of those who have tested positive symptomatically?

18. Is currently still being tested for other viruses, such as influenza,

wanted and also tested for it? "

19th

With a resolution also dated March 25, 2021 in parallel main proceedings 9 F 147/21 a collection of evidence was ordered. As regards the questions of evidence, the decision has the following Content:

“Proof of the questions listed under I. below should be obtained by Obtaining written expert reports.

The appraisal should expressly include the information contained in the updated legal information of the Court of 25.03.2021 should be included.

I.

Evidence should be obtained on the following questions:

1. Wearing face masks of different types can do that Reduce the risk of infection with the SARS-CoV-2 coronavirus (significantly)? It should be between children in particular and adults in General and between asymptomatic, presymptomatic and symptomatic people can be distinguished.
2. What damage can be physical, psychological and educational caused by the wearing of masks, especially with children?
3. Is there any risk of infection from wearing Face masks (or other measures) could be lowered?
4. Can reduce the risk of infection by observing distance regulations be lowered especially in children?
5. May even provide children with a "protective function" from spreading with the coronavirus SARS-CoV-2 in the sense that they prevent the spread of the Tend to slow down the virus and more likely to prevent severe Covid-19 diseases protect?
6. Which methodological level and, if applicable, which methodological shortcomings have existing studies on infection processes in schools and on the Effectiveness of measures such as wearing a mask and keeping your distance Schools on?
7. What is the significance of the detection of an infection with the coronavirus SARS-CoV-2 is provided by the RT-q-PCR test and those currently used Rapid tests? "

20th

To reviewers for the questions on I.1. - 6th were Mrs. Prof. Dr. med. Ines Kappstein and Prof. Dr. Christof Kuhbandner ordered. To the expert for question I.7. became a woman Prof. Dr. rer. biol. hum. Ulrike Kämmerer appointed.

Prof. Dr. med. Ines Kappstein, hygienist, is a specialist in microbiology, virology and Infection epidemiology and specialist in hygiene and environmental medicine. Your habilitation took place in the subject of hospital hygiene. From 1998 to 2006 she was at the clinic on the right Isar at the Technical University of Munich. From 2006 to 2016 she was chief physician in the department Hospital hygiene at the Kliniken Südostbayern AG in the districts of Traunstein and Berchtesgadener Land. Since 2017 she has been looking after several acute, specialist and rehabilitation clinics in self-employed.

Prof. Dr. Christof Kuhbandner is professor of psychology, holder of the chair for educational psychology at the University of Regensburg and an expert in the field scientific methods and diagnostics.

Prof. Dr. rer. biol. hum. Ulrike Kämmerer represents at the University Hospital Würzburg, Women's clinic, in particular the focus on human biology, immunology and cell biology.

VI. Opinion of the procedural adviser

The lawyer appointed as procedural counsel has with a brief dated April 6th, 2021

Extensive on almost 170 pages on all factual and legal questions
Commented. Reference is made to this for further details.

VII. Comments from the other parties involved

A statement from the Free State of Thuringia and the children's schools is available within the
The deadline set in the interim injunction proceedings here has not taken place.

VIII. Expert opinion by Prof. Dr. med. Ines Kappstein

Prof. Dr. med. Ines Kappstein, hygienist, is a specialist in microbiology, virology and
Infection epidemiology and specialist in hygiene and environmental medicine. Your habilitation
took place in the subject of hospital hygiene. From 1998 to 2006 she was at the clinic on the right
Isar at the Technical University of Munich. From 2006 to 2016 she was chief physician in the department
Hospital hygiene at the Kliniken Südostbayern AG in the districts of Traunstein and

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Berchtesgadener Land. Since 2017 she has been looking after several acute, specialist and rehabilitation
clinics in
self-employed.

The reviewer submitted her report, which is inserted in full here, as follows:

I will comment on the questions of evidence, as far as I understand them from my professional
Background of the protection against infection - with special consideration of the transmission
of infectious agents and the development of infections - can treat. This is true
to questions **1** and **3**, which are summarized in **Part A.**, **Part B.** and **Part C.** of the
Expert opinion, as well as to question **4.** to.

The digits [] refer to the list of references (in the order they appear in the text
appear).

I would like some information to make the report easier to understand
send ahead:

1. For work in **hospital hygiene** (= prevention of infections in
Connection with the medical care of patients, so-called nosocomial
or hospital-acquired infections) one must have knowledge of the
Routes of transmission of infectious agents have made up in individual cases
Have the necessary infection protection measures (so-called hygiene measures) taken.
Hand hygiene (usually as hand disinfection) plays the biggest role in this.
Masks (as so-called OP mask = surgical mask) are outside the OP department
so far it has been used comparatively seldom and then only occasionally at close ones
face-to-face contact in patients with respiratory infections. FFP masks (usually as
FFP2 masks) were almost exclusively used by patients upon entering the room
open airway tuberculosis (or bronchoscopy of
Patients with suspected tuberculosis).

2. The **transmission routes** of infectious agents can be summarized as a brief overview
as follows (further explanations follow in the course of the
Expert opinion):

(a) Contact. (1) Pathogen transmission **through direct contact** (= body contact) of a
infected with a non-infected person. (2) Pathogen transmission **through indirect
Contact** through shared objects or surfaces that were previously used
an infected person or who have been infected with infectious material
Person was contaminated and subsequently by a non-infected person
to be used.

Both in direct and indirect contact, the pathogens mostly get through
only on the skin of the (yet) uninfected contact person, especially on the hands.
Respiratory viruses must then be sent to their port of entry in the area of the
Mucous membranes of the upper respiratory tract (eyes, nose, mouth) are brought. This
usually happens through frequent and mostly unconscious hand-
Facial contacts. There is probably a quick sequence of the various steps
necessary so that there is an effective transmission of infectious pathogens with
subsequent infection of the contact person can occur. Such contacts distinguish it
People living together, especially in their private lives, but also, albeit less,

in the public area. Whenever several people are in a confined space are together for a longer period of time (e.g. breaks between colleagues, celebrations),

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need direct and indirect contact as well as droplets (see below) as Transmission routes should be considered.

(b) droplets. Special form of contact transfer through droplets ($> 5 \mu\text{m}$ in Diameter) respiratory secretions with close face-to-face contact ($< 1 - 2 \text{ m}$) with a Duration of at least 15 minutes between an infected and a non-infected Person.

It is about situations, for example, in which two people are at a distance of less as $1 - 2 \text{ m}$ vis-à-vis = face-to-face or from face to face

face to face and talk to each other. In principle, it is possible that the Speak to the respiratory droplets released by the infected person

Mucous membranes of the face of the person opposite and not (yet) infected (Eye, nose, mouth), so that the pathogens are transmitted in this way.

Contact transfer and droplet transfer have prevailed for decades

the basis of epidemiological studies as the decisive transmission routes for respiratory pathogens.

(c) air. Inhalation of infectious particles floating freely in the air ($< 5 \mu\text{m}$ in diameter)

Transmission of pathogens through the air (airborne transmission) has so far only applied to the Tuberculosis of the respiratory tract (lungs, larynx) as significant and is associated with tuberculosis even the only natural way of transmission, but only if the infected

Person has what is known as open tuberculosis of the respiratory tract, causing the release of the Tubercle bacteria come through the breath of the infected person. That with

The air of the room is contaminated by the pathogens of tuberculosis at the same time inhaled by people present (or by people who have just entered the room,

after the infected person has left it). Floating in the air

Tubercle bacteria can penetrate into the alveoli (alveoli), and

This is exactly where these pathogens have to get to in order to trigger tuberculosis at all to be able to. But whether other people who breathe this room air, the for the

Occurrence of an infection have necessary pathogen contact depends, among other things, on the

The size of the room and thus its air volume and the ventilation of the room

and thus of the dilution of the pathogen in the air and, last but not least, of the

Amount of the pathogen released by the infected person, e.g. when coughing (or released) and thus the likelihood that other people will be involved in the

Inhalation come into contact with contaminated air.

Exactly this transmission route was established in spring 2020 soon after the appearance of

Sars-CoV-2 postulated as an important transmission route for this new pathogen. in the

The course of 2020 is the idea of the so-called aerosol transmission of SARS-CoV-2

in international specialist literature as well as in the media - but not supported

through corresponding pronouncements by the international health authorities - see above

has become dominant that for months now various 'hygiene measures'

are required (e.g. air purification devices, ventilation) in order to reduce this allegedly high risk

reduce (see **part C.**). It has been about influenza viruses for years

discussed whether they might also be transmitted through the air, but it was found for it

no confirmation. In fact, influenza in hospitals was never used

Measures to protect against the transmission of pathogens have been established that affect the transmission

aimed via air. This has seen and still see, for example, the recommendations of the RKI not before.

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3. A large number of results from studies on the effectiveness of non-pharmaceuticals

Interventions to contain the pandemic, such as masks in particular in the Public, are based on **mathematical modeling**, their peculiarities should be briefly presented here:

Mathematical modeling (also called mathematical estimating) is from known from weather forecasting and climate research, but have been known for many years also used to track the course of epidemics and the influence of various Predict preventive actions. They are especially used when there is there is little meaningful data from direct investigations. With one very A large part of all studies on SARS-CoV-2 (e.g. effectiveness of masks) are about mathematical modeling, which has only a very limited informative value, because their results do not reflect 'real' life, but on assumptions are based. The results depend on these 'adjusting screws', which is why a reproduce a simplified picture of reality. Such studies can therefore always only deliver 'if-then results'. There's pure on one side of the spectrum theoretical models and, on the other hand, those in which with so much clinical-epidemiological data, as is available, is being worked on. But it always has The result is very limited, and the quality of the scientific The evidence is moderate at best. The results of such studies related to However, SARS-CoV-2 are often far in their significance for reality overestimated and, if the result is positive, as proof of the effectiveness of measures taken. This could be observed repeatedly in the course of the pandemic, and even with scientifically active doctors and bio-scientists.

Answering the questions of evidence

1. Wearing face masks of different types can reduce the risk of infection with the Coronavirus SARS-CoV-2 (significantly) lower? It should be between children in Particular and adults in general and between asymptomatic,

A distinction is made between presymptomatic and symptomatic people.

3. Is there any risk of infection that could be caused by wearing face masks (or other measures) could be reduced?

A. Masks

It is presented in this section, which specialist literature for the effectiveness of masks in public (e.g. shops, public transport, schools, offices, etc.), which

There are published studies that speak against the effectiveness of masks and what statements on pathogen transmission based on asymptomatic, presymptomatic and symptomatic persons are possible. All statements apply to Adults, teenagers and children alike.

The 'reassessment' of the RKI: What were masks based on?

This was the background and basis for the introduction of the mask requirement everywhere in Germany the so-called ' *reassessment* ' by the Robert Koch Institute (RKI) [1].

The 'reassessment' of the RKI resulted in masks not being used to protect the wearer (= *Self-protection*), especially as for the medical staff in patient care in the hospital), but to protect fellow human beings (= *external protection*; English *source control*, i.e. to protect other people from the source of the pathogen),

but not for people with symptoms of upper respiratory infections (Sore throat, runny nose, cough), but from - clinically - healthy people (who People with symptoms should stay at home anyway).

The RKI recommends masks in public ('... *as a further building block to To protect risk groups ...* ' [1]) so that the wearer of the mask may already is infected unnoticed and excretes the pathogen in the respiratory secretion, his cannot release respiratory droplets unhindered, e.g. when speaking. The Droplets should be retained by the mask to a substantial extent, so as to prevent other people from coming into contact with the pathogen.

All people should therefore wear a mask so that *the* (few) people who are already infected but do not yet (cannot) know because they do not have any symptoms

have (presymptomatic) or will not develop at all (asymptomatic), *all* other people they meet through their mask in front of a possible one Protect the excitation contact. Ultimately, directly or indirectly, in particular the People are protected who are due to old age and / or certain chronic diseases have an increased risk of severe infection from SARS-CoV-2 because it is well known that the virus poses no danger to all other people (das According to the current state of knowledge, this also applies to the new variants), because they either, as with typical of influenza, become seriously ill for one to two weeks and lie in bed have to (with fever, body aches and cough, for example), but in most cases they do develop only mild respiratory symptoms (as with a common cold) or not even get sick at all.

About the possible use of masks to protect fellow human beings (*external protection*) clinically healthy, but already infected and therefore potentially infectious people an international discussion developed in the specialist public in spring 2020 that masks are not out of self-protection, but out of '*altruism and solidarity*' (= *External protection*) should be worn [2]. This ultimately led to the mask recommendation of the RKI, which is about '*third-party protection*' - and not about self-protection especially by people from risk groups. That was true at least until January 2021. That self-protection also plays a role because of the new variants of the virus, was only then emphasized by politics, and thus the obligation was established instead of the everyday masks made of fabric, medical masks (surgical mask or FFP2-Makse) to wear. For all people who do not have to deal with how professionally Infectious agents are likely to be transmitted using masks as protection from a respiratory tract Virus can be quite plausible, with the self-protection principle always leading is.

At no point in the article about the 'reassessment' does the RKI expressly state that it a scientific basis (in the sense of scientific evidence or evidence = engl. evidence) for the use of masks in public [1]. These The text with its ambiguous formulations merely suggests a conclusion. The The RKI's contribution was published online in advance, as is common practice today in specialist journals,

on April 14th, immediately after Easter 2020. So the Opinion of the RKI for the Federal Government's decision on the Easing measures of the first lockdown, which will be for a week after Easter 2020 were announced, available in good time. The article was not printed until May 7th 2020, about a week after the introduction of the mask requirement (and this date is - see below - still relevant). It is interesting that the President of the RKI on April 28th

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2020, i.e. on the day of the federal government's decision to wear a mask, all in one Interview with the 'Deutsches Ärzteblatt' spoke of the '*low added value*' of masks which, however, only comes into play if they *are used correctly*' [3].

The official presentation of the RKI's mask recommendation in [1] soon became something modified, because just six days after the print version of the article on May 7, 2020, the RKI commented on May 13, 2020 under the heading '*Answers to frequently asked Questions (FAQ)*' on third-party protection through masks cautious:

'A protective effect has not yet been scientifically proven, but it does appear plausible.'

However, it did not stay that way, because it has been there since July 15th to read:

'For this third-party protection by MNB (= mouth and nose covering) there are now first scientific evidence.'

This representation is still up-to-date, most recently in the version dated February 17, 2021.

However, clues are not evidence. The question arises: what are '*first scientific evidence*' and also: why '*meanwhile*'? The supporting documents should be in themselves

had already been given with the publication of the mask recommendation [1]. I have therefore via e-mail from 07/19/2020 to the RKI according to the statement on which this statement is based

scientific literature and received a list as an email from July 21, 2020 of publications, which I will deal with in the further course of the report.

In the following, I would like to begin with the recommendation of the RKI [1] based on the ones cited therein

Evaluate specialist literature. Then the newer publications are presented, i.e. the only appeared after the RKI article and by scientists as well as by the Media were cited as evidence of the effectiveness of masks in public.

Finally, the publications are compiled that do not use masks have found.

The RKI recommends in its contribution

, A general wearing of a mouth and nose cover (MNB) in certain Public situations as a further building block to risk groups too protect and the infection pressure and thus the speed of spread of Reduce COVID-19 in the population '.

This recommendation is based

' On a reassessment due to the increasing evidence that a high proportion (Emphasis for this report) of transfers took place unnoticed, and even before the symptoms of the disease appear '.

In its contribution, the RKI speaks of the fact that a *' high proportion of transmissions unnoticed 'successes*, but does not refer to a source. In the literature list of the However, there are two publications on which the RKI refers in its statement probably related (and perhaps only the literature references were included in the text to forget). On the one hand, it is a mathematical estimate, according to which the Presymptomatic transmission was very high, namely between 48% and 77% should have [4]. The result of the second publication is also a mathematical one

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Estimate based on a very high presymptomatic transmission rate of 79% [5].

On the RKI website, it says under *FAQ > Infection protection measures > What is to consider when wearing an MNB in public?* 'from July 15th and August 21st then no longer a *' high proportion '*, but only a *' certain proportion '*, to finally be in the FAQ since on September 7 (last in the version dated February 17, 2021) of a *' relevant portion '* speak (emphasis placed on this report). References are not there available (and are also not common in the FAQ).

However, the RKI will provide a reference to the literature in a later article (online in advance on 23.09.2020) [6]. In this post, titled *' Weighing the Duration of Quarantine and Isolation in case of COVID-19 'states:*

' For example, He et al. Demonstrated that presymptomatic transmissions for a large part (44%) of SARS-CoV-2 transmissions are responsible ... '.

In the cited publication by He et al. a mathematical estimate is made based on assumptions about the viral load in the respiratory secretion before the occurrence of Could distribute symptoms [7]. This article was published on August 17, 2020 (i.e. a good 5 Weeks before the online publication of the new RKI article [6]) a critical opinion published, to which since then when the article by He et al. right before the start of the Text is pointed out. In it the authors state the following [8]:

' In terms of larger COVID-19 studies that calculated the proportion of presymptomatic versus post-symptomatic spread, a study examining 468 COVID-19 cases in China found that 12.6% of transmission occurred prior to symptom onset [Ref]. Likewise, contact tracing studies of 157 locally acquired cases in Singapore identified 10 cases of presymptomatic COVID-19 transmission, but this only accounted for 6.4% of transmission events [ref]. Although many factors are involved with transmission efficiency, it appears that asymptomatic / presymptomatic transmission measured by

direct contact tracing studies [Ref] is lower than that predicted by COVID-19 transmission models [ref]. ([Ref] stands for the references in the quoted Items).

It follows from this: When evaluating real contact scenarios, significantly fewer were found Rates of presymptomatic transmission, such as 12.6% (China; published in June [9]) or 6.4% (Singapore; already published in April [10]. In the mathematical estimates [4, 5, 7], which the RKI cites in [1, 6], are theoretical results that are compared results from reality are significantly higher (see below).

Evaluating contact constellations from contact tracing studies is tedious and tedious. When it comes to clarifying such questions, however, what really matters is real Evaluate scenarios, because this also makes it clear what type of contacts it acted. In the study from Singapore it was found that in 7

Contact evaluations 3 x (married) couples and 1 x a member from a shared apartment of a presymptomatic pathogen transmission were affected, i.e. situations with tight Long-term contact, in the case of the couples even with contact with the mucous membrane [10]. In such Life situations are with presymptomatic (as well as asymptomatic) Transfers to be expected (and yet they are rare; see below). It is different with the usual contacts in public space between people who are not (see above) come close or at most briefly pass each other or stand behind each other.

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In its article [6], the RKI neither considers nor cites the critical article [8], the was published long enough before the RKI's online advance publication in mid-August, the RKI is still referring to the studies from China that were published even earlier (published in June 2020) [9] and / or Singapore (published on April 1, 2020) [10], which in cited in the critical contribution [8]. The RKI does not adhere to the rules of the evidence-based medicine, all available data from scientific

Include investigations in his considerations. Instead, the RKI only appeals to a single investigation, which was theoretically determined from a model calculation and has achieved a very high rate of presymptomatic transmission. Those from real scenarios in The tracking of contacts found transfer rates that are much lower are not listed. This increases the risk of presymptomatic,

So 'unnoticed' transmission high, and that was exactly the reason, according to the RKI for the ' reassessment ' (' high proportion '). It is after that which has been established for decades Rules of (in Germany so-called) evidence-based medicine are incomprehensible that the RKI the critical opinion [8] and the ones cited therein, but months earlier published articles from China [9] and Singapore [10] are not mentioned and therefore not discussed.

The same can be said of a published in mid-September 2020 (according to the name systematic) review by other authors, which is included in the COVID-19 profile from the RKI is quoted [11]. Not only is there a lack of relevant literature on the subject in question (so that it is de facto not a systematic review), which is about material

fewer asymptomatic or presymptomatic transmissions were reported, but rather it all results are presented together, without any epidemiological information To differentiate between context: There is, however, a significant difference between whether a Pathogen transmission occurs in families where there is close physical contact and mucosal contact the rule is, or in public places, where there is such contact among people in usually does not come. It is therefore important in such examinations that to evaluate the respective settings separately.

In any case, in scientific discourse (and especially in systematic reviews) inadequate if cited selectively, because a selective one, and thus at least potentially Interest-guided selection of publications is not one of the established ones today scientific principles. Thus the basis for the ' re-evaluation ' of the RKI is missing , because the ' unnoticed transmission ' is not justified by scientific data is, and that was already the case when the RKI article appeared online in April 2020 [1]. Indeed was discussed at the same time internationally (e.g. CDC) on the topic, so that the

RKI certainly simply joined this trend [12].

Namely, that infected people can potentially be infected even before the symptoms of the disease begin are infectious (and as a rule excrete more viruses than during the symptomatic phase of the disease), has long been affected by other viral infections known, the pathogens of which are also excreted via the respiratory secretion (e.g. influenza, measles). That this is also the case with an infection with the new coronavirus The case is, therefore, nothing new or expected in itself for the professional world. Since the middle February was also in view of the new coronavirus about it in the international literature reported (compilation in [13]). This also applies to everyone respiratory infections that are asymptomatic (e.g. in influenza in about 1/3 of the Cases; see RKI guide), so these people are also potential or principally infectious.

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In reality, this only means that it is possible, but not that these people inevitably also spread the respective pathogen: About the extent of the (' *unnoticed* ') Spreading of pathogens with presymptomatic or asymptomatic virus excretion there is now more data showing that it is only a small proportion (see below).

A WHO scientist, Dr. Maria van Kerkhove, spoke at a press Briefing of the WHO in Geneva on June 8th, 2020 as follows [14]:

' From the data we have, it still seems to be rare that an asymptomatic person actually transmits onward to a secondary individual '.

And further:

' We have a number of reports from countries who are doing very detailed contact tracing. They're following asymptomatic cases. They're following contacts. And they're not finding secondary transmission onward. It's very rare '.

And these are the kind of contact tracing studies discussed above. One

The day after, a certain clarification followed by the same WHO employee [15]:

' The majority of transmission is from people who have symptoms and are spreading it through infectious droplets. But there is a subset of people who don't develop symptoms. To truly understand how many people don't have symptoms, we don't actually have that answer yet '.

So even if the WHO employee took her clear position from June 8th, 2020 on

The following day relativized something but did not revise it, the WHO stated that namely, most transmissions come from people who have symptoms, and that it is not clear how many transmissions are due to people who (yet) do not Have symptoms.

Overall, the virus excretion before the onset of clinical disease is therefore nothing New, but would also have been considering the new corona virus from the start can be included. However, it was implicitly represented by the RKI as if it were has been unpredictable (' *increasing evidence* ' [1]), and has been promoted by the media picked up, like so many other things, without asking how it actually works with other viral infections, which would have been obvious.

It has long been known that numerous viral infections (incidentally also with Gastrointestinal infections, e.g. caused by noroviruses, in which the pathogen is excreted via the Bowel occurs) the infectivity does not start with the appearance of clinical symptoms, rather, infected people can excrete viruses at the end of the incubation period and in large numbers, if you don't even know that you are a

Have an infection (and will be sick the next day, for example). For one numerically

' Relevant' (according to the RKI since September 7, whatever the term is meant) role of

There are pre- or asymptomatic persons in the transmission of the new coronavirus

but no evidence. This is very likely due to the fact that in infected people

without the clinical symptoms of an upper respiratory tract infection, i.e. without a cough and

Sneezing, a transmission of pathogens takes place especially when there is close contact, in other words in particular

with mucous membrane contact, as in couples and in families, but usually not with the mostly very short encounters of people in public space as well as not in schools. The theory of aerosol transfer is presented and discussed in **Part C**.

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As an important example of transmissions based on asymptomatic resp. In spring, the outbreak at the Webasto company occurred in presymptomatic persons Munich cited [16]. The authors of the - in the New England Journal of Medicine (NEJM; next to *The Lancet* one of the two most respected medical in the world Trade journals) very prominently, even if only as a 'letter to the editor' (but quickly because without peer review) - the study assumed that the Chinese employee (the so-called index case or patient 0), who shortly before Shanghai arrived and was already infected, none during her stay in Germany Had symptoms. However, this became apparent just a few days after the publication of the Publication as inapplicable and was approved by a Science journalists made public [17]. According to the state of health of the Chinese employees, the authors only had the German employees of Company on site and not interviewed them. First the Bavarian State Office for Health and Food Safety (LGL) and the RKI took part shortly after the publication contact her directly. During the telephone conversation (with a Chinese interpreter) posed it turns out that the employee from China did during her stay in Germany was already (slightly) symptomatic and right at the beginning a single pain and has taken an anti-inflammatory agent (paracetamol) [18]. This first Publication on the case therefore had to provide an exact description of her State of health during the stay in Germany. Since if you call up the article at the NEJM, there is also a corresponding one Supplement. The title of the article has remained the same and thus still lays a 'Asymptomatic' transmission close. Also and especially with this, so only apparently In asymptomatic cases, the mask requirement was established in Germany. In the few Then published months later the full description of this outbreak was not there is more talk of asymptomatic contact [19]. Another article (systematic review with meta-analysis as Preprint, in December as the final publication) on the proportion of asymptomatic cases all cases and about the extent of asymptomatic transmission appeared [20]. As a result, asymptomatic transmissions were very rare (between 0% and 2.2%) and symptomatic transmissions more often (between 2.8% and 15.4%), but in 4 Of the 5 studies with a maximum of 5.1%, they were also rare, so they were definitely less frequent, than one would expect in symptomatic individuals. The relative risk asymptomatic transmissions was when evaluating these five studies that covered reported secondary infections in asymptomatic and symptomatic individuals, based on asymptomatic cases, 42% less than for transmissions starting from symptomatic cases. The authors conclude that it is Asymptomatic transmissions are unlikely to be a major driver in the Formation of clusters (temporal and local accumulations or outbreaks) or during the Transmission of the infection in public, and therefore should be the meaning Asymptomatic cases for the spread of the infection should be viewed with caution. The The authors also criticize the unclear definitions of asymptomatic cases in the Studies that evaluated them. This could namely lead to asymptomatic Cases are mixed with less symptomatic cases (see above [16]). Would that occur frequently, then the frequency of true asymptomatic cases would be clear lower and thus also their share of transmissions. At the end of November 2020, a study from China was published about the result a PCR screening program across Wuhan between May 14 and June 1, 2020

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reported [21]. Almost 10 million (!) People were examined. New symptomatic cases were not found, but 300 asymptomatic persons were found. Under The close contact persons of these asymptomatic persons (N = 1,174) could not be found positive case. So there was no evidence of asymptomatic transfers, though only close contact persons were examined.

A systematic review with meta-analysis of corona transmissions in households appeared in December 2020 and, as expected, resulted in a higher transfer rate based on symptomatic index cases (18.0%) than based on asymptomatic cases in which the transmission rate was only 0.7% [22].

This result is of particular interest because (albeit from different reasons) there is consensus that the risk for respiratory Pathogen transmissions particularly high indoors and outside of buildings, ie in the 'fresh' air, is negligible, but was nonetheless asymptomatic Transmission rate in households is extremely low, although it is in a relatively small space with numerous direct (also via skin and mucous membranes) and indirect contacts lives together and thus can hardly avoid contact with the pathogen if a Member of the household is infected. So if the pathogen transmission is based on asymptomatic persons should play a role, this should be particularly important in tight, ie show close skin and mucous membrane contacts in households (= interior rooms). How but then the risk that a pathogen is transmitted from asymptomatic persons takes place in the casual contact in public space, has never been investigated. Nevertheless, despite this data situation, just under 80 Millions of people in Germany on numerous occasions in public, even outside of enclosed spaces (and this is even used by aerosol physicists for kept pointless; see **part C.**), wear masks.

In January 2021, another mathematical guess appeared on the question of how often asymptomatic people transmit the new coronavirus [23]. The authors come up the basis of their assumptions on the result that at least 50% of all new SARS-CoV 2 infections are based on contact with asymptomatic people, so a result like often in modeling studies: high transfer rates, but not real ones Contact evaluations.

Another review (so-called 'living systematic review', ie for which regular updates are planned are) was submitted in September 2020 and accepted in January 2021 [24]. The international team of authors wanted to determine the likelihood of infection People with different symptom status are infectious for contact persons, so that there are secondary cases with evidence of SARS-CoV-2. For rate analysis of secondary cases originating from asymptomatic persons, 10 studies were able to do so can be evaluated, resulting in an overall transmission rate of 1%. At In symptomatic cases, the overall transmission rate was 6% and presymptomatic cases in 7%. Also this evaluation of studies from the real one Life again showed that starting from asymptomatic individuals significantly less secondary cases arise as symptomatic or presymptomatic, but those were also rarely associated with secondary cases. Most of the transfers were possible can be traced back to the fact that the secondary affected cases with the index cases lived together or that the pathogen transmissions to group activities, such as shared meals or board games, went back, all of them with situations again direct contact, indirect contact or contact with droplets (vis-à-vis <1 - 2 m).

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The likelihood of transmission likely also depends on the virus concentration in the respiratory secretion, as in a study that will be carried out in Spain in spring 2020 was carried out, it was stated [25]: The transfer rate was between 12% a concentration of 10^6 RNA copies per mL and 24% for $\geq 10^{10}$ RNA copies per mL in the respiratory secretion. The time it took for the first symptoms to appear was shortened successively with increasing virus concentration: 7 days for persons with initially $<10^7$ RNA

Copies per mL, 6 days for individuals with concentrations between 1×10^7 and 1×10^9 RNA copies per mL and 5 days at $\geq 1 \times 10^9$ RNA copies per mL. A large part (around two thirds) of the cases included in the study were not related to secondary cases associated. Transmission events went significantly more often from index cases with high Virus concentrations in the respiratory secretion. Likewise, the exposure was in one common household associated with a higher risk of transmission, but none

There was an association with the presence of cough in the index case. the authors conclude from the results of their investigation that the virus concentration in the respiratory secretion plays a greater role than the presence of typical respiratory symptoms such as cough in particular. A connection with that

The authors found the use of masks to reduce the risk of transmission not (the authors of another study came to the same conclusion [26]). Due to the

The demonstrated importance of the virus concentration in the respiratory secretion suggest the

Authors suggest using the risk of transmission based on people who tested positive of the measured RNA concentrations into low to high risk.

They receive support for this in an accompanying commentary on their article [27].

There it is stated that the presence of low concentrations of RNA in the respiratory secretion both for the person who tested positive and for their contacts poses a problem because all of these people face unnecessary quarantine measures.

If you had not only qualitative test results, ie 'positive' (= virus RNA detection) or 'Negative' (= no virus RNA detection), but quantitative results (i.e. the

Number of RNA copies per mL of respiratory secretion of the individual tested positive Persons), one could assess the risk of transmissions in individual cases - and

Avoid unnecessary quarantine measures in numerous cases. The specification of the Ct-Values (cycling threshold: low values = high viral load in the initial sample) would be, although this only allows a semi-quantitative indication of the RNA copies per mL in any case better than the purely qualitative results. Since the Ct values also depend on the in the different laboratories available, but very different PCR devices

(Cycler) and also depend on the test reagents used in each case

the results from the same laboratory are compared with one another, but this one not with the results of other laboratories, as long as not every laboratory on hand from external

A calibration curve is created for reference samples with a defined concentration, whereby a

Only comparability of your own laboratory results with the results of external laboratories becomes possible. In its information from January 2021, the WHO also pointed out that that on the one hand the Ct values should be given in the report and that on the other hand the test results always in connection with the medical history and clinical findings must be seen [28].

That since the appearance of the new coronavirus, it has been increasing in clinically healthy people

Carries out PCR tests, incidentally contradicts an old rule for (serological)

Diagnosis of infections (antibody detection), which one already learns in medical studies, according to which one should not treat 'titers', but only patients, ie one should treat one

Make treatment dependent on whether the patient has symptoms related to the outcome

the laboratory examination are to be reconciled, because laboratory results do not have rarely of no significance for the individual patient. This principle was applied to the new

Leave coronavirus: people without clinical symptoms will be examined and with

positive PCR declared as 'infected' - and among other things sent to quarantine and that too

a test, the PCR, which is known to detect traces of nucleic acid in a sample

can prove.

With a PCR, only the genetic material of the respective virus (with

Coronavirus RNA) detected by multiplying (= copying) until the PCR

Device shows a positive result: the Ct value read off can be used to refer to the

Close the amount of virus material in the original sample. The relationship is there

inversely proportional: low Ct value means a lot of virus in the original sample and

vice versa.

But whether the RNA from infectious and thus replicable (= viruses capable of replication) cannot be determined with the PCR. To prove potential infectivity, one would have to try to get the virus from the same sample to grow in a cell culture. But that doesn't mean that detected virus would also be able to cause an in principle susceptible person Causing infection (see **Part C.**). So if you are in connection with a PCR speaks of, for example, 'virus detection', that is not correct in itself: it is a Simplification (one says 'virus', but only means the genetic material).

Summary of the 'reassessment' of the RKI

The RKI gave the reason for the ' *reassessment* ' of masks for the population in public space [1] that there is ' *increasing evidence* ' that one can already do so before The appearance of the first symptoms could be infectious, i.e. at a time when still there is no evidence that one is infected. However, that has long been from known to other viral infections and in no case means that the pathogen is also known is actually transmitted, but just that one transmission depends on numerous other factors is possible. The RKI supported itself as evidence that this was there is a high risk of so-called unnoticed transfers, to mathematical ones Estimates that with their models a very high proportion of such transfers have calculated. However, the RKI has obtained results from previously (i.e. before the publication of the RKI

Article) published contact tracing studies from which more realistic information are omitted. That is with the principles of scientific work not compatible, and thus the RKI does not take into account the for all authorities etc. in § 1 (2) IfSG formulated order, *according to the respective state of the medical and epidemiological science ...* 'to work.

Importance of experimental mask studies

Since masks have existed, there has been research into the effectiveness of various filters Mask materials (be it for normal medical so-called surgical masks, too surgical masks, or for FFP respirators), and every manufacturer must meet various test criteria in order to be able to bring the various masks onto the market. This is not to be discussed in more detail here, because it is the subject of this report The question of masks under discussion is not about whether masks are made of their material are principally effective, so what their filter effectiveness for larger and smaller up to smallest particles are concerned, but whether they are in the given epidemiological situation, for

the mask requirement was introduced at the end of April 2020 - namely for the normal Population in the so-called public space, which soon also included schools - one Have benefit. Such a benefit, for example when shopping for groceries, when searching after clothes in a fashion store or while using public transport, can't get out of the respective filter effectiveness of the masks used can be derived, but - on the Basis of the pathogen's possible transmission routes - only from the concrete possible ones Contact situations between people standing next to or behind one another or pass each other oncoming or overtaking from behind, even if the the respective distance is very small (up to a crowd).

The most important criterion for assessing the associated risk of infection is that these contacts are each short, even if the distance can be close, which is in 'Normal' times occur again and again. In the epidemiological context of the Meeting unknown people in public space is one for one Pathogen transmission, sufficient contact with respiratory infectious agents almost always extremely unlikely. 'Almost always' here means: as long as someone does not have one coughs directly in the face of the other person at a short distance (which hardly anyone in the Public, unlike perhaps in the private sphere, will have ever experienced) or as long as you do not have a (longer) conversation, i.e. of at least 15 minutes, and do not keep a distance of at least 1 m from each other. This length of time (as well as that RKI indicates) is derived from epidemiological studies in which one can analyze the

Has recognized contact situations that in the case of respiratory infections, a face-to-face Contact between an infected and a non-infected person comes into play, but so does that a certain and not too short minimum time must take for a pathogen contact can take place at all. A short contact, even if you are walking by Should feel the breath of the other is not at a realistic risk one Pathogen transmission connected. But if there is a conversation in public space should result from presumably longer duration, one can easily distance accordingly hold. A mask requirement for all people is therefore not necessary in order to be able to do so to prevent potential excitation contacts and all other transmission risks ('Unnoticed' transmission and 'aerosol' transmission) are not required by the scientific data and thus remain hypotheses - possibly up to the appropriate To prove.

In this respect, the assessment of whether masks are 'effective' in public space does not arise the question of what filter effectiveness professional or cloth masks probably have, apart from the fact that you can never come up with an even remotely accurate statement about it (also self-sewn) fabric masks will be able to make. Also the question of whether you can Can make fabric masks 'better' to protect public health does not arise [29]. Likewise the question is what improvement with the use of medical Masks (OP or FFP2 mask) that have been mandatory for shopping and public transport since the beginning of 2021 are, should be connected, completely open, because it comes from the principle effectiveness of Masks (of any kind) always depend on how they are used, ie whether they are worn correctly at all (see **Part B.**). Just like the population has been since wears masks for one year (regardless of whether the - often self-sewn - Cloth masks or, since the beginning of 2021, medical masks), masks are ineffective because they do not lie close to the face and do not always cover the mouth and nose, and if not even adults can handle masks of any kind properly, how are children supposed to do it then. Masks that are not used ' *correctly* ' (like the

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President of the RKI always demands), but are also due to the frequent hand-face contacts a potential risk of contamination (see **Part B.**).

So if it is found that masks ' *work* ' because the material is basically droplets and

Can hold back particles, that is no basis for a concrete effectiveness

to prove that this prevents the transmission of the new coronavirus

or

at least

reduced

and

the

' *Infection pressure and thus the*

The speed of spread of COVID-19 in the population can be reduced

[1]. A general mask requirement cannot be justified with such vague prospects.

This would require data from appropriately meaningful epidemiological data

Investigations.

The scientific basis of the RKI

Whether the RKI had such data or whether it was only possible after the publication of the RKI

Contribution from other authors were submitted, and what data as evidence at all

will now be shown below. These designs are

necessarily extensive because a substantial part of these publications are from

Scientists and the media are cited to demonstrate the effectiveness of

Masks is proven. But to be able to answer the question of whether this

Investigations that are really suitable for this must be examined in detail.

1. Study from Hong Kong

In its article [1], the RKI attached a lot of weight to a study from Hong Kong that

appeared in spring 2020 and since then has appeared in numerous international SARS-CoV-2 literature

was quoted [30]. Therefore it should be presented here in detail.

The RKI has in its contribution to the presentation of the differences from medical Masks (mouth and nose protection = MNS) and FFP masks on a 'current' study pointed out, in which it could be shown

, *That also (a) MNS lead to a relevant reduction in the excretion of Respiratory viruses via the exhaled air (...)* '[1].

The 'current' study referred to the study from Hong Kong. This study was

however, as stated by the authors in their article, between 2013 and 2016

was carried out, and was therefore no longer up-to-date when the RKI article appeared:

The study was only published 'currently' after the appearance of the new coronavirus, and that the RKI knew accordingly.

In this study, medical masks (professional surgical masks)

used. Primarily 246 patients were selected for the study who because of

respiratory symptoms of various causes in the outpatient department of a clinic

Hong Kong came. Ultimately, however, the investigation only concentrated on 111 patients

with detection of influenza viruses (N = 43), rhinoviruses (N = 54) or seasonal human Coronaviruses (N = 17), whereby two of the viruses were detected three times (all RNA

Viruses). The patients were asked to take part in an examination as test subjects,

in which the extent of the release of (1) respiratory droplets and (2) aerosol with

Virus RNA in exhaled air should be examined. The RNA detection was carried out by means of RT-PCR (= Real-Time-Polymerase-Chain-Reaction).

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The subjects received randomized (= randomly assigned) during the first examination either a surgical mask (the study directors made sure that it was correctly fitted) or none

Mask to determine the extent to which the mask has an impact on the release of the (respective) viruses that would reduce the virus release into the environment. Per se

it was planned to examine all subjects once with and once without a mask,

however, most (80%) declined a second examination due to lack of time: for the

In the investigation, the exhaled air was collected for 30 (!) Minutes. The

Particles obtained in this way were divided into the two fractions (1) > 5 µm (= droplets) and (2) < 5 µm (= aerosol particles) divided. The results must therefore take into account

that in the two groups 'with mask' and 'without mask' in most cases not

the same subjects were examined, although this is in itself the intention of the investigator was.

A remarkable result of the investigation, but not taken up by the RKI

was the following: Although all participants had an acute viral infection of the top

Respiratory tract (with concentrations of 10^{7-8} RNA copies per sample in nasal secretions and of approx. 10^4 RNA copies per sample in the pharynx), were only found in 6 of 23

(with infection by influenza viruses), in 9 of 32 (with infection by rhinoviruses) or in 3

of 10 (with coronavirus infection) of the samples taken droplets with detection

found the virus RNA. Virus-RNA-containing aerosol particles were among the same

Conditions, ie also without a mask, only in 8 out of 23 (influenza viruses), in 19 out of 34 (Rhinoviruses) and in 4 out of 10 (coronaviruses) of the samples.

Even without a mask, despite an acute viral infection of the upper respiratory tract (

high virus concentrations in the respiratory secretions) only a few samples show any virus

RNA detection. This result shows that - contrary to what is commonly assumed - one

A person with acute upper respiratory tract viral infection does not appear to necessarily be one releases high numbers of viruses.

And with the mask on, the results looked like this: A virus RNA detection in

Droplets were found in 1 out of 27 (with infection by influenza viruses), in 6 out of 27 (with infection by rhinoviruses) or 0 out of 11 (with infection by coronaviruses) of those taken

Samples are conducted. Virus RNA was detected in aerosol particles in 6 out of 27

(Influenza viruses), in 12 out of 32 (rhinoviruses) and in 0 out of 11 (coronaviruses) of the samples possible.

In its contribution, the RKI turns these partial results into a 'relevant reduction' of

Elimination of “respiratory viruses via the excretory air” through masks [1]. Thereby there the RKI does not indicate how low the virus concentrations in droplets and aerosol Particles was even without a mask (see below). The RKI only singled out the result in subjects who were infected with one of the seasonal coronaviruses than whether this could show that masks in coronaviruses and thus also in SARS CoV-2 'work'. In the subjects with the influenza or rhinovirus infection showed hardly any differences in the groups with or without a mask. The RKI did not take into account that such an effect could only be achieved can, if masks are put on correctly, what from the study directors for everyone individual subjects were respected. But nobody is available to (in to show people in public how to wear masks correctly (must) so that they could in principle be effective. But whether she even then in that given epidemiological context (e.g. shopping, public transport, schools, offices) would have to show corresponding studies, which however do not exist.

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However, the results are also special because in the samples in which virus RNA was detected at all (both with and without a mask), the RNA Concentration in droplets and in aerosol particles was consistently extremely low (mostly only 10⁰, i.e. 1 RNA copy per sample and only a few slightly higher values, but that too gave during the rehearsals with a mask; the detection limit was 0.3 RNA copies per sample), see above that the mask only compensates for the few higher values ('outliers') could be - very low values in view of the high values in the respiratory system Secretion.

In view of the efficient collection technology and the (long) collection time of 30 minutes the authors concluded from their results that probably a longer close Contact is necessary so that the pathogen can be transmitted at all.

However, when looking at the results of the Hong Kong study, the question arises, what practical relevance a mask should actually have: if namely (1) a large part of the infected person has not released any virus RNA even without a mask, and if so, then (2) in addition to those with virus RNA release despite high virus concentrations in the Nasal and pharyngeal secretions, the RNA concentrations are extremely low, speaks little overall for a benefit of masks. However, the authors put forward, despite their own clear analysis notes that their results suggest that masks (as a surgical mask as in the study used) could be used by sick people. But they only speak by sick, i.e. symptomatic persons and by no means by every citizen in the public space.

To this question, whether the widespread use of masks in public places, if but only in certain situations that make sense for every citizen, it also went in of this study - contrary to the impression one gets when reading the RKI article can win [1]. The authors judge their own results quite critically (das However, one of the usual rules in scientific articles is that the Authors themselves on the limitations of their investigation or on its informative value need to point out, because no study can be perfect), because with a large one Proportion of test persons - regardless of the type of virus infection - none even without a mask Virus RNA release could be detected, and this despite the (long) Measurement time of 30 minutes. They see a further deficit in the fact that only in individual cases and only in the case of influenza virus was examined whether the (in low concentration) released Virus RNA originated from intact viruses and these were infectious for cell cultures.

Conclusion from the Hong Kong study

The study is not suitable as a basis for recommending masks because:

Low virus release. Although it is cited as evidence in the RKI's contribution, it delivers the study did not indicate that the general wearing of masks (whether professional Surgical masks or so-called community masks) in public spaces (e.g. shops, public transport, Schools, offices) can reduce the risk of infection for the people you face encountered in the meantime - albeit with contact times that are in comparison to the

Measurement duration in the study of 30 minutes are generally significantly shorter. The Study results, however, show that the risk of having excreted viruses other Getting people into contact even if they are acutely infected and appropriate clinical symptoms have, once again, much less and probably to Neglect, if not directly coughed on, is a situation most people do People have hardly ever really seen them in public, even if just one

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such a situation is cited as a risk and thus as (a) justification for masks.

After all, it is incomprehensible that the RKI based on a study in which a maximum of 11 subjects with evidence of seasonal coronaviruses were examined and in which the head of the study also checked the correct fit of the masks or corrected, if necessary, which speaks that masks have a ' *relevant reduction* ' in virus Caused release. Only then did this little informative partial result of the Study explains why masks 'work'. But like the RKI of a result based on only 11 subjects (with acute respiratory Infection) to a similar effect when wearing masks by a population of close to 80 million (without symptoms) should not be questioned here.

Short contacts. In the case of encounters in public space, it is about the Life experience only in a few cases by narrow (<1 m) and long-term (≥ 15 min) face-to-face contacts, which however (in contrast to patient care in Hospital) usually do not extend over 15 minutes or more. Most of the time you go in the Public only briefly pass each other (e.g. aisle in the supermarket) or stand one behind the other (e.g. cash register in the supermarket) or next to each other (e.g. public transport). And even

if the journey by public transport does not only take a few minutes, you can Experience has shown that the position is almost always in such a way that there is no face-to-face contact with

other passengers, even if it should be full (to the possibility of Pathogen transmission through aerosol particles see **part C.**). Distance during conversations true, for example when doing banking or for advice, for example in a bookstore always possible - and makes masks superfluous.

Distance. That the face-to-face contact in the In the course of the pandemic at some point it was `` lost " (at least at the beginning it was at the RKI and in the media, at least 15 minutes of face-to-face Contact as a prerequisite for pathogen transmission) and through an all-round Distance of at least 1.5 m was replaced (at the same time as the introduction of the Mask requirement), is an important factor in the numerous misunderstandings and Misinterpretations (see **question 4 of the evidence**): It is not uncommon for some people to react afraid if someone comes 'too close' from any side. Since the discussion about the The role of 'aerosols' only emerged later, the RKI was able to address this aspect, which deals with the the required 1.5 m distance and the 'everyday masks' cannot be reconciled in not yet take his contribution into account [1].

2. WHO assessment of 2019

As a further source, the RKI used the WHO (World Health Organization). Therefore, their representations should now follow the question, what role masks could play in containing the pandemic.

In 2019, the WHO had an overview article on so-called non-pharmaceutical Measures (that is to say: without medication or vaccination) to contain epidemic and pandemic influenza non-medical masks only with reservation Protection of the general population in the event of severe epidemics, pandemics and surgical Masks recommended for symptomatic people in contact with other people [31].

At the same time, the WHO has determined that there is no scientific evidence for this admit, that is, based on the scientific data, one does not know whether this Measure is effective to reduce the transmission of pathogens, rather it is based on potential effectiveness on plausibility.

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If a measure is only plausible, it cannot be scientifically justified. Effectiveness can be derived. Something that can be described as plausible for the most who think about it is somehow plausible and understandable - and therefore, a plausible measure might be effective. That would be such a Theory can give occasion to examine it in a scientific investigation. However, plausibility cannot replace such an investigation. This is also for scientific laypeople understandable, otherwise one could jump straight to any scientific Refrain from investigation because much is plausible. To impose a mask requirement for (almost) the entire population in Germany can plausibility not be sufficient. In the meantime, the WHO has published two updates that will be presented later (see below).

3. Assessment of the ECDC

The ECDC (European Center for Disease Prevention and Control) is the scientific European Union (EU) health authority. Have the recommendations of the ECDC therefore for the individual European nation states, but also beyond the EU international importance, and of course the RKI also takes into account the pronouncements of the ECDC.

The ECDC made in April 2020 the potential effectiveness of masks against the Transmission of the new coronavirus only vague information [32] and has, among other things, on the WHO opinion of 2019 called upon [31]. According to the ECDC, there are limited indirect ones Evidence that non-medical masks (made from a variety of materials) the Can reduce the release of respiratory droplets into the environment when coughing, The available data suggest, however, that non-medical masks are used for the control the source of the pathogen ('source control' = external protection) are less effective than medical ones Masks.

However, the ECDC also says that one cannot infer from the fact that in Asian countries where wearing masks in public is common, therefore the corona infection rates are lower in some of these countries, because In addition to the use of masks, there are numerous other measures that be practiced to reduce the risk of infection. For example, be in these Countries raise awareness of so-called respiratory etiquette and hand hygiene more pronounced than elsewhere.

The use of (non-medical) masks in public could be primarily serve as a means of 'source control', but should only be used as an additional measure in Be considered, but not as a substitute for the central preventive measures, to which, among other things, careful hand hygiene and the avoidance of your own hand Facial contacts (eyes, nose, mouth) belonged. The ECDC has in its publication numerous arguments for and against the use of masks are given.

In summary, in its April 2020 publication, the ECDC says that the Recommendation for the use of masks in public addresses the loopholes scientific data and the possible negative effects carefully Would have to be considered. They should only be considered as a complementary measure , but should not lead to the established measures, in particular the careful hand hygiene and avoiding hand-face contact (eyes, Nose, mouth). So here, too, there is no question of one

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scientific basis for the use of masks in public and no clear recommendation for the use of masks in the normal population. In February 2021, the ECDC published a first update on this and stated the same assessment as in spring 2020 [33]. Already in the first sentence of The key messages are:

' *The role of face masks in the control and prevention of COVID-19 remains an issue of debate.* '

The ECDC goes on to say in the summary:

1. The evidence of the effectiveness of medical masks in the population for prevention of COVID-19 are compatible with a small to moderate protective effect, there are but still significant uncertainties about the size of the effect.

2. Related to non-medical masks, face visors and FFP2 masks in the Public effectiveness is sparse and associated with very little security. It high quality studies are needed to determine the relevance of the use of assess medical masks in the COVID-19 pandemic.

Ultimately, however, the ECDC recommends wearing masks in certain situations the public, e.g. if there are broadcasts in the general public and in this Situation when staying in closed public areas or in households for symptomatic persons and then also for the other persons in the household.

However, the ECDC also notes that due to the given (i.e.: missing) scientific evidence to be able to give no recommendation, whether in public rather medical or non-medical masks should be used.

The ECDC also states that there is very limited scientific evidence in relation to this on the use of FFP2 masks their mandatory use in public

instead of other mask types. Although it is not to be expected that FFP2-Masks are inferior to the other mask types, the difficulties should be their to achieve proper fit and use in public, as well as potential ones

Disadvantages due to difficult breathing should be taken into account.

Furthermore, as in the report from April 2020, it says that masks are the other preventive measures should not replace: (1) physical distance, (2) in the event of illness Staying home, (3) telecommunication work if possible, (4) respiratory etiquette, (5) careful hand hygiene, (6) contact of the hands with the face (eyes, nose, mouth) avoid.

And finally, the appropriate use of masks and the improvement of them

Compliance with their use, if used as a preventive measure for the Public health recommendations are key to the effectiveness of this Measure and can be improved through training campaigns.

4. Recommendations from the CDC

As another health authority of international importance, the RKI leads the US American CDC (Centers for Disease Control and Prevention), but cites it no publication. The CDC express themselves in a similar way to WHO and ECDC, but appeal At the time, not even on scientific evidence, except in relation to the early elimination of pathogens at the end of the incubation period [34]: Also from this side So there was no scientific support from the RKI when it came to recommending masks.

A scientific update was released by the CDC in November 2020, however

Both the information it contains and the scientific basis are great limited because there are no meaningful data on ' *real-world efficacy* ' [35].

Nevertheless, at the end of the article, the CDC recommend wearing masks and even go so far as to state the use of masks in public

prevent future lockdowns, especially if this is not possible with others pharmaceutical interventions such as distance, hand hygiene and adequate ventilation, connected.

The CDC therefore recommend a 'bundle' of measures without the individual

The effectiveness of the bundle's measures is clearly documented, as is the case with the Masks also apply to ventilation (see **Part C.**) and distance (see **Evidence Question 4**). The

The importance of hand hygiene is very likely high, although you can also find it never wash your hands often enough in public (or

disinfect) so that it can be effective, i.e. protective, which is why avoidance

your own hand-face contacts when you are on the move than much more important

is considered as washing or disinfecting your hands.

Like all other international health authorities, the CDC hold on to the mask Recommendation, although on the one hand the necessary scientific data are missing and on the other hand, masks are not used correctly by citizens who are not trained in them (can), so that they become a risk of contamination (see **Part B.**). Given this However, the CDC does not even begin to impose any significant restrictions Weighing up the measure with its potential disadvantages for all people and in Tried special for children of all ages.

5. Updated Cochrane Review

Cochrane reviews are current (or updated if necessary, if the original work already appeared earlier) systematic reviews (mostly with meta-analysis, ie one statistical analysis of different studies on the same topic) and are therefore for Relevant to any author when it comes to the scientific basis of one Question goes. Thus, the RKI also uses the for its mask recommendation appropriate Cochrane review.

A Cochrane review updated in 2020 will include studies on the effectiveness of Masks were evaluated in reducing the spread of respiratory viruses [36, 37]. As This review was available to the RKI preprint for its publication [36], the the final publication was not published until the end of 2020 [37]. In the studies evaluated therein However, it was not about wearing masks in public, as it is in Germany for all citizens in certain situations (shops, public transport, sometimes even in Outdoors) was made compulsory.

Rather, studies have been evaluated in completely different settings, and so it is misleading if it is in the text of the RKI article, in which it is explicitly about the use of Masks go in public, according to [1]:

' In a 2003 update of their Cochrane Review, the Authors, based on observational studies during the SARS outbreak den Use of masks also in combination with other measures '.

The current review from 2020 included, for example, an investigation at a large religious meeting in Australia to check whether wearing

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Masks (professional surgical masks) for participants with respiratory infection the transmission of pathogens within such mass events with close contact (e.g. Stay in tents) between the participants.

In another study, general practitioners in France made house calls Households recorded with cases of influenza. The sick people should wear a (professional surgical) mask for the rest of the household Not. The aim was to determine the rate of transmissions to other members of the Household. Another study from Australia looked at the effect of Masks in households with sick members. There were also other studies in which the effect of hand hygiene together with masks was investigated, for example with two Investigations in student dormitories, that is to say in a large one Shared apartment.

So all of them were studies that did nothing - not even in a broader sense - with wearing of masks in public (shops, public transport, schools, etc.). Most of the studies cited in the Cochrane Review were also in medical Personnel carried out and therefore play with the question of whether masks in public make sense, don't matter.

Summary assessment of the scientific basis cited by the RKI for recommending masks in public spaces

Masks not evidence-based. It is available from the specialist literature cited in the RKI article There is no scientific evidence that masks (of any type) used by the normal population in public spaces (shops, public transport, schools, etc.) reduce the transmission of pathogens in respiratory infections. Whether it so is possible with it

, *A sustainable reduction in the speed of spread of COVID-19 in the Population and falling numbers of new cases* ',

as it says in the RKI article is unproven, and there is also a lack of scientific evidence that the additional use of masks in the population could have the effect that thus *'several components (...) complement each other'* [1].

Because even that, i.e. the alleged interaction of various measures (in a so-called 'bundle'), must be proven and cannot simply be accepted or for be kept plausible. The so-called AHA formula was only used later (by an advertising agency - similar to the 'baby-elephant' distance in Austria).

In itself, it is logical in the RKI article, among other things, very cautiously [1]:

'A partial reduction in this unnoticed transmission of infectious droplets by wearing MNB could (emphasis in this report) *on*

Population level contribute to a further slowing down of the spread ',

a formulation that is used in scientific discourse due to an apparent lack of evidence for the serious mask recommendation of the RKI, is not adequate.

Undetected transmissions. The RKI does not provide any evidence for the statement at the beginning of the

Contributing to the fact that there is increasing evidence *that 'a high proportion of Transfers went unnoticed'* . It must be said: Exactly this alleged one

The possibility of unnoticed transmission was the reason for the *'re-evaluation'* of Masks in public by the RKI. But even then there was no evidence of this.

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Usually science evolves, and the actions derived from it are based on these development steps. On the subject of the unnoticed transmission However, the RKI sticks to the one established almost a year ago, but not even then exhaustive presentation: The scientific basis was published in spring 2020 not and will still not be included.

Epidemiological connection is crucial. The RKI states in the article, that

'Outbreak Investigations and Modeling Studies' (showed) that *'the rapid Spread of SARS-CoV-2 is based on a high proportion of diseases that Initially start with only mild symptoms, without the sick in their daily Limit activity. It can happen 1 to 3 days before the symptoms appear the excretion of high amounts of virus. A partial reduction this unnoticed transmission of infectious droplets by wearing MNB could* (emphasis added for this opinion) *at the population level become a contribute to further slowing down the spread .'* [1].

However, as mentioned above, these are known facts that do nothing with the supposedly new scientific evidence for the effectiveness of masks in the public space.

In addition, outbreaks are reflected in specific settings, e.g. in nursing homes or in Accommodation for asylum seekers or for employees in slaughterhouses or farms Operated, reflected a completely different epidemiological situation than the stay of People in public spaces (they should therefore not match the total number of persons who tested positive were included in the calculation of the incidence figures but there should always only be one case of each outbreak, the so-called index case, be counted, but that is a different issue). Modeling studies can, like presented at the beginning do not provide any information about the expected reality [38]. Despite all these obvious limitations in the informative value of the above alleged evidence ends the contribution of the RKI with the statement [1]:

'In the system of various measures (emphasis placed on this report) *general wearing of MNB (or MNS, if the Production capacity this allows) in the population another building block to Reduce transfers'* .

The RKI changes from 'can' and 'could' to 'is' or: from the possible to the actual -

with a significant impact. After that the RKI is on the first two pages has only been cautious about the possible positive effects (' *could* ', ' *can* '), In this last sentence it speaks with ' *is* ' but as if wearing masks actually thus confirmed by the results of scientific research, such a building block would, however, without a scientific basis being given for it (and could).

This formulation at the end of the article may be chosen for all readers (e.g. journalists) who only read the last sentence (or paragraph) of an article because there is often one (easily readable) concise summary is given. It sticks with the readers the impression that a positive effect of the mask recommendation for public spaces represents a 'fact' - which is precisely not the case, as has been shown and will be shown further on the basis of specialist literature published later. For politics was

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However, this statement is essential in order to be able to impose the mask requirement, because that means

RKI as the decisive scientific authority in Germany for the prevention of Infections, of which at least the administrative courts are usually very important who provided the decisive justification for the mask requirement.

Conclusion

At the time of publication of the RKI, neither the RKI nor the WHO (2019) nor from ECDC or CDC scientific data for a positive effect of masks in the public (in the sense of a reduced *speed of spread of COVID-19 in the Population* '[1]) because it - and this is still the case at the moment, i.e. about a year later (see below) - such data do not exist [1, 31 - 35]. The update also provides support of the Cochrane Review did not use masks in public spaces [36, 37].

This was already confirmed by two further reviews of the relevant literature in April 2020 confirmed [39, 40]. The same applies even more to the one that was carried out several years ago Study from Hong Kong [30].

Further publications on the effectiveness of masks

Only after the ' *re-evaluation* ' of the RKI [1] did a series of Publications that were largely taken up in the media. you are discussed below.

1. The WHO's 2020 assessment

The WHO recommendation of June 2020 states about masks in public (like already in a previous recommendation from April) that there are no Scientific data indicate that the wearing of masks (medical masks up to to so-called community masks) by (apparently) healthy people, i.e. people without Symptoms of an upper respiratory tract infection, in a public setting before infection with respiratory viruses, including those caused by the coronavirus, could protect [41]. The WHO With this new recommendation, has once again not opted for general wear Pronounced by masks in public, even if this is different in the media has been interpreted.

In the recommendation of June 2020, however, the WHO goes (in addition to the use of Masks in the medical field) for the first time in detail on the use of masks by the population in public space and provides differentiated information. According to this, the wearing of masks should be in certain situations of public life should be promoted - so the WHO does not see it as a 'regulation' or a 'duty'. Important is but that the WHO only gives this recommendation for areas (e.g. counties) with (1) known or suspected extensive transmission outside of localizable Outbreaks, so to speak, many infections in the area, not at individual hotspots, and in such an epidemiological situation (2) on occasions (e.g. public transport) in which Keeping your distance is difficult. Then this could be an additional measure and part of a take comprehensive action to suppress coronavirus transmission. The WHO notes at the same time that there is no direct scientific evidence for this (So as in the earlier recommendation from 2019 [31] it is only a matter of plausibility)

and that in addition to possible advantages, disadvantages must also be considered. An update of the June 2020 publication appeared in December 2020 [42]. It is but not fundamentally different from the June guideline. For the normal population

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only non-medical masks are recommended. Medical masks are supposed to People at increased risk of serious complications when using a spacing of at least 1 m cannot be maintained. Who cares for people with whom the COVID-19 is suspected or has been found to be infected, a Wear a medical mask while in the same room.

The WHO comments on children as follows:

- Children up to 5 years of age should not wear a mask for external protection.
- For children between 6 and 11 years of age, the decision should be based on the risk be: ability of the child to use the mask correctly and availability of Adults for supervision, local social and cultural environment, special Settings such as households with older relatives or schools
- From the age of 12, the same principles apply as for adults
- Special choices are made for immunocompromised children, for children with cystic Fibrosis or with certain other diseases (e.g. carcinoma) required and also for children of all ages with developmental delays, or disabilities other specific health conditions that involve wearing masks hinder.

Like the ECDC, the WHO advises that the use of masks alone, even if If they are used correctly, it is not sufficient to provide an adequate level of protection for non-infected persons or the transmission from a

to prevent infected person (external protection). Hand hygiene, physical distance from at least 1 m, respiratory etiquette, adequate ventilation of enclosed spaces,

Testing,

Contact tracking,

Quarantine,

isolation

and

other

Infection protection measures and infection control measures are whether masks are used or not, it will be crucial to the transmission of pathogens from person to person prevent.

The WHO gives very detailed guidance on what to look for for the correct use of Masks to watch out for:

- Carry out hand hygiene before putting on the mask (no indication of what exactly with it is meant, i.e. hand washing or hand disinfection)
- Examine masks for damage and do not use damaged masks
- Πύτ τηε mask on carefully and make sure that your nose and mouth are completely covered adjust the nasal clip and the ligaments so that there are gaps between the face and the Mask can be minimized. If earbands are used, make sure they are Do not cross each other, because this creates the gap between the face (cheek) and the mask is enlarged.
- Avoid touching the mask while wearing it. If you but was accidentally touched, hand hygiene should be performed
- Ρεμσπε τηε mask using an appropriate technique, ie do not touch the front, but instead loosen the straps from behind
- Replace the mask with a new, dry mask as soon as it becomes damp
- Either throw the mask away or put it in a clean, resealable one Place plastic bags where they can stay until they are washed and cleaned. The Do not wear the mask by the straps around your arm or wrist or under the chin or wrist. push into the neck

- Perform hand hygiene immediately after disposing of the mask
- Do not reuse masks for single use
- Dispose of disposable masks correctly after each use

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- Do not remove your mask while speaking
- Do not share the mask with other people
- Wash fabric masks, preferably at 60 ° C, at least once a day. If it doesn't is possible to wash the mask in hot water, then put the mask in with soap Wash in cold water and then add to boiling water for 1 min

To the scientific evidence related to the protective effect of masks in the Public says the WHO:

'At present there is only limited and inconsistent scientific evidence to support the effectiveness of masking healthy people in the community to prevent infection with respiratory viruses, including SARS-CoV-2'

[Ref.: Chou R et al., Living Systematic Review, in this Opinion No. 88-93].

Despite the limited and contradicting scientific cited by the WHO

Evidence for the effectiveness of masks in healthy people in public, will the **use of masks in public in** addition to everyone else

Measures (see above) in the event of known or suspected transmission in the population or advised during outbreaks. When decision makers consider the use of masks for that general population should consider their decision based on the given Support risk.

1. Inside closed rooms (indoor settings)

- In case of poor ventilation, regardless of the physical distance; limited or none Opening windows or doors for natural ventilation; the ventilation system does not work properly or cannot be assessed
- With adequate ventilation, if the physical distance of at least 1 m is not can be adhered to
- In households, when there is a visitor who does not belong to the household and when the Ventilation is poor, limited opening of windows and doors for natural Ventilation or if the ventilation system is not working properly regardless of whether the physical distance of at least 1 m can be maintained
- In households with adequate ventilation, if the physical distance of at least 1 m cannot be complied with

2. Outside of closed rooms (outdoor settings)

- When the physical distance of at least 1 m cannot be maintained
- People at increased risk of serious complications from COVID-19 should be in each Setting where physical distance cannot be maintained, a medical one Wear mask

3. During sporting activities

- People who do sports should not wear a mask because masks have the ability to easy to breathe, impair
- In the interior, care should be taken to ensure good ventilation and, in addition, careful ventilation disinfectant cleaning of the environment, especially of surfaces with frequent Hand contact.

The decision-makers are supposed to use masks for the general public in public spaces

It is recommended to consider the following points:

- The purpose of the mask should be clearly communicated, ie where, when, how and which one Mask type to be worn. It should be explained what can be achieved with masks

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could and what not. It should also be made clear that the mask is only one

Part of a package of measures is together with hand hygiene, physical distance among other things, all of which are necessary and are intended to reinforce each other.

- People should be informed and trained in when and how masks used safely, ie put on, carried, put down, cleaned and disposed of.
- The practicability of use, supply and replenishment issues, social and psychological acceptance (of both wearing and not wearing different Mask types under different conditions) should be taken into account.
- There should be ongoing scientific data and evidence on the effectiveness of the Mask usage (including different mask types or by others Face coverings such as towels) are collected.
- The effects (positive, neutral or negative) of mask use in the general population should be evaluated (including behavioral and Social science).

Potential Benefits of Masks in Healthy People in Public

- Reduced the release of respiratory droplets containing infectious virus particles, including infected individuals before they develop symptoms
- Reduced potential for stigmatization and greater acceptance of wearing a mask, to prevent infection in other people or in people who are patients Provide with COVID-19 in non-medical settings
- People get the feeling that they can contribute to that Stop the virus from spreading
- Promotion of concurrent behavior patterns to prevent transmission, such as Hand hygiene and avoidance of contact with eyes, nose and mouth
- Prevention of transmission of other respiratory diseases such as tuberculosis and Influenza as well as reducing the burden of these diseases during the pandemic

Potential Disadvantages of Masks in Healthy People in Public

- Headache and difficulty breathing depending on the type of mask
- Development of skin lesions on the face, or non-allergic contact dermatitis Worsening of acne with frequent use for many hours
- Difficulty communicating clearly, especially with people who are deaf are hard of hearing or have lip readings
- discomfort
- A false sense of security, which may make you feel less adheres to other crucial preventive measures, such as physical distance and Hand hygiene
- Poor compliance with wearing a mask, especially in younger children
- Issues of waste management, inappropriate mask disposal leading to increased Public waste and environmental hazards
- Damage and difficulty in wearing a mask, especially for children, for people with developmental delays, with intellectual disabilities, with cognitive impairments with asthma or chronic respiratory or breathing problems Individuals who have had facial injuries or have recently had an oral surgery had by and people who live in hot and humid climates

Summary of the WHO pronouncements

Although the WHO also stated in the latest statement from December 2020 (otherwise as previously in June 2020) expressly states that the scientific evidence supporting an effectiveness of masks in public in preventing respiratory Infections (including those caused by SARS-CoV-2) speak for the time being only are limited and, moreover, contradictory, it nevertheless makes a recommendation for Masks in certain epidemiological situations for the general population. The WHO mask recommendation is therefore not a scientific one

reasoned recommendation. It does not have to be here whether there was actually political lobbying behind it

to be discussed, but it must be noted that the WHO as scientific UN health authority for the entire world does not recommend their masks has taken on a scientific basis. This is shown by the results of this Expert opinion of evaluated scientific literature:

According to this, there is no scientific evidence that masks are made by healthy People in public, e.g. when shopping, in public transport, in offices and schools, must be borne, a comprehensible and quantifiable contribution to it do even to reduce the spread of the new coronavirus.

The possible benefits that the WHO associated with wearing masks are therefore, on the one hand, the more or less evident (in the German sense, i.e.: obvious) finding that this increases the spread of viral respiratory Droplets can be reduced. On the other hand, there are those mentioned potential benefits only to possible effects on a psychological level.

The WHO recommends only non-medical masks for the population and after as before, only in special epidemiological situations and therefore only in circumscribed regions with high numbers of infections in the area as well as locally Outbreaks, but without giving any indication of the extent of the number of cases, in any case but not as a general (nationwide) mask requirement, as Germany has been since spring Experienced in 2020. The WHO recommendation therefore cannot be used either.

2nd Lancet Review

The systematic review with meta-analysis published at the beginning of June 2020 was also published in respected medical journal 'The Lancet' provides no evidence of the effectiveness of Masks in public spaces [43]. But this publication was and will continue to be Cited as evidence when it comes to whether masks are effective in public. For but there is no basis for such a statement in the article itself.

This so-called 'urgent review' was the basis for the WHO recommendation of June 2020 [41] (and was also commissioned and funded by the WHO). In it it goes - in addition to physical distance and eye protection - also about masks, but not about that Wearing masks in public spaces to protect others. In most of there treated 44 comparative studies, which are included in the meta-analysis could, it is more about SARS or MERS, 7 of them about COVID-19, but - and that is crucial here (not the pathogen) - in no case an investigation that Conclusions about the wearing of masks in public spaces for reasons of Third party protection.

If you read the summary of the 'Lancet Review' and then Figure 4 with the meta-analysis of the studies in which the wearing of masks was evaluated one could say at first glance: masks have been well documented in terms of their effectiveness. But if you dig a little deeper into the figure, you can see that almost all of them Individual studies were carried out in the hospital setting and only three in the non-healthcare Setting (all related to SARS-1) [44 - 46], but not like the mask requirement in Germany for external protection in public, but for self-protection in the family (1 x) [44] or when leaving the apartment (1 x) [45]. Protective factors were used in This study also includes visiting farmers' markets and owning Pets are identified, i.e. factors that could be viewed as increasing the risk or, in other words, for the protective effect of which there is no rational explanation. From this can one concludes that so-called confounders (disruptive factors) were present, which is by the way the other results of the study are also called into question. The third study [46] could not show any effect of masks because 95% of the participants stated that they were Never wearing a mask in contact with SARS patients. So like this study at all included in the evaluation of the mask effectiveness of the Lancet Review is unclear. At this point it should be emphasized again that these three

The only studies in the Lancet review that even looked at wearing Masks in the general population went outside of hospitals. This review is therefore not suitable for a statement about the effectiveness of masks for people in the public space.

All other studies included in the review come from the area of medical facilities. But you cannot benefit from patient care in the Hospital where the wearing of masks for staff in certain situations Occupational safety reasons in the case of close and long-term patient contact (self-protection = no contact with the patient's blood and body fluids regardless of whether one Infection is known to the patient and, if so, which one has always been recommended, on a reverse effectiveness (external protection) of masks in the volatile Run out of encounters in public space. It happens in patient care namely to completely different potential pathogen contacts than when encountering People shopping, for example, in public transport, in schools or with colleagues in the office. Medical staff serving patients with respiratory infections or others Has to supply potentially infectious pathogens in the nasopharynx, on the one hand close contact (<1 m), and on the other hand, there is also a face-to-face vis contact, i.e. face to face.

Another important criterion is contacts in patient care typically take longer and take place repeatedly, and so has been for many years and also from the RKI a duration of at least 15 minutes of such close face-to-face contact as Prerequisites for a *possible* exposure of the staff to pathogens are listed. Such Duration does not occur in the public space with the short contacts that are usual there, it does not at all as face-to-face contact. Do you want to hang out longer with someone you meet on the road? conversation, you can easily keep your distance, and then there can be no contact come with the respiratory secretion of the other person. It is exactly the same with the Patient care: You don't have to care for the patient in close contact, but rather just want to discuss something with him, if you stand a little away from your bed, does not need to put on a mask and can talk to him normally, even when he is has an acute respiratory viral infection.

Mankind has always lived this way, even during seasonal influenza times, and it represents the question arises whether everything should be different with the new corona virus and also: whether only with this virus only or with all other respiratory viruses. This new one Virus, however, is nowhere near comparable to a dangerous pathogen like that Smallpox or Ebola virus, but according to current studies it is comparable to one Severe influenza, as we have experienced several times in recent years (e.g. 2016/2017 and 2018/2019) [47].

The 'Lancet Review' contributes to the effectiveness of masks as external protection in public nothing at (just as little as self-protection), because also this systematic overview work did not unearth any research, any or even any

Supporting statement on wearing masks in public spaces for reasons of Third party protection would allow - nonetheless, this publication will be in the media and cited by numerous medical professionals for it. That may also be due to the fact that the authors in the summary of their results and their assessment, if that read at all and not only looked at Figure 4, not really clear and have clearly expressed. So it says there:

'Although direct evidence is limited, the optimum use of face masks, in particular N95 or similar respirators in health-care settings and 12-16-layer cotton or surgical masks in the community, could depend on contextual factors; action is needed at all levels to address the paucity of better evidence'.

The summary of the authors of this review is in plain language: There are none scientific evidence of effectiveness of masks in public, if necessary their use can be made dependent on the epidemiological context, in each However, there is a lack of scientific evidence, and that lack must

be made clear.

The WHO does not rule out the use of masks in public (this also applies for children [48]). Exactly this was the basic statement of the WHO in 2019. Equal What has also remained is that the WHO explicitly says that there is no scientific evidence for it wearing masks in public. So again only plausibility remains (see above).

3. German Society for Pneumology (DGP)

The DGP comes in a statement from May 2020 on the effect of masks on the Internal and external protection to a positive evaluation [49]. On the one hand, the DGP gives it an overview of various experimental studies on the theoretical effectiveness of Masks. On the other hand, some individual studies from the Cochrane Review are cited [36]. As mentioned above, however, there are studies that show the effectiveness of masks in the Show public space for external protection, not included because there is such Investigations do not exist. So everything is not just about scenarios hinted at the meeting of people in public space would be comparable. In the end, however, the DGP does not pull this from a scientific point of view understandable conclusion that

, *Non-medical masks made from fabrics (...) have an external protective effect (have) '.*

However, this conclusion is not by any of the ones cited in the DGP statement Investigations have proven.

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4. So-called 'Jena Study'

In a modeling study published for the first time in early June 2020, the effect of Mask requirement using the example of the city of Jena and other cities and regions in Germany reports [50]. The study was slightly modified again in August 2020 published [51] and appeared for the third time in the second, already modified version in December 2020 [52]. The third publication was submitted to the journal in July, so only shortly after the first appeared (and shortly before the second), the Ultimately accepted on November 1st and published in December 2020. Was from the media they presented a new study in December, but what they dated The subject of investigation is not here.

The so-called Jena study - along with the 'Lancet Review' - is often seen as clearer in the media Evidence for the effectiveness of masks cited, otherwise also - actually - together with a study on golden hamsters ('Hamster' study; see below), so one animal work.

The authors of the 'Jena Study' are all macroeconomists who use the same methodology ('Synthetic control method') carry out investigations on behalf of politicians in order to determine the To mathematically 'model' the effects of political decisions (so-called 'reforms').

The study looked at the development of the corona case numbers after the introduction of the Mask requirement in Jena with that in comparable cities (= synthetic Jena) without Mask requirement compared. The authors conclude that the mask requirement is too led to an approx. 40% reduction in the daily growth rate of corona infections.

However, the study does not take into account the epidemiologically decisive aspect that from March 1, 2020 (about 5 weeks before the introduction of a mask requirement in the public space in the city of Jena) the rate of spread of the new coronavirus decreased and that on March 10th the R-value - according to the RKI - was already below 1

[53, 54]. From the end of March there were no more relevant infection numbers in Jena. It follows, that the introduction of the mask requirement (from April 6, initially in Jena, about three weeks later also throughout Germany) fell into a phase of the corona epidemic in which there is already a continuous and significant decline in the number of infections had come, a development that subsequently continued. An effect of

Mask requirement for the decrease in the number of infections can therefore not be deduced from this, because both overlap, but this was not taken into account in the modeling study.

It is particularly important for the assessment of the 'Jena Study' that the

According to the data from the RKI, the incidence of infection in Jena only lasted for a few days in March and the majority took place before mid-March: There were (1) approx. 3 - 5 positive cases at the end of February, (2) between 43 and 53 positive cases at the weekend March 7th - 9th and (3) between 59 and 73 positive cases between March 11th and 14th, (4) then a significantly declining number of positive cases on individual days At the end of March and (5) another 3 - 5 positive cases at the end of March. The respective close temporal Connection of events (2) and (3) suggests that it is Outbreak situations and not a successive spread of infection 'in the area'. In any case, at the end of March the infection rate in Jena was already so strong subsided that you no longer have an effect due to the mask requirement from April 6th could expect, because there is no longer any infectious process that can be influenced in principle gave.

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In addition, it must be taken into account that the reporting date of the cases in the study was used, does not permit any statement even remotely reliable about the time of the Infection that only spreads beyond the date of illness (= beginning of clinical symptoms) can be determined precisely enough how the RKI practices it in its modeling studies [54]. According to the RKI, the time between infection and the reporting date is 14-21 days, and this period is made up of: (1) the incubation period, (2) the time delay until the patient goes to the doctor because of increasing symptoms, (3) the time to perform of the test (including transport to the laboratory and evaluation in the laboratory), (4) the administrative Delays in reporting the test results to the RKI and (5) the publication by the RKI [55]. However, the 'Jena Study' only assumes a delay of around 8 Days [50] or about 10 days [51, 52].

In other words: the effect attributed to the mask requirement in this study the decline in the number of infections is superimposed on the one hand by the significant decline the positive tests that were carried out all over Germany a few weeks before the introduction of the Mask compulsory had begun in Jena and elsewhere. The other must be considered that the infections reported to the RKI arose 14-21 days earlier the mask requirement does not affect the at least in the first 2 - 3 weeks Could have had numbers of infections.

Another important aspect for assessing the effect of the mask requirement is that in the reported infection numbers can always conceal infections that result from Outbreak events, e.g. in homes, hospitals or communal accommodation, come. Institutional outbreaks are made public by a mask requirement Space not affected, so that a decrease in the number of infections in one place or in of a region may be due to the fact that the number of cases of infection previously had outbreaks increased, but thereafter the number of cases decreased due to the lack of further outbreaks were than before the introduction of the mask requirement. This is exactly what seems to be the case in Jena

to have played an important role when considering the events (2) and (3), as shown above, Considered in Jena: It was very likely a matter of time

limited outbreaks, each with high numbers of people with positive test results.

Outbreaks, for example in institutions such as old people's / nursing homes, are always individual Causes that are to be looked for in the concrete epidemiological context can, however, through a mask requirement when shopping or when using public transport does not affect become. Without taking into account the epidemiological context from which the Infection numbers reported in different locations come from (i.e., whether outbreaks were among them or not), the effect of masks in public on that remains Occurrence of 'new infections' (= positive test results) inevitably unclear.

Overall, this modeling study does not produce any results that require a mask would support, because in addition to the introduction of the mask requirement, the listed possible Influencing factors (likely outbreaks) especially from the time before were not taken into account. With these limitations the study can easily be one Come about because the authors, as economists, do not have any medical or

have epidemiological expertise and therefore important potential influencing factors, like the question of outbreaks and their possible causes, not their deliberations have included.

There are numerous examples from other countries where, such as Spain, despite the strictest Mask requirement between July and the end of October 2020 the case numbers of those who tested positive

People increased extremely while in Sweden without a mask requirement in the same

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Period were significantly lower [55]. There are other examples of this from other countries: Despite the requirement to wear a mask, the number of positive test results rose sharply [56, 57]. Man but can also see the same for Germany from the data of the RKI (introduction of Mask requirement on April 28th) (e.g. in the daily situation reports). Likewise said the Head of the Austrian AGES (Agency for Health) that neither the introduction of the Mask requirement nor their lifting measurable effects on the infection process in Austria [58]. In the last two months of 2020, in Sweden the number of people who tested positive increased significantly, but not in to the same extent as in Austria, where the mask requirement has been almost consistently since spring 2020 holds [58]. Even with all this empirical data from numerous countries you can Influencing factors may have remained undetected, but it is noticeable that they are not in any of the countries showed an effect of the mask requirement on the number of cases.

5. Mathematical estimation: Wuhan, New York and Italy

This is another modeling study carried out for Wuhan (China), but mainly for Italy and for New York City wanted to show that with the introduction of the Mask requirement in public the number of new infections decreased significantly [59]. This study was apparently quickly criticized for its lack of statistical methods (and the magazine was asked to withdraw the article, which it did not) [60]. A The journal accepted and published a critical letter to the editor on this study [61]. From an epidemiological point of view, there are fundamental objections to this study, through which their results will not be meaningful, no matter how well they may have been calculated should. As in the 'Jena Study', these authors (also none Doctors or infection epidemiologists, but chemists, including a co-chemical Nobel laureates from 1995, as well as physicists and geologists) overlook the fact that the Effects of a measure not immediately, but because of the interval between the The time of infection and the date of notification can be recognized at the earliest approx could be.

The authors also meant not only to show that the mask requirement has the greatest effect of all the measures had but are moreover convinced that they are with of their study identified the 'aerosol' transmission of the new coronavirus as the dominant one Have occupied the transmission path. What exactly they conclude that they do not explain, but possibly from the fact that masks create respiratory droplets mechanically stop and thus prevent it (i.e. from the smaller ones, which are not the same sediment) Aerosol particles are formed which are capable of suspension and may contain viruses can. They also claim that the airborne transmission route is the most efficient, because aerosol particles got deep into the lungs even when inhaled normally, and also that this route of transmission typically involves a low 'infectious dose' need. In addition, free-floating viruses would have great mobility and sufficient long 'survival time' for their spread.

However, on the one hand, these are consistently unproven assumptions and not scientific ones Evidence and beyond assumptions that are inconsistent with the findings in which anatomical regions the new coronavirus has to reach: because it multiplies located in the upper airways and mainly in the nasal mucosa, but not in the Lungs [62] (see **Part C.**). Furthermore, nothing was known about the so-called 'infectious dose' until then (i.e.: how many pathogens does a generally susceptible person have to come into contact with,

so that an infection can develop), and thus there was no evidence that a

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a small number of viruses is sufficient for an infection (a little more is now known about this; see **Part C.**). After all, coronaviruses, as viruses with a lipid envelope, are against Viruses most sensitive to environmental influences, all in all not good conditions to to 'survive' unprotected in the air even for a slightly longer period of time, or - In more scientific terms: infectious and replicative (= capable of multiplying) stay. The authors are natural scientists and apparently did not have such questions posed or, as a non-medical practitioner, cannot pose.

The authors have not shown, for example, as in the critical letter to the editor explained [61], (1) from which epidemiological connection the infections originate, ie whether they were acquired in the private sector or in patient care and, if the latter, whether the personnel have sufficient protective equipment available would have. And they did not take into account any other factors besides the (2) Mask requirement may also have played a role (so-called confounder), and (3) as well nor, as the masks were accepted by the population at all, because Even if it is compulsory to wear it, it cannot be assumed that all people will also wear it use and - also important - wear them correctly.

6. Mathematical-theoretical study

Another work is a purely published one at the end of April 2020 mathematical-theoretical modeling study [63]. The authors (all mathematicians and Statisticians) express themselves - similarly to the RKI in [1] - rather very cautiously, as far as the effectiveness of masks is concerned, they ultimately claim that masks together with other interventions (so-called 'social distancing' and in particular Hygiene measures) could have the effect of reducing mortality and stress on the Slimming medical system. According to the authors, masks are not a '*panacea*' but synergistic effects along with other non-pharmaceutical interventions to have. They go on to write that masks alone when they are not very effective and be used by almost everyone, would only have a small effect in severe epidemics, which, however, is not insignificant in relation to the absolute number of lives saved be. The relative benefit of general mask use could be achieved with other measures collaborate for the public. Masks should therefore not be used as an alternative, but should be viewed as a complement to other public health measures. they say then further that their simulations showed that even weakly effective masks, though if they would be widely used, they could help prevent many deaths. Their theoretical results put a significant - albeit potentially great - one variable - value close to even when using masks with low effectiveness if they widely used.

Towards the end of the 'discussion' they realize that their '*theoretical results*' with Caution must be interpreted because of a combination of potentially high rates the non-compliance with the use of masks, as well as the uncertainty with regard to their (intrinsic) effectiveness (especially with self-sewn masks), respiratory Trapping droplets and / or aerosol particles, and ultimately because of how they are really write, even surprising levels of uncertainty, what the address basic transmission mechanisms in respiratory infections.

Nevertheless, they close their contribution with the statement that - despite the uncertainty - (1) the potential benefit, (2) the lack of obvious harm, and (3) the The precautionary principle leads to the fact that it is emphatically for the most universal possible use recommend of masks in public (and everyday masks, unless

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medical masks could be used without breaking the medical system too affect). With this, the authors make surprising claims: (1) without

Evidence of a potential use of masks is simply assumed, (2) that masks are virtually free of side effects is one of the other unproven assumptions and Finally, (3) the precautionary principle cannot be used as a justification for measures that merely based on plausibility.

Provision generally means Follow-up care that you not only have potential hazards or risks recognizes before it occurs and evaluates its meaning, but also to this

Time - despite possibly incomplete knowledge - reacts to potential risks so that they either not occurring at all or, if it does, then only in a weakened form. The so-called precautionary principle comes primarily from environmental policy and was established in 1992 at the UN Conference on Environment and Development in Rio de Janeiro concretized as follows:

' Given the risk of irreversible environmental damage, a lack of complete Scientific certainty does not serve as an excuse for action procrastinating that are justified in themselves. ... '.

The idea behind the precautionary principle is that even then with measures to Protection against potential risks should be started if it is not yet known exactly what exactly these risks are based on and whether they are at all and, if so, how pronounced will be realized [64, 65]. The precautionary principle has also been extended to the Health and safety policy. It's always about

' Questions about individual and social decision-making under conditions of risk and uncertainty '[64].

Acting according to the precautionary principle requires a strict risk-benefit assessment, thus not the means or measures used to reduce or eliminate the potentially imminent danger that may lead to a burden on society is more harmful than realizing the potential danger. So it is allowed with one Acting according to the precautionary principle not only the negative consequences of the potential Risk must be taken into account, but it must be the same and equivalent possible negative consequences of the means or measures to be applied in the Decision to be included. This must have a solid scientific basis be created on the basis of which both the benefits and risks of one and the other Aspect can be assessed, even if not conclusively.

Acting according to the precautionary principle therefore requires some preliminary work with a description of the

potential risk and as much scientific basis as possible to an effect of the

To be able to prove the intended measures to the impending risk. Plausible

Considerations as a justification for the chosen measures are not enough if you are

Wants to justify action on the basis of the precautionary principle. That's exactly the case when you're without

further scientific justification refers to the precautionary principle and the wearing of

Masks declared as a measure to protect against the spread of the coronavirus

can [63].

It is not quite that simple, otherwise one could refer to the precautionary principle every one of them

Enforce measure. The federal government suddenly took off at the beginning of 2021

started the corona measures because of the new virus variants with the

Establishing the precautionary principle after it was not mentioned in 2020. However, there was

There are no further explanations on the part of politics as if the term spoke

'Precautionary principle' in itself and make any justification superfluous.

This modeling study looks somewhat similar to the RKI contribution [1]: Am

The conclusion is a statement that is consistent with the considerations of the authors previously, namely that

the meaningfulness of its theoretical results is completely open to reality, not in

Can bring harmony. If you only read the last paragraph of the publication you will not find out anything about the differentiated considerations of the authors.

7. 'Hamster Study'

In an animal study with golden hamsters it should be investigated to what extent surgical masks could reduce contact with respiratory droplets [66].

This study was apparently taken seriously by the media as evidence of the effectiveness of Masks are understood in public space and should therefore be mentioned here.

Without going into the details of the methodology, one proceeded as follows: One group consisted of hamsters artificially infected with the new coronavirus, the other Hamster group was without infection. The respective cages were close together and were either separated by a wall made of the material of surgical mask or Not. The mask material was used to simulate an infected person wearing a surgical mask become. So there was no direct or indirect between the animals of the two groups Contact so that pathogen transmission, should it take place, is through droplets respiratory secretions or aerosol particles must have come about. in the There were significantly fewer results when using the surgical mask material Corona infections in the exposed, i.e. primarily non-infected animals, from which the Investigators concluded that this protection was effective.

The question arises, however, whether one can draw on the result of such an animal study on the Effectiveness of (surgical) masks in humans can be inferred, especially if they be worn in public by millions of people, because the two settings are obviously in no way comparable with each other. Were in public Also, no surgical masks were worn in 2020 when the study was conducted, everything you liked, down to any cloth, was allowed. On the other hand the basic effectiveness of masks depends not only on their material, but largely on how they are worn, ie how well they fit all over the face. in the One can easily see public space that it is very different and generally there are no even remotely correct ways of carrying. So even if among the controlled conditions in the animal study a marked effect is observed, means not that the result could be transferred to the population. the authors however, themselves surprisingly come to this conclusion - and therefore have also reported to journalists in this way, although they too might recognize that the conditions are very different and cannot be compared with one another.

8. RKI: 'First scientific information' for third-party protection

In response to the question of the background to the '*first scientific Notes*' from 07/19/2020 in his answer of 07/21/2020 on the one hand two experimental

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Laboratory studies (from 2008 and 2013, which have been known for a long time) in which the principle ability of textile MNB to hold back droplets has been shown, however with a great influence on the effectiveness of the material used [67, 68]. For The RKI has indications of the '*infection-preventive effect at population level*' in the three modeling studies discussed here [50 - 52, 59, 63] (whereby [50 - 52], like stated above, there are three publications on the same study).

With experimental and modeling studies, the RKI (at the time of the Request in July 2020) his then new statement and still present in the FAQ today from the '*first scientific evidence*' of the effectiveness of masks as external protection occupy.

At the beginning of 2021, a request from the population was sent to the RKI according to Freedom of Information Act placed. The RKI was asked to provide the scientific Basics (1) for the statement that from asymptotically infected with SARS-CoV-2 People assume a relevant proportion of transmissions, and (2) for the mask requirement specify. The RKI responded with a list of a total of 8 quotes: 2 for asymptomatic transmission and 6 on the effectiveness of masks. These are the following References included in this report. (1) Asymptomatic transmission [11, 23] and (2) mask effectiveness [29, 43, 71, 75] (another experimental study by Konda A. et al. for the filtration performance of aerosol particles through various substances is in the Review article [29] included). One of the references was not dealt with here because it is a hospital examination of medical personnel

(cloth masks compared to medical masks). All 6 quotes on effectiveness of masks, the RKI apparently obtained the BfArM's statement on how to use them copied out with masks (there are the same citation errors, and also the order of the quotations corresponds to the information provided by the BfArM). The BfArM's contribution is presented in

Part B. treated.

A little more than six months after the July inquiry (see above) about the effectiveness of masks, the RKI shows that there are no masks for third-party protection. With its current information, the RKI shows that there is no scientific evidence of the effectiveness of masks for healthy people in the public for external protection and that there is no scientific evidence either to ensure that pathogens are transmitted starting from asymptomatic people have a relevant share in the spread of SARS-CoV-2.

Additional publications on the effect of masks

After publications have been discussed up to this point, especially those in the media, but were also always mentioned by scientists when it comes to the supposedly secured effectiveness of masks in public went, and therefore relative lesser-known publications are said to have achieved popularity in the following to be introduced.

The publications were predominantly via the literature lists of other publications found, so for example also the current international health authorities to order from publications cited by the respective authors as evidence of their assessments to check for their informative value. They are each in the chronological order, how they were submitted to the journals or published (depending on the information), briefly discussed.

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a) Publications 'per masks'

A total of 17 publications showing a positive effect of masks are presented determine, 10 of which are mathematical estimates, i.e. Modeling or simulation studies (= 'if-then results').

1. Narrative overview (letter to the editor, and therefore without peer review = expert opinion by Experts from the same subject, submitted in April 2020) [69]: It is a small review of the literature, with most of the studies covered from the Clinical area originate, if it is mask examinations and not at all other issues or general statements from international Health authorities act without specifying specialist literature. Ultimately, there will be masks endorsed by the authors, although no scientific data are given for it to have.

2. Mathematical estimate (submitted in April 2020) [70]: In this mathematical Modeling study should evaluate the possible effectiveness of masks in combination with Lockdown periods on the infection dynamics of the new coronavirus can be determined. The authors come to the following conclusions: (1) The base reproduction number R_0 can be reduced below 1 if masks are always worn in public not only if there are signs of a respiratory infection. (2) Be There are no lockdown periods with 100% mask usage introduced Infection spread more, secondary and tertiary 'waves' are 'smoothed out'. So is the epidemic under control. This effect is also given when the used Masks are only 50% effective in stopping the exhaled virus (in the case of a same or lesser effect during inhalation). (3) Even without lockdown Periods have advantages for mask wearers, even if there is only a lesser mask load. There is acceptance. Overall, the authors conclude that masks in combination with Keeping your distance or lockdown periods an acceptable way of preventing the coronavirus Manage the pandemic and reopen economic activities. A 'Key message' of their analysis to support the widespread adoption of masks, be: '*My mask protects you, your mask protects me*'.

3. Mathematical estimation (submitted in April 2020) [71]: The contribution became a

Time submitted to the magazine when masks are scarce in many places and not even for medical staff or staff in nursing homes were sufficiently available. The Authors wanted to contribute to the epidemiological importance of masks to investigate in public. According to the calculations made in it Even with a limited effect, masks can treat infections as well Reduce deaths and may delay the peak of the epidemic. they are coming to the conclusion that masks precisely with a pathogen that is often asymptomatic is in place, is an effective intervention strategy. What is important is the optimal one Distribution of masks so that they are available at all. Obvious are the authors in the calculations of different mask effectiveness started without it being clear what efficiencies they were based on and on what basis they were adopted. So it is Calculations on a theoretical basis.

4. Narrative overview (Version 1 submitted in April 2020, by the end of December 2020 as Version 4 without a completed peer review process, finally published in January 2021 [72]: 'Narrative' means it was not used for evaluation after *all* Investigations on the subject wanted. This publication whose title is the effectiveness suggested by masks, is cited very often, but is selective by the

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Literature selection not an '*evidence review*', as it says in the title. Scientifically sound No conclusions can be drawn from this.

5. Mathematical estimation (submitted in May 2020) [73]: The authors emphasize that they take a different approach than most modeling studies that are mainly on the dynamics of the transmission of the virus and on the resulting Reproduction number (R_0) concentrated. Rather, they wanted the people affected Include different groups of people (e.g. susceptible, symptomatic, hospitalized) wanted to ensure optimal control of the Represent infection with various non-pharmaceutical measures. in the As a result, the following measures were most effective in their model: At home stay, wash hands, early detection of cases (using PCR) and masks. Introducing all strategies at the same time for at least 50 days could be the number greatly reduce new cases.

6. Narrative overview (submitted in May 2020) under the heading 'Viewpoint' in the respected science *magazine* '*Science*' [74]: This was repeated Publication referred to as a '*study*' with evidence of the effectiveness of the masks. It However, this is not a study, but a simple one Opinion contribution. It is a small overview article (of 2 ½ printed pages) in which mainly hypotheses and some questions and only a few studies (including an animal experiment with golden hamsters; see above) mentioned, but not and certainly not to be discussed exhaustively. The aim of this publication was apparently (the is legitimate in a scientific context) to raise some question, but the authors do not try to give fixed answers. So this publication is not suitable to prove the effectiveness of masks in public.

7. Narrative overview (submitted in May 2020) [75]: The (very numerous) authors have made a very limited review of the literature, but no statement about The effectiveness of masks in public allows, since numerous experimental ones Mask studies and mask examinations from the hospital area below were. There were no studies on wearing masks in public, but there are no such studies either. The authors come anyway concluded that masks are always worn when distance is not possible should be (e.g. in public transport), because it is very likely to spread virus-containing droplets and thus the transmission of SARS-CoV-2 can be reduced could. The authors also say that it is undisputed that infected people do Days before the onset of symptoms can transmit the pathogen. That was middle May 2020, when the article was submitted, the prevailing view, but

even then without scientific evidence, but based on assumptions and misleading publications [16], but was already questioned at that time or corrected [17 - 19]. This article does not contribute to the effectiveness of To support masks for healthy people in public (but is used by RKI and BfArM listed for this; see above).

8. Mathematical Estimation (letter to the editor, ie not peer reviewed, submitted in June 2020) [76]: 42 geographic regions on six continents were included.

It should be checked whether there is a relationship between that in some, especially in Asian countries as opposed to frequent use of masks other, e.g. European countries, where the use of masks in the early stages of the pandemic (from January 21st to March 11th) has not been established and not yet was prescribed. The question of this investigation was whether the early use of masks in the coronavirus pandemic could have helped the pandemic contain. The result of the authors was that the number of cases in some

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Asian countries (masks were used earlier) was lower than in others Countries (later mask use). According to the authors, masks are then one independent factor in controlling the pandemic. They come anyway but only to the conclusion that it was reasonable to assume that the use of masks could mitigate the pandemic because they prevent the release of aerosol Could reduce particles and droplets. They believe they write that one wider use of masks is key to controlling the pandemic, and it is regardless of hand hygiene, so-called social distancing and other measures.

9. Mathematical estimation (submitted in July 2020) [77]: For employees in Businesses with regular customer contact stopped using masks investigates the use of masks in public, as is mandatory in Germany is, however, cannot be compared with this setting. So the results cannot the question of the effectiveness of masks in public spaces for almost everyone Citizens are transferred. In addition, the authors themselves say that their results should be interpreted with great caution.

10. Mathematical estimate (submitted in August 2020) [78]: The basis was US states with and without mask compulsory between April 8 and May 15, 2020. Compliance with the However, the use of masks could not be determined, as the authors explain, so it is unclear how often masks were worn at all (and whether they were correct were worn, especially not). Also, only the 5 days before the Imposition of the mask requirement taken as the reference period, which is by far is little for a before-and-after comparison, because it takes significantly longer for the Can show the effect of a new measure (approx. 10-14 days). For that reason alone would be the investigation is not conclusive. However, the authors only conclude that their results suggested that wearing a mask in public would help could mitigate the spread of COVID-19, so assess the informative value reluctant to investigate.

11. Mathematical estimation (submitted in August 2020) [79]: All authors come from of ophthalmology and have the most different countries of the World included and compared with each other. Were included in the study Countries like Africa, Latin America, Asia and Eastern Europe with very different Infection rates, population structures and climatic conditions. Effects, however, on regional geographical observations and related peculiarities (e.g. climatic) are unsuitable for a comparison with or with one another. The corresponding limitations apply to this modeling study: There are different causes for increases in the number of cases (e.g. outbreaks), one different compliance with masks, which cannot be checked retrospectively, and other factors (so-called confounders, i.e. variables that both have an influence on the Occurrence of risk factors as well as the result of an observation) resulting in a such a study cannot be detected.

12. Mathematical estimation (submitted in September 2020) [80]: It was the Compliance with the wearing of masks in 24 countries evaluated to the possible To determine the influence on the number of cases. The authors themselves say in their résumé, that it is possible that the estimated decline in new cases is not due to wearing from masks, but to other variables that are not in the model could be taken into account. As a result, the authors very cautiously conclude that that because of such disruptive factors and also because of the variations in mask types as well as randomized controlled trials on the use of Masks in public places are required to get the real effect of wearing Masks to determine the weakening of the transmission of respiratory pathogens.

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13. Mathematical estimation (preprint, submitted to *Science* in September) [81]: According to the authors, this investigation should address the problem with the Use of assumptions in complex mathematical modeling thereby Avoid just the illnesses, hospital admissions and Deaths and the respective date were plotted against each other. There were However, here, too, possible other (disruptive) factors are disregarded and only those political measures such as school closings etc. included. It is also not stated where the respective case numbers come from, and one does not find out in which epidemiological context the cases have occurred, for example in the Public or in hospitals or nursing homes and, if the latter, whether the Employees there take adequate protective measures, such as protective clothing typically narrow and long-term care is available to the patient had, or what proportion of the cases came from outbreaks. The authors also go assumed the virus was new to the population, which is immunologically incorrect is, as we know, since more than 80% get sick only slightly or not at all, so we have one Background immunity from contact with similar viruses or ours natural immunity. There was no exponential growth anywhere because of such Infections always spread in the form of a Gompertz curve (and exponential Growth always has a natural end, even for example bacterial growth in one Nutrient solution). Incidentally, this work is one of the numerous advantages Publications (preprints: as of the beginning of January 2021), i.e. around those at the magazine Submitted manuscripts by the authors that have not yet been subjected to a so-called peer review have gone, which can still change a lot, because very few manuscripts just go through the peer review process and be without the authors Need to make changes, published.

14. Systematic overview (summary of a so-called ' *Rapid Review* ' by authors des RKI, published in September 2020 on the RKI website) [82]: In this work was related to a total of 27 mathematical modeling studies the effectiveness of non-pharmaceutical interventions in controlling COVID-19 Pandemic evaluated.

On the one hand, this work from the RKI has not yet been published in a specialist journal, but the entire manuscript has not yet been published as a preprint, but rather it there is only a summary of it on the RKI website. On the other hand numerous works are cited as preprints in this overview, that is to say, those in turn have also not yet been independently reviewed in specialist journals. Nevertheless, the RKI writes under the link on the corresponding website The following (last viewed on April 3rd, 2021):

' *As part of a rapid review, the Robert Koch Institute (RKI) in Journals published studies on the effectiveness of non-pharmaceutical Interventions (NPIs) to contain the ...* '(emphasis added for this report).

The RKI pretends that the investigations discussed are already in Journals are published. However, this applies to the 6 quotations in which, among other things the effectiveness of masks was investigated, with 4 quotations not to be found, because they are (also) are still in the preprint stage. This preliminary publication also lacks the

Citation of papers that deal critically with the corona measures.
In addition, a noticeably large number of preprints are cited in it. You can see that but only if you look at the literature list. With those not yet appraised and thus also manuscripts not yet accepted by the magazines in one Working on the literature review is not without its problems because it extends to the final

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Publication can change essential aspects of a work (if the work is ultimately accepted for publication at all).
In the media, for example, this was not previously referred to as a complete manuscript, ie not verifiable in detail available work in the way relation taken that the recommendations of the RKI are based on a comprehensive Evaluation of the currently available scientific Knowledge was based and on the other hand therefore the recommendation to wear Masks as a protective measure against SARS-CoV-2 are quite evidence-based. These However, no conclusions can be drawn from the RKI on the basis of the ' *Rapid Review* ' possible still scientifically permissible.

15. Mathematical estimation (summary, authors from the RKI, published in September 2020 on the RKI website) [83]: Also in this RKI article was cited selectively. Although he was published by the magazine ' *Lancet Public Health* ', where he was submitted, has not yet been independently assessed, but like [82] it is also on the RKI pages already published in a summary. Therein should be in a Modeling study based on the publicly available databases the effects the non-pharmaceutical measures used in each case to contain the Infection examined within the 37 OECD member states from January - July 2020 become. The authors conclude that limitations of Meetings and gatherings are most effective. In addition, could the wearing of masks, school and work closure regulations and that Test volumes contain the number of positive cases. Missing from the literature list however, publications in which the corona measures are critical and have no influence on the infection process was assessed. On request at the RKI with the request for When the full manuscript was sent, it was announced that there were numerous ' *Suggestions from the specialist public* ' have given the manuscript, which is why it revised and re-submitted. It remains to be seen whether the literature list will follow the revision will be completed.

These two RKI publications by Pozo-Martin et al. [82, 83] help the Federal government to justify the corona measures taken. Probably therefore they have already been put on the RKI website as a short version, but without the publish complete manuscripts as well. Readers unfamiliar with The rules of publication, can address the problem with such as a summary nor do they recognize incomplete pre-publications (see above E.g. journalists who treat them as if they were closed Publications).

16. Mathematical estimation (preprint, submitted in October 2020) [84]: All authors come from economics. Subject of investigation of this mathematical On the one hand, the estimate was the effect of the indoor mask requirement in Ontario, the most populous province of Canada, between March and mid-August 2020. There the mask requirement in the 34 regions was staggered over about two months introduced so that the regions with previous mask requirements are compared with those where the mask requirement came later. In a second approach, all 10 provinces of Canada the impact of all non-pharmaceutical Interventions (NPI) including masks are calculated. The differences between the provinces in terms of both mask effectiveness and effectiveness the other NPI analyzed. Estimating the differences between regions with or (still) without masks in the province of Ontario yielded (already) two weeks after Introduction of the mask requirement a reduction of the weekly new positive

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Corona cases by 25 - 30%. At the level of all provinces, this was the result confirmed and was even higher at 36 - 46%. This time interval to The mask requirement is very tight, because after about two weeks it begins to only show the first effects of a measure, when it should actually exist. Apparently, however, there was no further reduction in positive cases in the period afterwards, otherwise the authors would have reported on it, and that is how the result becomes out epidemiological point of view even more questionable. As usual in math Here, too, modeling studies could - of necessity - other possible (disruptive) Factors are not included, only the political measures, i.e. in in this case the mask requirement.

17. Narrative overview (first submitted in October, revised version dated November, published in December 2020) [85]: It is a review article that mainly newer (and not all) publications on masks are considered. Therefore the authors describe the work as a 'narrative update'. It is a text, the one Assertions are lined up next to the others and cannot offer any new work because it there are no corresponding studies.

b) Publications 'contra masks'

In the following, 7 publications are presented that do not have a positive effect from masks in have proven to the public, even if they partially result in the application recommend of masks (again in the chronological order as they - depending on the Information in the publication - submitted or published).

1. Systematic overview (submitted in May 2020) [86]: 9 randomized controlled trials conducted outside of medical Institutions (households, student residences). An effectiveness of masks as sole measure for the prevention of influenza-like diseases (influenza-like illness = ILI) was not found. In 6 of these studies 3 groups were compared: (1) Hand hygiene alone, (2) masks and hand hygiene, and (3) no action. It found there was a significant reduction in ILI only when using masks together with Hand hygiene, but not with masks alone. However, the authors state that the exact protection of masks beyond other measures, such as hand hygiene, unclear remains.

2. Systematic overview with meta-analysis (commissioned by WHO in 2019 and funded, published in May 2020) [87]: The work should prepare for the Development of a guideline for the application of so-called non-pharmaceutical interventions serve in the general population in pandemic influenza. There were 10 randomized controlled trials of masks evaluated to determine their effect on the To determine the transmission of laboratory-confirmed influenza infections. It turned out no evidence of effectiveness of masks in reducing Influenza transmissions and neither when they are from infected people for protection Worn by contact persons (third-party protection), even if they were not infected People used for their own protection. The authors also note that the Correct use of masks is essential, because otherwise there is a risk of transmission could be increased.

3. 'Living Rapid Review' (first part published in June 2020) [88]: The following are a total of five updates have been published (most recently in March 2021) [89 - 93]. Checked the effectiveness of masks should be included in this continuously updated overview in the reduction of respiratory viral infections, including SARS-CoV-2, on the one hand in In the context of patient care in medical institutions and, on the other hand, in the

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Population. So far there has been no evidence of the effectiveness of masks outside the medical field.

4. Umbrella Review (published in July 2020) [94]: In this work, all available systematic reviews of randomized controlled trials evaluated (in the usual systematic reviews, on the other hand, the original studies are evaluated). The subject of investigation was the use of masks for Protection against respiratory infections in medical personnel and normal Population in public. There was no evidence for masks as Third-party protection, and even for the porters themselves, there was possibly only one Reduction of the risk of infection (self-protection).

5. Mathematical estimation (preprint, submitted in October 2020) [95]: There were eight various so-called non-pharmaceutical measures (in addition to wearing masks e.g. limitation of meetings, closing of shops, school closings) examined in 41 countries for their effect on the reduction of the R-value. It showed However, when including masks in the evaluation (together with the other measures) no further reduction in the R value resulted, i.e. masks have no effect.

The study was published in *Science* in December 2020, but the Evaluation of the masks no longer available [96]. The article does not explain this. If So if you haven't read the preprint, you don't notice that it's there in the first place The measure listed is missing in the final publication. It is mentioned at the end only that it is difficult to estimate the effect of masks in public spaces, because the other measures put into effect only have a limited public Life was there. In the preprint it said about masks [95]:

'Mandating mask-wearing in various public spaces had no clear effect, on average, in the countries we studied. This does not rule out mask-wearing mandates having a larger effect in other contexts. In our data, mask-wearing was only mandated when other NPIs had already reduced public interactions. When most transmission occurs in private spaces, wearing masks in public is expected to be less effective. This might explain why a larger effect was found in studies that included China and South Korea, where mask-wearing was introduced earlier. While there is an emerging body of literature indicating that mask-wearing can be effective in reducing transmission, the bulk of evidence comes from healthcare settings. In non-healthcare settings, risk Compensation may play a larger role, potentially reducing effectiveness. While our results cast doubt on reports that mask wearing is the main determinant shaping a country's epidemic, the policy still seems promising given all available evidence, due to its comparatively low economic and social costs. Its effectiveness may have increased as other NPIs have been lifted and public interactions have recommenced.'

6. Randomized controlled study (carried out in April and May, published in November 2020) [97]: In Denmark, this study examined whether the Recommendation, in addition to the other known protective measures (keep your distance etc.) wearing a surgical mask every time you leave the apartment, the risk for infection with the new coronavirus in a population with moderately high Can reduce infection rates. At the time of the study there was wearing in Denmark Masks are rare in public and have not been recommended to the public. At the Study could take part, who does not wear masks professionally and at least three Hours a day had to go outside the home and among people. Through the A total of 3,030 study participants were randomly assigned to the mask group

and 2,994 participants in the control group. An infection with SARS-CoV-2 could through Antibody detection, PCR test or hospital diagnosis can be established. In the In the mask group, 42 participants (1.8%) became infected with the new one Coronavirus detected in the control group in 53 participants (2.1%), the At 0.3%, the difference was therefore small (and not statistically significant). The The investigation aimed at self-protection and was therefore - different from the Mask requirement in Germany until January 2021 - not on third-party protection aligned so that this study does not contribute to answering the question

whether the wearing of masks by healthy people can have a protective effect has, i.e. whether it protects other people from contact with the pathogen can. However, the study is just as unsuitable for self-protection through based on medical masks on which politics in Germany is under the impression of the new variants ('mutants') since January also sets. For this too Decision that since then, when shopping and in public transport, OP or FFP2 masks (in Bavaria only FFP2) have to be used, there is no scientific one Basis.

7. Experimental study (published in December 2020) [98]: From Deutsche Bahn AG (DB) and the German Aerospace Center (DLR) was established on the occasion of the Corona pandemic carried out the project ' *Air Quality in Rail Vehicles* '. There should be carried out with an experimental procedure in a stationary test vehicle (type ICE 2) the propagation paths of particles in the order of magnitude of aerosol particles (simulated by the release of CO₂ as tracer gas or artificial saliva particles with a diameter between approx. 3 - 4 µm from a source at head height of a seated person in the train wagons). The measurements were performed with and without a (surgical) mask. Result (already) without a mask was that the spread mainly takes place directly and immediately at the source. A There was spread throughout the car or an indirect one via the ventilation system Not. Interesting is (1) the result that one is at a table of the exciter source Passenger sitting directly opposite (i.e. close face-to-face contact with approx. 1 - 2 m distance) only comes into contact with 0.2% of the released particles at the seats in front of and next to it on the other side of the aisle, on the other hand, only 0.01% arrived. With In other words, there would be practically none even for the person sitting directly opposite Risk of coming into contact with a released pathogen. Another important one Point is that (2) the ventilation system with a very high air exchange rate and also works with a high proportion of fresh air, so that about every 5 minutes the entire Air in the wagon has been exchanged once (ie 12 air changes per hour). That in turn means that it is for the passengers in view of the constant dilution by the supplied air could not come to any relevant pathogen contact, also because the contact time is far too short to be low, as the results show Spreading of the particles away from the source of the pathogen can lead to an infection, if it were infectious particles. DB and DLR would have based their results (which are very good on the ICE 1/2 fleet, but can also be easily transferred to many other types of rail vehicles) need that masks are not required on trains because there is (1) hardly any Aerosol spreads and (2) through the ventilation system all air of the Wagons are exchanged within minutes, making potentially infectious Particles are removed in no time. That means concentration infectious particles due to the high air exchange with fresh air supply constantly and very much is effectively reduced, i.e. a dilution of the particles in the air of the wagon takes place which increases the potential risk of transmission continuously, very quickly and at a high level

Dimensions reduced. The mask makes this risk only insignificant and only for the immediate neighbors reduced. For these reasons this study was here contrary to the interpretation of DB and DLR in the group of contra-mask studies included because the results contradict the fact that masks have an effect in the Sense of infection protection. But whether the 'aerosol' transmission that occurs in the Study taken for granted in the transmission of the coronavirus plays a role at all is the crucial question discussed in **Part C**.

Summary of the scientific basis for masks

Despite a lack of scientific evidence, both WHO, ECDC, CDC and RKI - all usually highly respected national and international scientific health authorities - wearing masks in the public space more or less recommended, albeit, as with the WHO [41, 42],

limited to special epidemiological situations, but with clear ones from all of them 'Warning notices' are provided, with the result that politicians focus on these, but without based on scientific assessments, the 'warnings' but limited to the need to keep your distance anyway.

One has to notice all national and international health authorities, though also cautious, contrary to the scientifically established standards of evidence based medicine with an assessment of the wearing of masks in public places have given great scope, which is only based on so-called plausible considerations, but this may not be enough to make politics in such a situation, ie for use with millions of people, a scientifically sound basis for decision-making convey. A clear scientific opinion on how to get it from these authorities can expect looks different.

It is therefore not surprising that the specialist literature published since spring 2020 no evidence of the wearing of masks by the population in public has been shown has, even if the authors of mathematical estimates claim so and the authors of opinion contributions in e.g. narrative reviews (cannot) submit any data for this. Numerous medical professionals from various disciplines and scientists from others Disciplines like to refer to such 'positive' publications, in particular often based on modeling studies that are for those with not particularly well-informed mathematical basics (not very rare among medical professionals) anyway are understandable and thus act as a deterrent, but perhaps precisely because of that suggest that it must be a particularly meaningful 'science'.

The scientific quality of Pro-Masken publications is (very) low because it is mostly about mathematical estimates, narrative reviews and opinion contributions acts, but there is a lack of meaningful systematic reviews. On the other hand, the quality of the Evidence of the contra masks publications high due to multiple systematic reviews (including meta-analysis).

As for the frequency of its citation for confirmation of mask effectiveness, is the so-called 'Lancet Review' at the top [43]: it has been and is almost reflex-like since its appearance at the beginning of June 2020, this publication by countless medical professionals as evidence called. You think you're on the safe side, probably because of this magazine (together with the NEJM) one of the two most important medical journals belongs to the world. This means that medical professionals can be sure that what is published there has a hand

Fuß, is put through its paces by a relentless peer review and can

be accepted with confidence. This assessment is complete with this article obviously not appropriate. In addition, this is easy to see, without that you have to know how meta-analyzes work mathematically. The WHO had this , *Urgent review* 'commissioned (and funded) because they apparently results urgent (therefore an ' *urgent* ' review) for a new evaluation of the mask Question needed for the new coronavirus. As early as 2019, the WHO had based on Influenza pandemics commissioned a similar review [87]. But there was influenza apparently not sufficient or sufficient for decisions about the new coronavirus. was considered meaningful and perhaps also because this review was not protective Has shown the effect of masks, the WHO requested an 'urgent review' in which only publications on the three special, because non-seasonal, coronaviruses SARS, MERS and SARS-CoV-2 should be evaluated (whereby SARS-CoV-2 likely to be a seasonal one).

For this, the WHO needed a publication in a journal that was beyond reproach. Ever The more recognized a professional journal is, the easier it is to get the messages published in it Article accepted and disseminated by the readership. But to what extent the result the literature search met the expectations of the WHO is unknown. You can Considered benevolently, express it like this: Both the authors of the Lancet Review and the

WHO with their mask recommendation of June 5, 2020 at least tried to pull out of the affair with scientific decency, so to speak. But the rest remains nevertheless, that the WHO has apparently submitted to political pressure, as has been reported, however then it makes the clear statement that the scientific evidence for the effectiveness of masks worn by healthy people in public is lacking. The Lancet Review says this too, albeit in a somewhat hidden way.

The WHO had a review on non-pharmaceutical measures incl. Masks commissioned, which has shown no effectiveness of masks [87]. In addition, was A systematic review with meta-analysis was published in 2017 in which the effectiveness of hand hygiene and masks were examined [99]. This meta-analysis indicates a significant protective effect only for hand hygiene, but not for Masks. The studies evaluated in it from the so-called community setting were included in Families with people with influenza. And also the 'Lancet Review' [43] was unable to show any effectiveness. Also those published afterwards Investigations or opinions could not prove the effectiveness of Show masks in public (see above). Thus there is after the scientific accepted criteria do not indicate that masks are worn by healthy people have a positive influence on the infection process in public (but possibly a negative effect; see **part B.**)

The fact that the mask requirement was imposed in Germany is not due to the To bring requirements of the IfSG in § 1 (2) into line, according to which Infection control measures should be evidence-based. Political decisions sees the IfSG is not proposed, and yet since the first lockdown in March 2020, political Made decisions that have no scientific basis.

It is clear that due to the worldwide shortage of professional masks (of which there is In spring 2020 there was nowhere near enough in clinics and nursing homes, so that they are for the use of the population in Germany was out of the question anyway) the general Mask requirement in Germany could only be introduced with the indication that Self-made masks or just a cloth over the mouth and nose were also sufficient.

Naturally, no statements can be made about the quality of non-medical masks be made because every citizen could use what they wanted. For that reason alone As stated in the article by the RKI, there may be no data on this [1]. It would be transparent been due to the lack of scientific data for the general use of Express reference to masks in public spaces. At least in the last one Sentence of the RKI article [1], as everywhere before in the text, only should be spoken of that the masks could be a building block to reduce transmissions, but not, to formulate this as a fact.

All expansions of the mask requirement, such as in schools, in parliaments and on Hiking trails (e.g. through the Höllentalklamm in the Zugspitz area due to bottlenecks the way), in pedestrian zones in city centers or in parking lots in front of shops possible crowds or in some communities when cycling in urban areas are based not least on the unscientific 'aerosol' discussion that bio-Propagated by scientists and by aerosol physicists as well as by manufacturers air conditioning systems ('air conditioning') has been taken up (see **Part C.**). At the beginning of September 2020 an article (in the politics magazine *Cicero*) dealt with the Fate of schoolchildren while wearing the masks [100]. The author (social scientist and educational researchers) thinks it is certain that no study will involve children for hours or days and weeks should wear masks, approved by an ethics committee in Germany would have been. But even pediatricians have spoken out in favor of school children Should be able to wear masks or be able to wear them without being damaged, even during the Teaching [101]. In, *Open Letter* 'a pharmacist has to expressed their opinion and expressed his incomprehension that the opinion of the pediatric societies lack any scientific and ethical quality let [102]. He asks whether the mask is not more of a political instrument than a

reasonable medical measure and the authors and signatories less than Doctors, rather than political functionaries, fulfilled a political mandate. Then, so the author continues,

However, *it would be appropriate to present this mandate transparently and to grant it declare that wearing masks for children is politically wanted and that it is part of it possibly existing risks must be accepted* ' .

A few months earlier this author had an article in the *German Pharmacist Newspaper* published in which he criticized, among other things, that all so far for the effectiveness of Masks important standards are overridden, and just some piece of cloth in front Mouth and nose are important without affecting the filter effectiveness (in view of different Particle sizes) and the correct handling of the masks is important or the actual risk of transmission plays a role [103].

Masks have been the only visible measure since the introduction of compulsory wear by the Politics and the scientists who advise them upheld and usually strictly demanded, although they had noticeably no effect over the months. Instead of them - as obvious useless, potentially harmful, and just nowhere near being scientific too Significant data confirmed - but the mask requirement was gradually abolished expanded to include, for example, the irrational obligation to wear outdoors in busy places or in pedestrian zones (which virologists and aerosol physicists also speak out against), to be worn by students even during the entire class and the FFP2-Mask requirement in shops and in public transport in Bavaria.

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The fact that students are now forced to wear masks for hours and that sometimes even during the break in the school yard and in physical education, is already given The complete lack of medical evidence is incomprehensible. On top of that there is there are no systematic studies on possible harmful side effects and that such examinations are not even carried out by the professional societies of paediatricians are required. That the side effects are by no means harmless or rare shows one (already published in December 2020 as a preprint and now finally published) Study by the University of Witten-Herdecke, in the preliminary results from a Online register in which, for example, parents, teachers or doctors can record the complaints of children in the

Connection with the wearing of masks will be presented [104]. The At this point in time (within 1 week of the start of the register) approx. 18,000 participating parents comprised nearly 26,000 children at an average Wearing time of 4.5 hours per day the following complaints (with the respective percentage Frequencies): irritability (60%), headache (53%), difficulty concentrating (50%), depression (49%), aversion to school or kindergarten (44%), Feeling unwell (42%), learning difficulties (38%) and sleepiness or tiredness (37%).

S3 guideline of the AWMF. Despite the lack of confirmation of the effectiveness of masks in the Public from scientific investigations became with the participation more numerous Specialist societies published an S3 guideline of the AWMF on February 1, 2021 in which the Wearing masks with the recommendation grade 'Strong Recommendation A' as 'Evidence-based Recommendation' was made although the quality of the evidence was rated as 'low' became [105]. The preamble to this S3 guideline states, among other things:

'(...) The aim of this guideline is to provide scientifically sound and to provide agreed recommendations for action.

The guideline recommends adaptable and suitable packages of measures for Reduction of the risk of infection and to enable the safest possible, regular and continuous school operation in pandemic times. (...)

These recommendations were made by a representative group of experts scientific societies, those involved in school activities and

Decision-makers worked out according to a structured approach. you are based on the currently available studies on the effectiveness of measures for Control and prevention of SARS-CoV-2 transmission in schools.

(...)'

Under the notes it goes on to say:

Standard package of measures. *For the prevention and control of SARS-CoV-2 Transmission in schools always requires a package of measures: measures must be implemented in a coordinated manner in order to be effective. starting point is a standard package of measures, which is generally in the population applicable AHA + L rules and the specific distance, hygiene, wearing provides an adequate mask and ventilation.*

(...)'

Evidence base. *The evidence on the effects of the measures regarding SARS-CoV-2 transmission was reported using a Cochrane Rapid Review systematically collected [Ref]. The knowledge gained is based to a large extent*

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on modeling studies with quality defects [Ref]. For the possible effects Concrete measures resulted in particularly meaningful individual studies the Cochrane Rapid Review [Ref]. For all effects considered the trustworthiness of the evidence is very low or low. '

The recommendation for 'ventilation and reducing the aerosol concentration in classrooms' shows very low evidence, but the level of recommendation is the same as for Mask recommendation 'Strong recommendation A'.

The requirement for the scientific basis of the guideline formulated in the 'preamble' is - as is usual with scientifically based guidelines - high. The concrete recommendations of the guideline in stark contrast, because despite the lack of meaningful scientific evidence (quality of evidence: 'very low' or 'Low') are both masks and ventilation with the recommendation grade 'strong Recommendation A' with a high level of consensus (100% for masks and 93% for airing) recommended. Contrary to the presentation in the 'Preamble', both are involved Recommendations are not 'scientifically founded (...) recommendations for action', only the degree of consensus among those involved was high, but this was due to the lack of scientific knowledge of the

recommended actions can not compensate. Otherwise you would be back in time before evidence-based medicine (around the beginning of the 1990s, i.e. around 30 years ago), where the experts presented their opinions and, if necessary, they voted on them, if there was no agreement anyway. Scientific basics hardly played a role at the time Role, but it came down to the 'experience' of the individual experts and their prestige in the Group of the respective colleagues. However, the S3 guideline follows the old one almost exactly Template. The only difference is that the underlying scientific evidence has been noted and classified in terms of its informative value. It is astonishing that the The level of recommendation was not influenced by this in any way (possibly for the Discussions, but not on the outcome, and that's the only thing that counts for a guideline). As a result, the S3 guideline of the AWMF is not compatible with the claim to such guidelines, but rather represents a perversion of what a scientifically founded guideline. She is ultimately misleading those who are not familiar with the importance of (high-quality) guidelines (S3). The She is very accommodating to political decisions and is possibly due to came about from subjectively perceived political pressure.

In July 2020, a study by the University of Leipzig on cardiopulmonary side effects was launched published by masks in adults [106]. The authors come to that afterwards Conclusion that in healthy individuals breathing, cardiopulmonary performance and Well-being when wearing surgical masks is reduced. Considerable However, there were limitations in this regard in connection with FFP2 masks observed. These negative effects would have to counteract the potential protective effect of Masks are weighed before virus transmission and should influence medical recommendations and policy decisions.

Another investigation (carried out in the first half of June 2020, i.e. within the

first approx. six weeks of the federal German mask requirement) dealt with the psychological, psychosocial and psycho-vegetative effects of wearing a mask [107]. The author comes to the following conclusion: The fact that approx. 60% of the (approx. 1,000) study participants already under the mask requirement at this early point in time suffered severe (psychosocial) consequences, e.g. greatly reduced participation in life in the Society (due to the desire to avoid wearing masks), social withdrawal,

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decreased health self-care (up to and including avoiding doctor's appointments) or the intensification of pre-existing health problems (post-traumatic Stress disorders, recurrent herpes simplex, migraines), indicate that the The results of the study urgently require an examination of the risk-benefit ratio of the mask Regulation made necessary.

The use of the masks by politics as an important measure to contain the Pandemic and the observations that have been made in the media by politicians and in the (normal) public to deal with the masks can show that it is well it is not about the fact that masks have to be scientifically proven to be effective, nor that they are handled in such a way that they do not pose a risk of contamination. The RKI could have pointed this out long ago or repeatedly and have to do what you have to do with the correct handling of masks in order to protect against infection understands, but there is only an occasional brief reference to it. This aspect too shows that the mask requirement is less about the claimed benefit in the sense of Infection protection is about, but about their (psycho) social function, as it is very clear in a Publication from the time of the so-called Spanish flu was expressed [108]:

' If doubt arises as to the probable efficacy of measures which seem so lacking in specificity it must be remembered that it is better for the public morale to be doing something than nothing and the general health will not suffer for the additional care which is given it. '

Even today, the mask seems to have the decisive function of serving the population show that the government is doing something to protect them from the suspected risk of infection protect. On the other hand, it should represent a kind of reassurance for the population that they are wearing the mask for their own benefit and that of others can contribute. The mask is used by both politics and the population, who trusts the measures of politics, needed to maintain the mental and spiritual condition stabilize - of course also those of the politicians who are practically naked, i.e. without 'protective measures'

for the population in times of the pandemic, if they did not have the mask, there would be and therefore hold on to it, although experience since spring 2020 shows that it cannot have the desired effect because the number of people who tested positive is uninfluenced high or rose and rose from time to time even in unknown Heights - in spite of the extensive mask requirement. That the mask requirement is off psychological reasons and because of their symbolic meaning as early as July 2020 for the reintroduction of the strict mask requirement in Austria both the Federal Chancellor and the Minister of Health of Austria was expressed in ZIB 2 on ORF 2 and at a press conference [109].

B. Hygiene

At the beginning of June the federal government published the AHA rules [110]. The 'H' stands here for 'hygiene', and that means (1) coughing or sneezing into the crook of your arm and (2) often and wash your hands thoroughly for at least 20-30 seconds. (3) the correct handling of masks. By the time the AHA rules were in place, there were about six Weeks passed after the mask requirement was imposed, and by then it was enough known about the inadequate and thus potentially infectious handling of the Population with the masks. In this section, therefore, are the risks from the point of view of infection protection, with the mandatory use of masks for almost the entire population are connected, discussed when the politicians are already betting on it.

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Use of masks is not self-explanatory

The population never learned how to use masks correctly, and has continued to do so. Imposition of the mask requirement not trained in it. The RKI has never done this, e.g. in Press conferences, specifically expressed. It always stayed with the population meaningless formulations, they have to be used '*correctly*'. Instead of constantly repeated requests to stay at home would give people one Provide continuous training in the use of masks and make it clear to them in the process must that and why certain rules are followed when using masks Need to become. In addition to the lack of a scientific basis for the mask requirement (see **Part A.**) So this aspect is important: If there are masks, then the right one has to be Dealing has a central role to play, so don't risk yourself through the masks the spread of the pathogen is increased. It's hard enough to make the necessary rules to convey these rules in their minds to the medical staff anchored so that as an employee in the field of hospital hygiene one does not repeat have to remind you (but you have to). Why this is important is explained below become.

The RKI points out in two places of the (short) article, with the masks in public were justified, insistently on the problems associated with the application from masks (MNB) to [1]:

1. ... that '*the use of MNB the central protective measures, such as the (self-) Isolation of sick people, keeping the physical distance of 1.5 m, the rules of coughing and cannot replace hand hygiene to protect against infection. This central Protective measures must therefore continue to be strictly adhered to*'.
2. *The hygienic handling and maintenance of MNB must also be observed. Out For this reason, it is important to ensure that the MNB - especially when opening and closing Withdrawal - not touched (emphasis added for this opinion) is to a Prevent contamination from hands. In general, a longer wearing time is possible also associated with an increased risk of contamination .'* (here the RKI refers to the Notes from the BfArM = Federal Institute for Drugs and Medical Devices; see below [111]).

However, the correct handling of masks is not self-evident for the population. It is rather confusing when the RKI writes that you shouldn't touch the masks, too not - or even '*especially when putting on and taking off*'. It doesn't sound like this comprehensible. Only experts know what is meant by this. The BfArM provides more information Comments on this (see below). The citizen should therefore have the important information search together from the pronouncements of various higher federal authorities.

Correct use of masks is important

There is a mask requirement according to RKI, which stipulates the obligation to use masks in the Public has only made possible through its publication [1], because every citizen unrecognized that new coronavirus can carry in the nasopharynx and because it is supposed to '*Unnoticed*' transmissions of the pathogen to fellow human beings during encounters in the public space (see **Part A.**). Almost everyone in Germany so have to wear masks because we can't know if we're currently infected with the virus Have nasopharynx even when we don't have symptoms of an upper respiratory infection

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have, and therefore, because of this ignorance, cannot stay at home to protect other people from contact with 'our' virus. The mask - which one Whatever the type, originally just the so-called everyday fabric mask (MNB), since January In 2021 the medical mask as an OP or FFP2 mask - should prevent that Virus that may be present in us is released into the environment. What all mask types have in common is that they must be used correctly in order not to quasi becoming an infection risk yourself. Because if we go undetected the virus

or if it is in our nasopharynx without symptoms cause, increased or increased, then we are according to the theory of 'Unnoticed' transmission with our nasopharyngeal secretions a potential source of pathogen, from which it leads to the spread of the virus from our bodies to other people could come. So the mask cannot be the only one to prevent this. Be protection, because people - for whatever reason - very often deal with the Hands in the face, which is a well-known fact that everyone can check himself and his fellow human beings in daily life at any time [112]. And when you wear a mask, your hands are more often on your face because they Mask bothers. For example, you sweat underneath, it itches, your glasses steam up, your mask is corrected, or you do not get enough air (this also applies to the Everyday masks, not only with FFP2 masks). So people are with theirs all the time Hands on the mask, which according to the RKI - correctly - should not be touched. Either way, you can either yourself or your fellow people over the mostly unnoticed Hand-face contacts come into contact with infectious agents precisely where the Respiratory pathogens must reach in order to produce an infection can, namely to the mucous membranes of the upper respiratory tract, including the eyes (or where they if you are already infected). Incidentally, we have known for decades that respiratory viruses (whether enveloped, such as rhinoviruses, or enveloped, such as influenza and Coronaviruses) also outside the body for a certain period of time (depending on the extent of their Embedding in remains of respiratory secretion) can be grown in cell cultures and thus can remain potentially infectious [113 - 115]. Because you are on different occasions (in your own household, at work as well as in public) can contaminate the hands almost constantly and inevitably has frequent hand-face contacts of his own, hand washing is a must View of all health authorities in the world as well as, for example, the results of the Cochrane review updates [1, 33, 35, 37, 42, 111], to the acknowledged indispensable measures to prevent the transmission of respiratory infectious agents to reduce. But that is precisely what you cannot do when you are out shopping, for example or uses public transport. Hand disinfectants are also not always available.

Hand hygiene: hand washing

When all the health authorities in the world on the importance of hand washing Always wash your hands thoroughly with soap and water over the age of 20 - 30 meant sec. For the general education of the population about individual protection against infection - in addition to emphasizing the general need for frequent hand washing - is It is also necessary to point out that you should not touch your face with your hands if possible should grasp as long as you couldn't wash your hands. That's exactly what they say international health authorities clearly, the RKI also says so, but less often and not in a prominent place and also not in the AHA rules. However, it's not easy, man

but can train it: If you know that it is important, you can train yourself observe and reduce your own hand-face contacts. Therefore, information campaigns for the population should not only focus on the Point out the necessity of frequent hand washing, but also expressly why hand washing is so useful and important: so that one does not become contaminated with Hands on eyes, nose and mouth. Only then can the request for Hand washing really understood and not (so easily) dismissed as an annoying hygiene rule become. It is for this reason that all health authorities in the world point to the large one Importance of hand hygiene towards the transmission of respiratory viruses through to reduce indirect contact or through your own hand-face contact (the same applies in Otherwise for the prevention of gastrointestinal infections whose pathogens, e.g. noroviruses, can also be acquired through contaminated hands and subsequent mouth contact can).

For the prevention of the transmission of respiratory pathogens, this means that you should should not touch or under the mask, as this will contaminate your hands and

so that through surface contact he can expose his fellow human beings to the risk of being in contact with to advise your own pathogens and to get an infection, but what exactly should be prevented by the mask.

Hand hygiene: hand disinfection

You have to learn how to use hand sanitizer correctly, because Hand disinfection is by no means trivial (and is done with medical staff trained repeatedly, e.g. by using a UV lamp to check after using a fluorescent hand sanitizer under the UV light to see if really the entire skin of the hands and especially the fingertips including the thumb disinfection included). For those used for hand disinfection Means are alcoholic solutions with mostly 60 - 80% alcohol, the Contain moisturizers so that the skin does not get too dry, because alcohol dries the skin otherwise off (hand washing as well). They are usually very well tolerated (alcohol is not toxic), but it is sufficient despite the addition of lipid-replenishing substances Skin care is important if you have to disinfect your hands frequently, as is the case with medical personnel is the case. If done correctly, hand disinfection is more effective than washing hands (eliminates or reduces more potential infectious agents in less time Time), but in normal life, hand washing is the method of choice while in medical area in patient care (among other things for skin protection reasons) hands should only be washed if they are visibly soiled.

When you go shopping in public, for example, you usually don't have any Ability to wash your hands. Therefore, for example, grocery stores have about Hand disinfectant at the entrances to shops since early summer 2020 provided, in addition to other disinfectants intended for surfaces (i.e. especially to wipe the handle of the shopping cart with it), but none Contain refatting agents if they are also alcoholic, because that's for them Purpose is not required. One may therefore confuse them Do not use hand sanitizer with the surface disinfectant, especially if this Means contain other active ingredients and not alcohol, because other active ingredients are not allowed on applied to the skin because they are toxic to humans or maybe 'only' have an allergic effect. In this respect, the provision of

Disinfectants lead to misuse by the population who use the Does not know the difference between hand and surface disinfectants (and usually does not have to know either). The shelves on which the disinfectants are Self-application are offered, also usually look messy and convey so that it does not give the impression that all of this is supposed to be about cleanliness. But assuming the right hand disinfectant is used, there is there is a further difficulty for the population untrained in hand disinfection: it It is not enough to simply take any amount of the disinfectant solution, it has to be sufficient to cover the entire skin of the hands to be able to wet. This is a little different depending on the size of the hand, usually it is about 3 mL, which is required even for smaller hands (for larger accordingly more). With this amount you have a puddle in the palm of your hand, and that means but also that a lesser amount or even just a little spray does not result in a effective hand disinfection. Then you have to - not this puddle unlike when washing your hands, ie in the truest sense of the word according to the principle: 'One Hand washes the other' - distribute over both hands so that on the one hand the whole The skin of both hands is moistened with the agent. On the other hand, you have to have the means Rub in all over the place until your hands are dry again. This takes a total of 20 - 30 sec, which only seems short, and only then can you talk about an effective one Talk about hand disinfection. Distributing the funds everywhere, however, also has to be very conscious happen, because it is not enough to just rub the palms of the hands together. Much more one must make sure that particularly fingertips and thumbs are included because you have the crucial contacts with objects or surfaces.

For effective hand disinfection, the spaces between the fingers and the Wrinkles of the palm of the hand, but in normal life (as in the case of the medical care of patients) you actually have important contacts with the fingertips (this is why long fingernails are an obstacle to effective Hand disinfection because you are no different than when you wash your hands when you do not Used a nail brush that does not get under the fingernails). Contact with the Flat hands or the spaces between the fingers are much less common. The population does not know anything about this (nor does it have to), but it got to be also not explained. So it can happen to people who are themselves in the field of medicine work and therefore know how to properly, ie effectively disinfect your hands With people being criticized, they shouldn't get so much of the remedy and hurry, because others wanted to disinfect their hands too. In summary, it can be said that with some certainty the possibility of Hand disinfection cannot replace washing hands with soap and water wherever you have at least a certain mechanical wash-off effect by the water, even if you don't really spread the soap all over the skin of your hands. In addition, the hands, no matter what you did before, so Hand washing or hand disinfection, immediately re-contaminated when you come back touches the mask or other objects. That is also not the case with the population consciously, because she has not learned (and neither had to or must learn) that namely, even a proper hand disinfection does not protect the hands from being in the next moment, i.e. the next contact with an object or a surface, can come into contact with potential infectious agents again, i.e. are contaminated. But this is what medical staff learns. In this respect, what is provided in front of the shops helps

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Hand disinfectant does not, but only leads to a deception and creates (again, like the masks) a false sense of security.

Disadvantages of masks in terms of hand hygiene

All health authorities, the BfArM and the Cochrane Review give clear indications on the use of masks or the necessary handling of masks and the associated Indispensable hand hygiene so that it does not spread through their use comes from SARS-CoV-2 [1, 33, 35, 37, 42, 111].

Contamination. Masks are used by the wearer when exhaling and speaking from within contaminated and can through hand contacts and respiratory droplets of others People are also contaminated from the outside. Masks used in public spaces are worn should serve as 'external protection' or 'source control', according to the theory, ie for those who wear masks who are (still) undetected infected, they should be in Potty-released pathogens can be caught by the mask so that they can be as possible do not get into the environment (or at least not in large numbers).

With this assumption, the inside of the mask is potential (because you don't know whether one is already infected) contaminated with the pathogen. That means that you can at least when contacting the inside of the mask with your own hands with those from the own nasopharynx (NRR) in the case of pathogens released (still) unnoticed can contaminate, similar to touching one's own mucous membranes Eyes, nose or mouth happens. With the hands that may be contaminated in this way one then also touches public surfaces (e.g. the handle of the shopping cart or the handrail of escalators). Subsequently, these surfaces are used by others People also touched, which leads to the spread of the pathogens from the NRR of the mask wearer can come.

Moisture penetration. Every mask (even the professional medical mask) is included in the Longer wearing sooner or later moistened by the exhaled air and thereby permeable and then no longer represents a barrier. Rather, the potential Infectious agents from the NRR (by the way, these can also be bacteria, such as in particular Staphylococcus aureus, one of the most common causative agents of purulent infections of e.g. random wounds) not only found on the inside of a moistened mask,

but also on the outside.

As an employee in hospital hygiene, this is what the clinically active staff is advised of, like the medical staff incidentally, also repeatedly to the correct use being reminded of masks, e.g. not to shake hands with potential

To contaminate infectious agents from your own NRR if the mask against the Rules is worn hanging around the neck to be put back on later.

RKI, ECDC, CDC and WHO emphasize the need for extremely careful hand hygiene and avoidance of hand-face contact are essential and through use of masks in public should not be neglected.

The BfArM also has corresponding warnings and precautionary measures for handling published with masks (MNB, MNS or OP mask, FFP mask) for the public.

In the spring of 2020, the BfArM explicitly stated that sponsors of community Masks cannot rely on the masks to be used by them or others in front of a person

Protect the transmission of the new coronavirus, as there is no corresponding one for these masks

Protective effect has been proven. This (correct) representation has been in place since November 2020

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no longer available on the BfArM website. Instead it said there with the date from November 12th, 2020:

'Independent of normatively defined performance records, such as those for medical Face masks and particle filtering half masks are required meanwhile on the basis of the broad, internationally gained experience the Effectiveness of the mouth and nose coverings in a general sense Civil protection confirmed in numerous scientific publications (Ref.). The protective effect of the masks depends on the tightness and Quality of the material used, the adaptation to the shape of the face and the Number of layers. For example, tightly woven fabrics are better in this context suitable as lightly woven fabrics. By properly wearing good 'everyday masks' According to the current state of knowledge, the risk from pathogen-containing Droplets are significantly reduced.'

But after the federal government decided in January 2021 that only medical Masks (mouth and nose protection = MNS or surgical masks or FFP2) may be worn, the text has been adapted accordingly and is now (last viewed: March 29, 2021) [111]:

'Everyday masks do not provide the ones defined in the technical standards Proof of achievement such as those used for medical face masks and particle filtering Half masks are required. So they usually offer less protection than this regulated and tested mask types. But that doesn't mean they don't Have protective effect. Internationally there are numerous scientific Publications that reflect the experience gained on the effectiveness of the Mouth and nose coverings in terms of general civil protection confirm (Ref.). The protective effect of the masks depends on the tightness and quality of the material used, the adaptation to the face shape and the Number of layers of fabric. Tightly woven fabrics are in this context for example more suitable than lightly woven fabrics. So can the right one According to the current state of knowledge, wearing good everyday masks is therefore the risk significantly reduce with pathogen-containing droplets.'

(The references given do not confirm the effectiveness of masks; see above under the heading RKI: 'First scientific information' for the External protection, p. 32 of the report).

The BfArM has formulated the rules for the use of masks as follows (here summarized for the different mask types) [111]:

- The masks should only be used for private use.
- The tips on hygiene, as they are in the recommendations of the Robert Koch Institute (RKI, www.rki.de) and the Federal Center for Health Education (BzgA, www.infektionsschutz.de) should be followed. This is the only way to protect ourselves and

others from the spread of the coronavirus.

- Even with a mask, the safety distance recommended by the RKI should be at least 1.5 m to be followed to other people.
- MNB.** The mask must fit well and sit over the mouth, nose and cheeks. The edges of the mask should fit snugly so that as little air as possible passes the mask is breathed. It is best to try different mask shapes until you can find a suitable one.

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- MNS.** The mask must fit well and sit over the mouth, nose and cheeks. The edges of the mask should fit snugly so that as little air as possible passes the mask is inhaled. By adjusting the length of the ear loops (e.g. knot) you can improve the sealing fit.
- FFP2.** The mask must fit well and sit over the mouth, nose and cheeks. The edges of the mask should be snug and no air currents past the mask allowed. An FFP mask can only achieve its full filter performance if it sits tight.
- When using the mask for the first time, it should be tested to ensure that it has enough air in order to impede normal breathing as little as possible.
- A moistened mask should be removed and changed.
- When putting on and taking off the mask, it should, if possible, only be carried out by the straps of the mask.
- After taking off the mask, hands should respect the general Hygiene rules should be washed thoroughly (at least 20 to 30 seconds with soap).
- After removing the mask, it should be hermetically sealed in a bag or something similar stored or washed immediately. The storage should only be about as much as possible for a short time, in particular to avoid the formation of mold.
- MNB.** Masks should ideally be washed at high temperatures. At the best at 95 ° C, but at least at 60 ° C. Do not use short wash programs and then let it dry completely. Be sure to note all other Manufacturer's information, such as the number of washes the mask can withstand without to lose their function.
- MNS / FFP2.** The masks are intended as single-use products by the manufacturer. you should be changed regularly and disposed of after use.

Reality when dealing with masks in public

Correct handling of masks is essential for medical staff, as already mentioned, not always easy to get to. With the population, however, all of these are considered indispensable respected requirements cannot be realized even in the beginning. That's how it is with shopping e.g. to observe:

- The mask is often adjusted with the hands.
 - It is often worn with the nose uncovered.
 - It is particularly problematic for people who wear glasses because the glasses fog up because in contrast to a professional surgical MNS, the community mask is missing usually a slightly flexible bracket that fits well to the anatomy of the nose can customize. So you have to take off and put on the glasses repeatedly and inevitably comes with your hands on the outside of the mask.
 - Even if the weather is not particularly warm, you sweat under the mask and therefore always goes with the hands on the mask or even under it.
 - Outside the shops, the mask is often only partially removed and then hangs with a noose over one ear, is pushed under the chin, is on the wrist or forearm or it is removed and simply put in the hand, pants or jacket pocket. It can also be observed that the mask (sometimes several at the same time) so that it is always at hand for the next use, in the Car hangs on the rearview mirror.
- However, you also have to ask yourself how to do it differently on the go, yourself

if you try not to contaminate your hands on the mask as much as possible:

- You cannot wash your hands when you get out of the car and in front of you
- Entering the store you have to put on the mask, and you can also go after

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When the mask is removed, leave the store, not your hands to wash.

- Hand disinfectants are also not always available.

The next question is how to do it contamination-free after the masks to supply any use when you have to go to several shops:

- One possibility would be to simply leave the mask on after leaving a store, as has been observed in some people. Then you could all Errands (and the distances in between, if there are footpaths) with a single Make mask. People then walk around outdoors wearing a mask where they can is usually not required.

- It is likely that the mask material will wear out during multiple purchases moistened.

In everyday life this is an impossible task if one wants to get tens of millions of citizens to do this necessary precautions to be taken when using masks if that even with medical staff is not that easy, but where with the Hygiene specialists (hygiene specialists, hospital hygienists) always have people on site Can remind you of the right way of dealing with it: It is unrealistic. That is why the mask Recommendation of the RKI cannot justify that on the necessary Precautions is pointed out because these are unsatisfactory claims acts that are inevitably and noticeably not implemented by all specialists (can).

Every day tens of millions of citizens in Germany can Millions of contaminations result, most of which are avoidable because the already frequent hand-face contact of people through the Mask requirements are becoming more common, but hand washing on the go is only an exception is possible, and for a correspondingly frequent hand disinfection every citizen would have to Have hand sanitizer with you. There is a risk that the - yes inevitably - improper use of the mask and an increased tendency to self touching your face while wearing the mask actually runs the risk of The spread of pathogens and thus the transmission of pathogens is still increased, a risk that one does just want to reduce through the mask. The increase in positive test results since The beginning of the mask requirement can therefore also be traced back to the mask requirement itself become.

C. Aerosol transmission

In the following, the question will be discussed whether and, if so, what role infectious 'aerosols' play in the transmission of the new coronavirus. The question of aerosol transmission is in connection with the potential effectiveness of masks and also under the aspect the so-called unnoticed transmission as well as for the distance requirements of great Importance.

Almost all of the 'hygiene measures' used by politics have the aerosol Transfer as a basis, even if it is not (always) explicitly justified with it: But there are measures such as the all-round distance or the FFP2 mask requirement or the ventilation no other explanation. As shown in the following considerations should, the theory of aerosol transmission is medically neither plausible nor plausible scientifically proven.

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The increasing importance of aerosol transmission in Germany

A mixture of suspended particles in air is called an aerosol. Of the

From media coverage to specialist articles, however, the term 'aerosol' is used frequently reduced to the suspended particles. One must correctly speak of aerosol particles. It does not have to be an infectious agent, because all suspended particles can form an aerosol.

In the meantime, many people with SARS-CoV-2 keep the transmission route via aerosol (i.e. a Airborne or airborne transmission) is relevant. According to the most recent Presentation of the transmission routes by the WHO (from 01.12.2020) will be the new Coronavirus (like all other respiratory viruses) via (large) droplets respiratory secretions and through direct and indirect contact with respiratory secretions infected people [42, 116]. An aerosol transfer outside the medical care (where aerosol-producing measures may be used such as open endotracheal suctioning of intubated patients) cannot be excluded, but the detailed examination of all published clusters which the respective authors postulate an aerosol transmission or at least for probably held, suggested, according to the WHO, that transmission via so-called large droplets and / or contaminated objects (i.e. contact) the Could also explain the transmission of pathogens within these clusters [116]. The other international health authorities (ECDC, CDC) also vote on it agree that the causative agent of COVID-19 - like other viral respiratory pathogens - is mainly transmitted via large droplets and contact [117, 118]. The RKI sets does not hold on and considers the aerosol transfer to be possible in principle, emphasizes this But not the transmission route [119]. The role of airborne transmission in SARS-CoV-2 is therefore at least scientifically unclear.

Nevertheless, shortly after the pandemic began in spring 2020, different scientists (especially from virologists, but soon also from Aerosol physicists) put the aerosol transmission in the foreground (this also in the With regard to the alleged asymptomatic / presymptomatic transmission) and subsequently in public through the media as at least as important Transmission path as shown for transmission by (large) droplets ($> 5 \mu\text{m}$). In the meantime, transmission through aerosol particles is used in politics and in Considered so important to the public that in September 2020 the federal government approved the Has included 'ventilation' in their AHA rule. For the same reason it has been used in numerous Clinics, on the initiative of the respective clinic management, use FFP2 masks for made the staff compulsory - but this without the RKI having recommended it, because there one remains - so far at least - unchanged with the recommendation, FFP2 masks only when there is close contact with the patient (= requirement of occupational health and safety) and with so-called aerosol

to use manufacturing measures [119]. Even if, for example, the virus RNA of the new coronavirus (or the nucleic acid other respiratory viruses) from the air could be detected from it not be concluded that they are reproductive and infected viruses [42]. Likewise, the release is already there floating droplets when speaking, sneezing, coughing or singing are not evidence of one Transmission by aerosol particles, because an infection occurs in addition to (1) the Defense situation of the contact persons and possibly existing predisposing chronic ones Diseases, (2) the type and duration of contact, (3) the stability of the virus in the

Air, (4) on the amount of pathogen and (5) on the number that can in principle be reached susceptible cells (= cells with ACE-2 receptors) depends.

One result of the constant mention of 'aerosols' is that interiors are now often and in spite of the cold, not only should the room be ventilated for a short time so that schoolchildren in the

had to sit warmly dressed in class during the cold season, or, for example, at a longer dental treatment starts to freeze because the windows are open all the time. It is also seriously considered (or by politicians and aerosol researchers

required), expensive high-performance air purification devices with particulate filters (so-called HEPA filters

Class F 14, i.e. a filter material that is able to remove even such tiny particles as To secrete viruses, which are many times smaller than bacteria, for their elimination one, e.g. in operating theaters, 'only' uses class F 13 filters), e.g. for schools or Restaurants to buy, but without solid scientific evidence. Because The WHO also calls for high quality scientific research to be carried out To clarify or check transmission routes, the infection dose and the settings, see which transmissions with SARS-CoV-2 occur more frequently [42].

Behavior of aerosol particles in the air

Respiratory droplets consist of glycoproteins and salts in an aqueous solution, and infectious agents can be distributed in it. Potentially infectious aerosols are created the one hand outside the body when the water content is small respiratory droplets in the (compared to the respiratory tract) dry ambient air through evaporation is reduced and in this way suspended particles are created [120 - 128]. Such tiny droplets are also exhaled from the deep airways [123, 124]. If, for example, a cloud of larger and smaller droplets (droplets) is generated when coughing released, the large ones sediment close to the point of release, and the smaller ones quickly become smaller and smaller due to evaporation and sometimes disappear completely, if they did not include a pathogen, that is, if they did not have a 'nucleus'. We have therefore been speaking in the international specialist literature on infectious diseases for decades of so-called droplet nuclei (aerosol particles). The initially released cloud In addition, it does not simply stand in the air in front of the person, but becomes additionally to the Reduction through sedimentation and evaporation also through air movements divided, so thinned by the air, until individual particles float freely and with the Air movements are distributed in the room air. Larger and therefore heavier droplets are shortly after being released from the air disappeared after sedimenting on any surface. The rest are left smaller ones that sediment much more slowly and usually evaporate very quickly, so quickly and successively smaller, and also the tiny droplets that are in the exhaled air are already floating, i.e. already as aerosol particles from the (deep) airways are released [123, 124]. Extent and speed of Evaporation are dependent (1) on the relative humidity: the lower, the more faster, (2) on the air temperature: the higher, the faster, and last but not least (3) on yours initial size: the smaller, the faster up to lightning-fast [127]. When coughing and sneezing, a particularly large number of droplets are released, and that too be thrown into the air by the force of coughing or sneezing and therefore being able to cover greater distances (several meters) [120, 121]: Most have a diameter of $<100\ \mu\text{m}$ (for comparison: $1\ \text{mm} = 1,000\ \mu\text{m}$). This size have about 80 - 95% of the droplets released when coughing and about 99% of those released when sneezing.

When coughing, almost 50% of these droplets are smaller than $4\ \mu\text{m}$, and when sneezing, they are scarce 20%, and thus they are already initially floating, but they also get through immediately Evaporation even smaller, until they have possibly disappeared (if no 'core' was present). The remaining somewhat larger droplets also dry up quickly and can therefore also become suspended particles, but again only if after the Evaporation of the water content remains, e.g. salt crystals or dried egg white, or if the droplet contained an infectious agent as a 'core'. If such a nucleus was not present, however, such droplets can logically arise no potentially infectious aerosol particles are formed after evaporation. Even if aerosol physicists use the droplet clouds, for example when coughing, or with artificial ones Most people can visualize aerosol particles released droplets disappeared from the air within a very short time (by rapid Evaporation and sedimentation). Only the part of the droplets can lead to the formation of

infectious aerosol particles which, when released, form a core
Contained infectious agents that after evaporation as suspended particles in the air
stay.

Aerosol physicists always emphasize that an aerosol is in principle in the air for hours
can stand 'if it is not broken up by air movements and by ventilation - natural
Ventilation through windows or mechanical ventilation through ventilation and air conditioning (RLT)
Systems (so-called air conditioning systems) - is removed. In principle, this also applies to droplet nuclei,
which arose after a coughing blow, for example. When droplet cores out
Infectious agents exist, their potential infectivity depends largely on three factors
from (see below): (1) How long can the pathogens float freely in the air
remain infectious? (2) Can the pathogens reach the specific target sites (more precisely:
Cells) get into the airways where they have their port of entry, i.e. where they are
have to get there in order to trigger the respective infection? (3) achievement
enough pathogens reach the target cells of a basically susceptible person to cause an infection
can arise?

Aerosol particles which, for example, after coughing from the respiratory secretion released in the process
caused by evaporation or released as particles that are already floating
but do not all contain the pathogen that may arise from the respiratory secretion
can be proven. That is true even if a person has an acute infection of the
Respiratory system, i.e. a correspondingly high concentration of pathogens in the respiratory system
Has secretion. So you are not, for example, with a viral infection of the upper respiratory tract
inevitably a so-called 'virus thrower' (this is also shown, for example, by the results of the Hong Kong
Study [30]). A large part of the released larger and smaller to tiny ones
So droplets are not infectious even if you have an acute cold,
but this only affects a small part of the droplets of all sizes [122, 125].
One article shows that a virus concentration of 7×10^6 copies
per mL the probability is only 0.01% that a $1 \mu\text{m}$ droplet (at its
Release with a water cover still $3 \mu\text{m}$ in size) contains a virus particle [129]. For a $50 \mu\text{m}$
Droplets, the probability of evaporation is approx. 37%, for a $10 \mu\text{m}$ droplet
but already reduced to 0.37% and that such a droplet is more than a virus particle
contains (assuming a homogeneous distribution in the nasopharynx), be
negligible [129].

In the meantime it is known to the general public through countless media reports,
that suspended particles move with the air movements (with or without mechanical

Ventilation, so-called air conditioning) can distribute the air in the room over many meters
as a result, however, they also become massively diluted the further they move away from the source
mostly not mentioned, although this aspect is crucial for the risk of infection. Also at
the mask requirement in the open air, which - unspoken - as well as the all-round distance
(see **Evidence Question 4**) is due to the aerosol theory, the aspect of
Dilution in the air, which is very effective in the outside air, is far too little taken into account
This factor is essential and would help calm the people who are facing
fear the virus. It follows that a mask requirement in the open air, whether in
Pedestrian zones or, for example, at a farmers' market, an irrational measure without
Infection protection effect is.

Behavior of aerosol particles in the respiratory tract

Since so-called large droplets ($> 5 \mu\text{m}$) sediment shortly after the release, they can only
with close face-to-face contact ($< 1 - 2 \text{m}$) and only possibly (because not all of them land
there, but also, for example, only on the skin of the face) the mucous membranes of the eyes, nose
or mouth, meaning they can only go into the upper airways, if at all
reach. The smaller the particles, the further they penetrate into the deep respiratory tract.
These properties are used for aerosol therapies [122]: (1) At
For diseases of the nose, particles $> 5 \mu\text{m}$ in diameter are used,
(2) for diseases in the area of the trachea and the large bronchi particles from $2 - 5$
 μm and (3) in pulmonary diseases particles of $2 - 0.5 \mu\text{m}$, down to the smallest

Bronchi and alveoli can penetrate. From simulation models is the deposition rate for aerosol particles in the respiratory tract is known [123]: After that, 94% of particles of 1 μm are deposited in the lungs and only 6% in the upper respiratory tract including the windpipe (trachea). Particles with a diameter of 2.5 μm will be deposited in the nose only in 4%.

However, very small aerosol particles cannot only get into the lungs from the ambient air are inhaled, but they are also produced there, i.e. in the lungs exhaled [123]. These particles were exposed to test subjects using laser technology measured [124]: It was found that when breathing calmly, no particles $> 5 \mu\text{m}$ were released, but very many tiny particles of about 0.4 μm in diameter be exhaled, so the lungs are a kind of ' *aerosol generator* ' (through special breathing Maneuvers could be shown that these tiny particles arise in the lungs and not only in the upper airways).

From this one can conclude that these aerosol particles can only be infectious if if a person has pneumonia (= pneumonia), and that is an infection with SARS-CoV-2, as is well known, not the case for most people - and if you do If you had pneumonia, you are (1) seriously ill and therefore cannot under any circumstances (2) People go (restaurant, public transport, shops, etc.). So one comes for these reasons also not in question as a source of pathogen transmission in public space. As decisive prerequisite for the fact that inhalation of aerosol

Particles could lead to an infection, the released particles must carry the pathogen and for this purpose the particles must arise at the site of the infection [128].

For aerosol-physical reasons, it is precisely the very small ones that accumulate in the room air Particles (produced in the lungs) about 0.4 μm in size and can stay in the Air remains while the larger and also the smaller ones disappear [124]. A

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Particles of this size can presumably take up at least one virus particle, and thus the author (an aerosol physicist) concludes that individuals with infection are due to it SARS-CoV-2 release suspended particles that contain the virus while breathing, and that these infectious particles remain in the room air for a long time - and thus from others Humans could be inhaled [124]. For this (see above) an infected person would have to be have pneumonia because these tiny particles are made in the lungs.

The majority (70%) of the inhaled respirable particles between 0.1 and 0.5 μm is exhaled again, meaning only about 30% of these smallest particles is somewhere in the deep airways (= lungs), the greater part only penetrates briefly when inhaled in, but then leaves the airways again on the next exhalation [123, 124].

In order for respiratory viruses to cause a respiratory infection, they must infectious particles land (impact) on the special cells of the mucous membrane where the Pathogens find their specific binding sites, not just somewhere in the Airways on any cells. With SARS-CoV-2, these are primarily the cells with so-called ACE-2 receptors, which are particularly pronounced on the ciliated cells of the Nasal mucosa are present [62]. Cells with ACE-2 receptors are in descending order The area of the deeper airways gradually becomes much less frequent [125]. So the new one Coronavirus can cause infection, it must be the ciliated cells

Reach the nasal mucosa and bind to the specific receptors. With degraded Mobility of the ciliated cells (= reduced so-called mucociliary clearance, e.g. with strong Smokers or in the case of diabetes mellitus), the duration of the pathogen there is longer, so to speak can persist, thereby increasing the chance of binding to the receptors [120].

Typically, patients infected with the new coronavirus will primarily develop one upper respiratory infection, if they develop symptoms at all. A pneumonia, well Infection of the deep respiratory tract, if at all, only occurs secondary to one Delay of about 7 days after the onset of the initial symptoms in the upper Airways. So it also happens in the case of patients who have one in the course of the disease Develop pneumonia, not already primarily as a disease of the lungs. this happens probably only via microaspiration (which incidentally also occurs in healthy people

Deep sleep), which causes infectious secretions from the nasopharynx to enter the Lungs get there and especially in old age and chronic diseases secondary to infection, making the course of the disease difficult and becomes life-threatening [122].

The new coronavirus has to settle primarily in the upper respiratory tract in order to get a To be able to cause infection [62] and therefore initially only creates one upper respiratory tract infection and only secondary (after a latency of about one week) People with certain risk factors due to the pathogen descending, possibly also one Pneumonia. Most people have rather harmless symptoms of the upper respiratory tract with or without a cough.

For the theory of aerosol transmission this means: Because aerosol particles in far predominantly penetrate the deep respiratory tract immediately, but an infection there, if it did come about at all, not the symptoms of an upper one Respiratory tract infection can lead to pneumonia on the spot would, if cells with ACE-2 receptors are reached (this course of infection with primary pneumonia does not occur), aerosol transmission of SARS-CoV-2 de facto play no role from a medical point of view.

Importance of aerial virus RNA detection

Whether the detection of virus nucleic acid in the case of respiratory viruses (in the case of coronaviruses: RNA)

by means of PCR outside the body, for example from air samples, means that the found Nucleic acid from an intact (and thus in principle infectious) virus particle originates, cannot be answered with pure RNA detection - and is rather rare investigated because it is relatively complex. But also the confirmation of an intact (ie capable of replicating) virus by means of cell culture cannot provide evidence of infectivity these viruses are equated under normal living conditions. Because the so-called.

Inoculation of a cell culture is a laboratory process in which the virus artificially and ideally brought into contact with its target cells because it (1) directly and (2) in addition to that in unchanged concentration on the cells. At a virus contact in normal life, however, must potentially infectious droplets or Aerosol particles released by an infected person first - quasi 'themselves' - the way not immune to the mucous membranes of the upper respiratory tract of another (and at that) Find person. Once there, if that happens at all, the number of potentially infectious viruses high enough for at least a portion of them to be there creates through the protective respiratory secretions to the surface of the To get to the mucous membrane cells and also to adhere there, in order to subsequently enter the Cells to invade and multiply.

In addition, there is the following: Coronaviruses have a lipid envelope, so they belong to the so-called. enveloped viruses and as such are sensitive to environmental influences (e.g. UV light).

Certain aerosols (approx. 0.4 μm) can in principle remain in the air for several hours remain, but medically the most important question is whether such viruses in an aerosol, So floating unprotected in the air, generally infectious over a long period of time can stay. The detection of viral RNA is neither evidence that this is RNA originates from viruses capable of replication (in a cell culture), nor that they (which by no means directly comparable to cultivation in a cell culture) for humans infectious, i.e. intact viruses [42, 116].

The detection of viral RNA in air samples is sufficient to confirm an airborne one Transfer not from as well as the results of investigations in which Aerosols are experimentally generated, counted and measured as well as their residence time in experimental situations is determined. Overall, it is a complex one Question that primarily affects infectiological and epidemiological factors and which various environmental conditions (indoor, outdoor air) as well as aerosol must include physical features (see above). So should go

From an infectious point of view, for example, it should be clarified whether infectious aerosols are even in

a sufficient number of 'land' at the crucial points in the upper airways, ie adhere, where SARS-CoV-2 has to go, because it is primarily in the Epithelial cells of the nasal mucous membrane, but also: increased in the upper respiratory tract [62] - and not in the deep respiratory tract, where aerosol particles go almost exclusively reach.

Number of pathogens required for infection

For any infection to occur, contact with a certain (and often unknown) minimum number of pathogens required, and this contact must be in order for an infection to be successful take place in the parts of the body where the Pathogens have to penetrate in order to multiply. This is the same as above

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carried out, with the new coronavirus mainly the nasal mucosa [62], to a lesser extent Measure the mucous membrane of the throat, but not the lungs (otherwise the SARS CoV-2 infected people primarily to pneumonia, which is known not to be the case). With what number of coronaviruses a person has to have contact in order for it to become a Infection is currently not (yet) exactly known, although from one in December The study published in 2020 shows that, according to a mathematical estimate, based on 39 transmission events, an average of more than 1,000 Virus particles must be transmitted from one person to another in order to become infected to cause [130].

If the excitation contact is significantly or at least to a relevant extent through the air, So via inhalation, would take place, one would have to be of a relatively high number of Follow-up infections (triggered by an infected person) go out because the air is all Surrounds people and no one can escape from them [116, 131]. The base reproduction number (R_0) of approx. 3 (i.e. approx. 3 subsequent infections by an infected person with a lack of immunity the population against the pathogen) would be low with the new virus; man would because of the inevitable air exposure of all people at one Expect pathogen transmission through the air with significantly more secondary cases. Indeed R_0 could also be so low for the new coronavirus because it is for an infection required number of pathogens (so-called 'infectious dose') for this virus is rather high, so that despite airborne transmission there are relatively few secondary infections because there are there is seldom contact with the mucous membrane with sufficiently high numbers of pathogens [131].

Outbreaks as evidence of aerosol particle transmission

There were various publications in 2020 about outbreaks that the aerosol Transmission of the new corona virus has allegedly been proven, but with all of these Outbreaks were not considered or only marginally considered that instead of the aerosol Transmission the other transmission routes via (large) droplets and / or (direct and indirect) contact also come into question and first of all evaluated in terms of their importance would have to be to ascribe a significant role to aerosol transmission. In the Media is spread that contact transmission (mostly with the unscientific Term "smear infection") does not play a role in SARS-CoV-2. Instead but one would have to say: This transmission route was not investigated or not sufficiently considered, because it is not enough for such a determination that the virus was not or rarely found in environmental investigations.

One of the most important of these publications for Germany was Outbreak investigation at Tönnies in North Rhine-Westphalia [132]. The authors state that the cause of the outbreak in the special working conditions of workers in this (and other) meat (as well as fish) processing factories where at low Temperatures (10°C) and hard physical work (with strong exhalation) on the one hand and On the other hand, air conditioning systems without fresh air supply (low air exchange rate and constant Re-circulation of the air in the work hall) an efficient pathogen transmission via aerosol is obvious.

The common (close) accommodation of the workers in their living areas and

Bedrooms and the shared trucks - and thus the diverse range of them associated direct and indirect contact options, including droplet contact - do not play a major role in the study for the authors of the study Occurrence of the infections played. The limitations of your study are the

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However, the authors then state that (1) all information on the accommodation of the workers and the shared use of the trucks came from the entrepreneur (and not from his own Inspection of the living conditions) and that (2) all air examinations are qualitative only (ie only detection of virus RNA in air), but not quantitatively (ie number of RNA copies per m³ of air). Finally, the authors themselves state that theirs Investigation should not be viewed as an *epidemiological study*. The authoritative The study's authors are predominantly virologists and geneticists, but none population-based epidemiologists who (in the list of authors The latter) so-called senior author is a biologist. So it is all in all predominantly bio-scientists, not medically-infectiously trained Epidemiologists.

There have been other publications about outbreaks that are consistently cited for being with aerosol transmission is proven to them, e.g. a restaurant-associated outbreak in China [133] and a choir rehearsal in the USA [134]. However, a transmission path with Outbreak investigations are not proven because the important question is always whether when investigating an outbreak, actually all of the possible ones Transmission routes have been adequately checked (or retrospectively when the Events could be checked) before it was concluded that the Aerosol transmission was the most likely route of transmission. The restaurant-associated outbreak was attributed by the authors to an air conditioner, the one had faulty air flow [133]. If this is the cause of air transfer in had been proven in this specific case, then it would be open whether it was, for example, in a Room without air conditioning would also have given airborne transmissions, so could one does not speak of the fact that the new coronavirus almost naturally takes over the air is transmitted, but perhaps only if the air conditioning system is incorrectly routed. In the report on the choir rehearsal in the USA [134] it is noticeable that 9 of the 10 authors do not Medicines, but for example (heating-ventilation) technicians, engineers, chemists were only a co-author was a medical microbiologist. The article was published (consequently) in a technical journal ('Indoor Air') and not in a medical one. From the Opinion from the peer reviewers, all of which can be viewed, shows that Infectious epidemiologically critical comments were made: So were E.g. 3 choir members symptomatic 24 hours after the choir rehearsal and 7 more within 48 hours thereafter [135]. This suggests that it is not just the so-called index case the article could have been infected, but also up to 10 other choristers who however developed symptoms only later (and possibly already during choir practice had very few symptoms that they did not notice or that caused them the later questioning as part of the processing of the outbreak can no longer be remembered were, a common problem in the investigation of outbreaks, always retrospectively must be done). Another question is whether there are actually any indirect contacts about contaminated objects, because at least the singers were for 2.5 hours together and also had a break together. From the original report of the CDC also reveals that the singers were in very close contact because they were sitting only at a distance of a maximum of approx. 15 - 25 cm, so that also next to direct and indirect contact, contact with large droplets (<1 - 2 m) appears possible [135]. However, this was not dealt with accordingly in the outbreak investigation [134].

Masks as protection against the formation or release of aerosols

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As so-called community masks, i.e. everything from the purchased one to the medical oral
Nose protection-like mask over the (self-sewn) fabric mask to the cloth
Mouth and nose was from the end of April 2020 (beginning of the mask requirement) to the end of January
2021

everything is possible and 'allowed', the main thing is that something was in front of the mouth and nose
[103]. Just

such masks and towels do not offer any protection against the formation of aerosol particles
the air or its release from the deep airways, but can only
reduce the formation of aerosol particles somewhat (but how much is unknown) by adding
namely, the larger droplets are caught by the fabric and therefore not
more reach the outside air, where it - the smaller, the faster - it closes within seconds
So-called droplet cores can dry out, if they contain a 'core' at all
(see above).

However, no one can say how much retention of droplets is necessary for the formation of
to prevent infectious aerosol particles. The RKI's statements on this are also not
conclusive, but in public discourse masks are '*effective*' in public because they
Can hold back droplets. However, this is unscientific. What (big)
Droplet presumably applies, but does not apply to the smaller droplets and certainly not
for aerosol particles. In addition to the larger droplets, humans usually also give
Aerosol particles (see above), which not only penetrate the mask material directly,
but can also escape laterally or above and below, i.e. wherever the
Mask is not close to the face (but of course even there, if not so
numerous). This does not only apply to the so-called community masks (made of cotton or other
Substances), but also for medical mouth and nose protection (surgical mask), its
The function is 'only', on the one hand, to protect against contact with droplets (i.e. as a personnel
or self-protection in patient care with close face-to-face contact) or
to prevent the release of droplets (ie to protect the exposed surgical wound from
Droplets from the nasopharynx of the surgical team during the operation = protection of the
Patient to be there).

So if aerosol transmission were indeed as important as it has been for months in
Germany is portrayed, all people would have long since worn respiratory masks
must, so so-called FFP masks (at least FFP2), because only these masks are yours
In principle, the material and design are suitable for separating free-floating particles, so that
the wearer cannot inhale or release them. However, this could only be done then
apply when such masks are worn correctly, that is, they fit tightly to the skin everywhere
and don't have an exhalation valve, and then it's hard to breathe through it because that
Mask material is very dense. FFP masks (almost only FFP2, very rarely also FFP3)
in the medical field only for the personal protection of the staff from inhalation potentially in
infectious agents present in the air (in open tuberculosis of the
Respiratory tract) and, if necessary, of very weak patients also for self-protection
to protect against inhalation from the mold spores that are always present in the air
(they can have exhalation valves for both indications). FFP masks are used in
medical area never to protect other people from the exhalation of aerosol
Particles carried, i.e. for external protection. However, that would be precisely the indication for
People in public because masks are there for reasons of external protection
should be worn (but they should not have exhalation valves). That was true
at least until January 2021. Since then there has been an FFP2 mask requirement in Bavaria (and in the
federal government
the obligation to wear a medical face mask, i.e. a so-called surgical mask
or FFP2 mask).

The ability of different mask types to increase the aerosol concentration in indoor air
reduce (i.e. for third-party protection), has been examined several times in experimental studies.
One of these studies worked with volunteers, almost of whom
all (N = 208) had a laboratory-confirmed acute influenza infection and in 6 people of the

Acute COVID-19 was suspected [136]. It was checked whether there was a difference between medical and self-sewn cotton masks in it, how many aerosol particles (20 - 1,000 nm) are released when coughing and sneezing and thus in the room air are measurable. The test subjects were given a medical mask and then a 3-layer cotton mask or no mask at all. Two measurements each (during one hour) of aerosol particles in the immediate vicinity of the test persons, i.e. each with one of the masks or without a mask at all were placed in a mechanically ventilated (= with so-called air conditioning) room (with closed windows) and in a car (also with air conditioning) carried out. The aerosol concentration in the room air was also determined in the room and in the car without the test subjects wearing one of the masks. All subjects had an acute upper respiratory infection with the typical symptoms (coughing, sneezing). According to the results of this study, there were no significant differences in aerosol concentration between medical mask and cotton mask. The authors' conclusion was that cotton masks were used in infected (i.e. symptomatic) people using a replacement for medical masks in rooms. Air conditioning could be (with air conditioning because the investigations so far have been carried out and therefore you do not know how the results without air conditioning would have failed).

In a further experimental investigation, a result was found that tends to contradict so-called community masks, which are mostly made of cotton fabric [137]: It came with cotton masks (compared to without a mask) lead to an increased release of (smallest) aerosol particles (<0.5 µm), which are tiny cotton fibers. These according to the interpretation of the authors, cotton fibers could be asymptomatic or presymptomatic infection of the carrier may be contaminated with the virus and thus they even increase the release of potentially contaminated aerosols.

Another experimental study showed that all mask types (surgical, FFP2 / N95 and cotton masks), although some protection against transmission of infectious aerosol particles [138]. However, in this simulation model it can be shown that virus RNA is released even with optimally applied FFP2 masks has been. FFP2 masks in particular are rarely correct, even by medical staff worn because these masks were worn for hours (as it has been for months in common in numerous clinics) are hardly bearable. Therefore can from these study results be derived that the viral RNA in real life in clinics and of course, even more so when FFP masks are used in public by inexperienced people be worn, which has become more and more common over time, despite the masks - and possibly to a not inconsiderable extent - is released. But especially FFP masks suggest increased security, which they do not offer if they are not worn adequately, i.e. all masks (types), but especially FFP masks convey a particular degree of deceptive feeling of security, lead to a careless way of carrying (and incidentally, to particularly frequent hand-face contacts) and are therefore more likely overall counterproductive than protective.

In an article (an opinion piece) in the prestigious NEJM was published in September 2020 hypothesized that by wearing masks the release of

Reduce aerosol particles, a limited contact of other people with the virus takes place, i.e. contact with low virus numbers [139]. This could cause it to mild forms come, which equate to a kind of 'vaccination'. The authors used the historical term 'variolation' for this, a method that was used for a long time in East Asia in children was carried out to immunize against smallpox by secretion from smallpox vesicles of a sick person was taken and the 'vaccinated' people on it the nasal mucous membrane gave [140].

The theory of variolation related to the new coronavirus is one hypothesis, as the authors themselves write several times in their article [139]. Nothing supports the hypothesis. You can put it this way: the authors think it is conceivable. There is no scientific background of any kind, because

there is not even any evidence that masks may be less
Number of released and potentially infectious aerosol particles leads to the severity of the
Infection from contact persons is attenuated with the result that the so supposedly
(mildly) infected persons then have protective immunity.

Obligation to wear medical masks

In January 2021, an FFP2 mask requirement for shops and
Public transport introduced. Shortly afterwards, the federal government (federal government and prime
minister)

decided that when shopping and when using public transport only
medical masks, either a medical mouth and nose protection (MNS or so-called OP-
Mask) or FFP2 mask. The rationale for this is medical
incomprehensible, because both mask types are for different purposes
conceived, but have now become interchangeable through the decision of politics, with what
any medical foundation has been lost.

From the end of April 2020 (beginning of the mask requirement) to mid / end of January 2021 (in Bavaria
a little earlier than in the Bund) the so-called everyday mask made of fabric (or even just a cloth in front of
it

Mouth and nose) as adequate for the implementation of the mask requirement. You should be as
Serve 'external protection' (see above) to prevent the release of larger droplets,
from which smaller inhalable aerosol particles could arise. So about nine months
the everyday mask was correct because, from the point of view of the federal government and the RKI
was suitable to prevent the so-called unnoticed transmission or at least as strong
to restrict the fact that the obligation to carry appeared justified for the politicians. In the new year
The transferability of the new virus had not changed in 2021. There were in particular
no new knowledge about the transmission routes, because the aerosol theory existed
Almost since the beginning of the pandemic in spring 2020. A crucial one for politics
Change came along with the increasing reports of the virus mutations
Great Britain, South Africa and Brazil, which are said to be 'more contagious', i.e. easier
transferable, should be (and possibly actually are).

The reason given in Bavaria for the FFP2 mask requirement was that it was in view of the
Virus mutations would now also depend on 'self-protection'. So it had to be meant by
Protection principle of the FFP2 masks the protection against the inhalation of aerosol particles,
while the FFP2 mask also guarantees 'third-party protection'. The remaining
Since then, federal states have been able to decide whether they also make the FFP2 mask mandatory
make or limit yourself to the medical MNS. The rationale for this was
limited to the fact that medical masks are 'better' effective. For what or against
was not clarified. Neither does an MNS offer better protection against inhalation

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of aerosol particles than the everyday mask made of fabric, so it can be an improved one
'Self-protection' cannot be guaranteed because the MNS has other functions: (1) It can act as a
Protecting 'external protection' from the release of larger respiratory droplets is
but not more suitable for the public than the cloth masks have been before,
especially since it is not worn better, i.e. 'correctly', as the RKI always says, and (2) can be a
MNS 'self-protection' from another person's respiratory droplets in tight
Ensure face-to-face contact (<1 - 2 m). In principle, both can also be done so far
usual cloth mask.

A medical sense of the new obligation to wear an MNS or an FFP2 mask,
there is no such thing. According to press reports, both the ECDC and the
EU Health Commissioner on the use of FFP2 masks in the population
expressly not because it has no added value [141].

Ventilation as a hygiene measure

In rooms that are used by several (e.g. offices) or even numerous people (e.g.
Classrooms) to let in lots of fresh air is always a good idea, because we
constantly breathe carbon dioxide and have to breathe oxygen and we give
Body odors and heat away, leaving rooms in which are at the same time and for hours

several people, such as classrooms in particular, are dated without any doubt Ventilation benefit. But that in the meantime, however, the ventilation of rooms is one 'Hygiene measure' considered, is a step backwards into the time of earlier centuries, where the development of diseases was attributed to the 'air that causes disease' (Miasment theory [142]), because no infectious agents were known yet. Back then were That is why hospitals are built in such a way that the bed rooms are not only large in area, but also were also high, i.e. had a very large volume of air, and there were large ones everywhere Windows through which the 'sickening' air could be discharged and fresh air could be introduced (but also ingenious supply and exhaust air ducts were used as early as the 18th century Use) [143]. These times with their the state of medical science there are corresponding ideas about the development of communicable diseases but long gone. Today we know a lot more about the formation of infections, and it gives the principle of evidence-based medicine.

Summary: aerosol transmission and scientific evidence

In the public and in the media it is said that aerosol transmission has meanwhile been carried out 'Recognized', and even the Society for Virology has already recognized this in its ad hoc Statement of August 6, 2020 claims [144]:

' One of the important new findings about SARS-CoV-2 that came with the school opening must be considered concerns the now recognized possibility of Aerosol transmission, i.e. transmission through the air, especially in Indoors with insufficient air circulation . '

The WHO publication from July 2020 is quoted on this statement [116]. However, one goes such a statement cannot be found in the WHO text, because it says:

' Outside of medical facilities, some outbreak reports related to indoor crowded spaces (Ref) have suggested the possibility of aerosol transmission, combined with droplet transmission, for example, during choir practice (Ref), in restaurants (ref) or in fitness classes. (Ref) In these events, short-range aerosol transmission, particularly in

specific indoor locations, such as crowded and inadequately ventilated spaces over a prolonged period of time with infected persons cannot be ruled out. However, the detailed investigations of these clusters suggest that droplet and fomite transmission could also explain human-to-human transmission within these clusters. Further, the close contact environments of these clusters may have facilitated transmission from a small number of cases to many other people (eg, superspreading event), especially if hand hygiene was not performed and masks were not used when physical distancing was not maintained. (Ref) (In the case of 'Ref', literature references are in the WHO contribution indicated)

So that aerosol transmission is a recognized possibility of transmission of the new coronavirus is stated in the WHO contribution, which expressly deals with the Deals with the transmission of the virus and the preventive measures derived from it, nothing, so that one must assume that the authors of the GfV statement comply with the WHO Post you cite have not read. This also applies to the WHO contribution from December 2020 [42].

In doing so, the question should immediately be raised as to what actually comes from the Distance rule should be used when aerosol transmission actually plays an important role should play (see **evidence question 4**). Would 1.5 m or 2 m be sufficient or 1 m, as recommended by the WHO and in Austria ('baby elephant') until the beginning of 2021 (since then 2 m) prescribed? How much distance would we need to be in front of the aerosol particles of the To protect with-people? And: Does the aerosol theory only apply to the new coronavirus or also for the other respiratory viruses? If you consistently finish it thinks would be the aerosol theory, i.e. the transmission of respiratory infectious agents through the air (because this transmission path could not only be for a single respiratory virus apply or should at least be of importance for all coronaviruses have), have the consequence that humanity would have to radically change the way they live together, and therefore would have to be clarified with the necessary scientific precision, in

to what extent, if at all relevant, the pathogen transmission via aerosol in the new one Coronavirus plays a role. But why is aerosol transmission important with SARS-CoV-2 should be, but not with the other coronaviruses or respiratory viruses, is biological and medically incomprehensible.

Such considerations require a differentiated presentation, which has so far been the case with the Aerosol theory for the new coronavirus does not exist. The question would have to be the role of masks (see above) and spacing (see below) are dealt with

would, if airborne transmission were a fact to be considered relevant, whether

So the mask would continue to be about external protection or maybe self-protection

should be put in the foreground. But only (but then also

only: correctly worn) FFP2 masks in question (which is not the case with full beard wearers, by the way

is possible). Normal medical masks would not be suitable to be used prior to inhalation of

Protect aerosols. As a result, people would have to wear FFP2 masks (and

always best, because respiratory viruses are on the go all year round)

others before the release of their own (= 'third-party protection') and oneself before inhalation

to protect from aerosol particles (= 'self-protection').

All of these crucial questions have so far been completely unanswered (perhaps because not

it is understood what dimensions the aerosol theory has and what consequences there are

would result from this) and are not even discussed. Especially the media

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and influential scientists have long left no doubt about the importance of

Aerosol transmission (e.g. Christian Drosten in the NDR podcast from May 12th, 2020 [145]:

' When I put all of this together, my gut feeling is: almost half that

Transmission is aerosol, almost the other half is droplet and maybe ten

Percent of transmission is smear infection or contact infection. '

First, ' gut instinct ' has nothing to do with science, and second, aerosol

Transfer also through such utterances by someone recognized in his area

Scientist into a (but only apparent) fact. Neither

His admission about 'bad breath' and 'aerosols' [146] is scientific:

' That bad breath, it's aerosols. There are also gases in it - they are not

just vapors, not just tiny droplets of liquid - but now simplified for ours

Discussion is enough if you imagine it that way. Can you imagine,

same situation, you stand at the same cake buffet and speak in the same

Distance with someone but both have masks on. Can you imagine,

that you still notice that the person you are talking to has bad breath? (...)

Exactly, you won't notice that anymore. And this "no longer noticing",

We can also translate that as "I'm not going to be that fast anymore

infect". And that's something that those who have doubts about its effectiveness

of everyday masks, perhaps to take home with you as an everyday example

should. '

In contrast, information on bad breath from the perspective of dentistry [147]:

' Bad breath is caused by volatile sulfur compounds (sulfides) that are

Mix with the exhaled air. They arise from being gram-negative

anaerobic bacteria organic material, e.g. food residues, proteins, in the

Decompose oral cavity. Hydrogen sulfide is the best-known representative of sulfides.

It smells like "rotten eggs". Another group of sulfur compounds are those

Methyl mercaptans. They are considered to be the main cause of bad breath. you

produce a smell of rotting cabbage or a musty-rancid smell

Odor. If the breath smells like fish, rotten meat or faeces, then there are

biogenic amines are responsible for this. They are created from amino acids through

bacterial release of carbon dioxide. '

So 'aerosols' have nothing to do with bad breath. Similar to the WHO (see above and

[116]) say other scientists [131]: Based on the (compared to measles

with 12 - 18) quite low base reproduction number of SARS-CoV-2 with approx. 3 appear

such situations to be the exception rather than the rule. Furthermore, it is retrospective

difficult to determine the potential interactions between the people who took place during and immediately after the event. The ways for viruses to get quickly and far - but not necessarily over the air, but primarily over direct and indirect contacts - to spread in premises with numerous people, should not be underestimated. Experimental studies marked with Bacteriophage (= special, only pathogenic for bacteria, but not for humans Viruses) would have shown that viruses contaminated from a single one within hours Door handle or contaminated hands of one person to other people and Objects can be transferred. These are also speculative considerations that the The possibility of transmission via aerosols could not be ruled out, but they were

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possible alternative explanations for the formation of such clusters - and must must therefore also be taken into account [131].

The CDC also argue that the epidemiology of COVID-19 indicates that the Most of these infections arise through close contact - and not airborne [118]:

' Diseases that are spread efficiently through airborne transmission tend to have high attack rates because they can quickly reach and infect many people in a short period of time. We know that a significant proportion of SARS-CoV-2 infections (estimated 40-45%) occur without symptoms and that infection can be spread by people showing no symptoms. Thus, SARS-CoV-2 spread primarily through airborne Transmission like measles, experts would expect to have observed considerably more rapid global spread of infection in early 2020 and higher percentages of prior infection measured by serosurveys. Available data indicate that SARS-CoV-2 has spread more like most other common respiratory viruses, primarily through respiratory droplet transmission within a short range (eg, less than six feet). There is no evidence of efficient spread (ie, routine, rapid spread) to people far away or who enter a space hours after an infectious person was there. '

The transmission of SARS-CoV-2 via aerosols currently remains a hypothesis. These Statement is consistent with the assessment of the WHO and the statements of the CDC [42, 116, 118]. Transmission by aerosols is just one, as shown above, rather unlikely possibility. From this we can therefore approach something more scientific Do not derive any necessary protective measures, such as an FFP2 mask requirement or special 'air purification devices' or air conditioning systems with particulate filters or even frequent ventilation. Nor is there currently sufficient evidence from careful studies that that, for example, choir singing represents a risk of transmission through aerosols or that contacts between people over a distance of more than 1.5 m (WHO: 1 m) when speaking etc. released aerosol particles can be a risk of infection. You can't go out aerosol-physical studies on the spread of artificially generated Inferring a risk of infection from aerosols. Whether the aerosol transmission is actually a could play relevant role in the acquisition of this pathogen only by carefully Planned epidemiological studies in different settings, including randomized controlled studies.

In general, one can state on the question of the airborne transmission of infectious agents, that whenever the possibility of airborne transmission is considered, almost regularly as well as transmission by large droplets and / or by direct ones or indirect contact.

This corresponds to the fact that recently an aerosol physicist (who incidentally broadcasts in Considers outdoor areas to be almost impossible) has said that the indoor area also The greatest risk of transmission in the vicinity of an infected person is because you are then in the still undivided cloud of aerosol particles that the infected person would releases [148].

From my professional point of view, I also see the greatest risk of transmission when you are in is in the vicinity of an infected person, but for other reasons, namely because on the one hand one is exposed to possible droplet contact, on the other hand, it is much more likely to have direct and indirect contact options than if

one stands a few meters away in another place in the room.

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The aerosol theory does not have anywhere near an adequate scientific basis, and it is lacking therefore proof that this transmission path is responsible for the natural course of the SARS CoV-2 infection is relevant. At the same time, this theory is utterly detrimental to that Coexistence of people overall and has a destructive effect on contacts between people of all ages. Therefore would have to be planned accordingly epidemiological studies direct and indirect contacts - via (large) droplets and / or contact (especially hand contact) - safely excluded to a to be able to consider airborne transmission.

Summary assessment of the scientific data on masks

The effectiveness of masks for healthy people in public is not through scientific evidence. Likewise, 'external protection' and the 'unnoticed Transmission ', with which the RKI justified its' reassessment', does not go through supported by scientific facts. Plausibility, mathematical estimates and subjective Assessments in opinion contributions can be based on population-related clinical do not replace epidemiological studies. Experimental studies on Filter performance of masks and mathematical estimations are not suitable for a Prove effectiveness in real life. The international health authorities speak out in favor of wearing masks in public spaces, but also say, that there is no evidence from scientific research for this. Rather speak all currently available scientific evidence that masks do not Have an effect on the infection process. Consistently all publications that serve as evidence for the Effectiveness of masks in public spaces can be cited, leave this one Conclusion not to.

Every mask must be worn correctly in order to be effective in principle. Masks can become a contamination risk if touched. But you will on the one hand not worn properly by the population and on the other very often with the Hands touched. This can also be seen in politicians who are seen on television are. The population was not taught how to use masks properly, it wasn't explains how to wash your hands on the go or how to do an effective one Hand disinfection is carried out. It was also not explained why the Hand hygiene is important and that one must be careful not to touch the hands To grasp eyes, nose and mouth. The population was practically alone with the masks calmly.

The transmission of SARS-CoV-2 through 'aerosols', i.e. through the air, is not medical plausible and scientifically unproven. It is a hypothesis that mainly can be traced back to aerosol physicists, understandably from their field of expertise unable to assess medical relationships. The 'aerosol' theory is for that human coexistence extremely harmful and leads to that People can no longer feel safe in any interior space, and some are even afraid outside of buildings from infection by 'aerosols'. Together with the 'Unnoticed' transmission leads the 'aerosol' theory to a Risk of infection can be seen.

The changed policy statements on masks, first cloth masks in 2020, then since At the beginning of 2021, either surgical masks or FFP2 masks, lack any clear line. Even if surgical masks and FFP masks are both medical masks, they have different functions and are therefore not interchangeable. Either politics

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who made these decisions didn't even understand what type of mask was used for is suitable in principle, or it does not matter to her, only the symbolic Value of the mask. The mask decisions of politics are from my professional point of view

To be called implausible in an incomprehensible and gentle way.

A brief digression on masks in Japan

As early as the spring of 2020, media reports in this country repeatedly pointed out that Japan and other Asian countries have known for a long time what benefits Have masks in public. Therefore, I would like to take a few at this point Provide information on why the Japanese in particular so often use masks wear and how the wearing of masks has developed there. That question was split into two Articles (long before the current corona pandemic) discussed in detail [108, 149]. After that, masks became public in Japan (such as in the USA) for the first time used at the time of the influenza pandemic of 1918/1919. While the other countries are in The 1920s then quickly came off masks again, they stayed in Japan to some extent (but nowhere near as much as in the last 10-20 years) over the decades, but less to protect against infection and more under the aspect of the traditional symbolic order of 'purity' and 'impurity' as well an idea of 'miasms' (see above [142]) instead of viruses or others Infectious agents. In the 1970s emerged (as a observed for Japan in the Measures new medical problem) hay fever related to that of cedar trees which were only planted there after the Second World War. Masks were then worn during the spring pollen season. Then it was again more quietly about masks, until the 1990s, than mask-wearing in Japan gradually became a socially accepted general protective measure, namely through a combination of influences through (massive) advertising of the leading Mask manufacturer as well as social and political pressure due to the increasingly widespread neoliberal ideology, according to which, among other things, everyone for his own Health protection is responsible ('self-healthcare'). In the 2000s came with SARS (2003), bird flu (2004), MERS (2006) and swine flu (2009) several Epidemics in quick succession, and especially the swine flu boosted the again Use of masks, so the sales of masks increased enormously. The wearing of a mask but also became a social norm, especially on commuter trains, so that those who did not wear a mask stood out. In addition, sneezing and coughing applies in the Public in Japan has always been considered rude. In retrospect, the authors see 2009 as a kind of turning point: Zum masks maintained a certain level of fear in the population and for one for others they established themselves as the front line of defense among the people. Then came the Probably very crucial given the increasingly insecure jobs Aspect that employers require their employees to wear masks and from then on one was under pressure to give in or, if necessary, his job to endanger. The wearing of masks was revived after the nuclear disaster of Fukushima 2011, because masks were also used to protect against radioactive radiation set. In the spring of 2013, air pollution was reported coming from China reached the southwest of Japan and the people were advised in the media that Wear masks that can filter microscopic particles (i.e. FFP masks). Everything in all, the whole development led to a consolidation of masks as General purpose means for personal protection.

According to the authors [108, 149], the mask ('safety blanket') in Japan is *one* aspect of a broad one established kind of risk culture: It is more of a ritual of the Self-protection as a selfless community practice and thus has with the in this country for the mask requirement in the foreground 'outside protection' to do nothing, and finally, it is apparently not just intended to protect against infectious agents serve, but should in addition to the (still comprehensible) protection against pollen exposure and Air pollution even the only irrational protection against radioactive Include radiation. After all, masks are allegedly also used by women to protect themselves

not having to put on make-up when they go out or under
Being able to hide blemishes and from men when they don't shave
could [150]. Further motifs are that you withdraw behind the mask and
could thus signal that one does not want to be addressed and that one is with
Mask could go undetected in public.

For the mask in Japan (and probably in other East Asian countries as well) there is
a conglomerate of very different reasons, of which infection protection is only one
among several, but perhaps not even the leading one.

Evidence question 4

By adhering to distance regulations, the risk of infection can be increased in particular
Children are lowered?

Keeping one's distance is particularly emphasized in the government's corona rules
and is therefore probably at the beginning of the so-called AHA rule (distance - hygiene -
Everyday masks or since the beginning of 2021: everyday life with a mask). It was always emphasized that
it was in spite of this

The most important thing for masks is the minimum distance of 1.5 m from other people
to be observed. According to the original AHA rule, masks should only be worn
if the minimum distance cannot be maintained (these are now available
Restriction no longer). In reality, the masks seem to be more important because
its application has been expanded more and more.

The distance requirement was introduced in Germany at the same time as the mask requirement,
so at the end of April 2020. Since then, there has been an all-round distance of 1.5 m in public
to be observed. However, there is no international agreement on how big the distance to others is
People should be. The WHO speaks of 1 m, as does Austria in 2020
('Baby elephant'), but since the beginning of 2021 it should now be 2 m. The CDC speak of
'Six feet', and that's about 2 m. In Germany, 1.5 m is a kind of middle ground. Nice
the diversity of these determinations shows that there is no
scientific basis.

For decades there has been in the medical care of patients in

The rule practiced in hospitals, for face-to-face contacts, a distance of at least 1
m to hold, if that is possible (e.g. if there is only something to discuss), but only
when the patient has respiratory symptoms. But you have to - as is so often the case
in the care of inpatients - come closer, then the medical one should
Personnel put on a medical mask (surgical mask) in order to avoid the direct

Contact with droplets of respiratory secretions on the mucous membranes of the face (eyes,
Nose, mouth).

This distance rule, known for a long time, is based on the transmission of respiratory
Pathogens through so-called large droplets ($> 5 \mu\text{m}$) from the nasopharynx of infected people
People who only fly a short distance in the air due to their weight (e.g.
while speaking) and then fall to the ground. Once sedimented, they do not produce any
Risk of infection is more. If you stay away from a person with
respiratory infection, there is no contact with the droplets. At least that
is the rule. Especially when sneezing heavily, but also when coughing, the
Droplets are also thrown a further distance through the air. If then
If another person were standing there, they could possibly be attacked by such far-flying droplets
hit the mucous membranes of the face.

Such a situation that you can see other people even without respiratory
Symptoms would have to be seen as a potential risk of infection, was before 2020 in the
Infection control measures in hospitals have never been a problem, not even in the
Influenza season, finally, patients with respiratory infections cough and sneeze
not all the time. That it is appropriate to keep a certain distance from other people
hold, if you have a respiratory infection, was also in the (not in the medical
Area) known to the normal population, if then expressly to the
Interlocutors were told that they would rather stand a little further away

not to bring the other person into contact with the pathogen (and also not to use the hand Wanted to extend a greeting).

These precautionary measures only applied when dealing with symptomatic ones People, even in the hospital. For example, in the influenza season never symptomatic patients or colleagues simply because

Influenza season was considered potentially infected, and therefore it wasn't already

Keep a prophylactic distance if there is no apparent respiratory disease was. There have been repeated very violent influenza seasons in recent years where the hospitals were overcrowded and the patients lay in the hallways had to. It was then no longer possible to keep your distance.

Keeping your distance is a plausible measure if you are yourself or a person with whom you are wants to speak, has a respiratory infection, even if it is all

Probably just a banal cold. Is also uncomfortable

a cold, and one would like that to others or even oneself (if the other the Symptoms) and therefore keep a little distance.

For about a year now, people have been supposed to keep their distance from one another, too when no one has respiratory symptoms. This was going unnoticed with the so-called

Transmission in the event of asymptomatic or presymptomatic transmission by the SARS CoV-2 virus justified. That this risk in reality - unlike in mathematical Modeling - hardly plays a role, has already been explained in **Part A**.

The requirement introduced by politics in 2020, an all-round distance of 1.5 m there is no rational basis for compliance, because, if at all, only a vis-à-vis distance makes sense. Droplets fly forward, but not to the side and back, this one Demanding distance to the side and to the rear can be done with the Droplet transfer have nothing to do with. But it should be about the 'aerosol' theory had gone, a distance of 1.5 m would not be sufficient. At the time

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but in Germany the 'aerosol' transmission was not yet an issue. Maybe it appeared

It is easier to convey to politics to speak of an all-round distance than that

Restrict the distance requirement to face-to-face contacts. One can only guess hire, because politics has not explained itself.

There is no scientific research on keeping distance outside of the medical patient care.

All in all:

1. Maintain a distance of around 1.5 m (1 - 2 m) for face-to-face contacts if a The two people who have symptoms of a cold can be considered a useful measure are designated. However, it is not secured in a scientific sense, but there is only evidence or can be described as plausible that it

An effective measure is to prevent droplets from coming into contact with the pathogen

Protect respiratory secretions when the contact person shows signs of a cold

Has. An all-round distance, on the other hand, does not make sense to protect yourself if the Contact person has a cold.

2. An all-round distance or just a vis-à-vis distance of about 1.5 m (1 - 2 m)

to be complied with if none of the people present shows signs of a cold unsupported by scientific data. But this makes life together

of people and especially the carefree contact among children is very strong impaired without any benefit in terms of infection protection being discernible.

3. Close contacts, i.e. less than 1.5 m (1 - 2 m), between students or between teachers and Even then, students or colleagues at work etc. do not pose any risk

when one of the two contacts has symptoms of a cold because of the duration such contacts in school or with adults somewhere in public

is far too short for droplet transfer to occur. Show that too

Investigations from households, where despite the close coexistence with numerous

Skin and mucous membrane contacts only a few members of the household fall ill, if someone has a respiratory infection.

Comprehensive answer to the questions of evidence

Let on the basis of the above representations of the scientific literature answer the questions of evidence put by the court as follows:

1. Wearing face masks of different types can reduce the risk of infection with the coronavirus SARS-CoV-2 (notably) lower? It should be between Children in particular and adults in general and between asymptomatic, presymptomatic, and symptomatic people can be distinguished.

There is no evidence that face masks of any type do that Reduce the risk of infection from SARS-CoV-2 at all or even significantly. This statement applies to people of all ages, including children and Adolescents as well as asymptomatic, presymptomatic and symptomatic People.

On the contrary, there is more of a possibility that by wearing masks More frequent hand-face contacts increase the risk of even having the pathogen in To come into contact or to bring other people into contact with it.

3. Is there any risk of infection from wearing face masks? (or other measures) could be lowered?

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For the normal population there is neither a public nor a private one Risk of infection from wearing face masks (or other measures) could be lowered.

4. Can reduce the risk of infection by observing distance regulations be lowered especially in children?

There is no evidence that distance compliance is the Can reduce the risk of infection. This applies to people of all ages, including Children and adolescents.

The reviewer has added the following literature list to her report:

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IX. Expert opinion Prof. Dr. Christof Kuhbandner

Prof. Dr. Christof Kuhbandner is professor of psychology, holder of the chair for educational psychology at the University of Regensburg and an expert in the field scientific methods and diagnostics.

The appraiser submitted his report, which is completely inserted here, as follows:
In the following I would like to be professor of psychology, chair holder of the chair for Educational psychology at the University of Regensburg and an expert in the field scientific methods and diagnostics my professional assessment of the represent the questions raised. I will go into each of the individual questions and describe the state of the art, with reference to the underlying scientific sources.

1. Wearing face masks of different types can reduce the risk of infection with the coronavirus SARS-CoV-2 (notably) lower? It should be between Children in particular and adults in general and between asymptomatic, presymptomatic, and symptomatic people can be distinguished.

To answer this question, an evaluation scheme for the classification of the Quality of evidence from studies with different methodological approaches presented. Then the recommendations of the Robert Koch Institute (RKI) on measures in School sector, the recommendations in the S3 guideline "Measures for prevention and Control of SARS-CoV-2 transmission in schools" and the recommendations of the WHO on Wear masks especially for children and those on which these recommendations are based scientific studies received. Next is the state of the art

in terms of high quality studies from an evidence-based perspective summarized. In particular, the special features of Child wearing masks received. Building on this, it is shown in which The extent to which the risk of infection can be reduced by wearing masks in schools.

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Finally, on the current occasion, the observed increase in reported positive SARS-CoV-2 test results in children and the relevance of the virus variant B.1.1.7. received.

Assessment scheme for classifying the quality of evidence from studies

When studying the effect of masks are different in research methodical approaches to be found. Many studies are so-called Observational studies where, for example, people are asked if they have masks in the Wear everyday or not, and the infection process is compared. The methodical The problem is that such studies do not suggest a causal effect of the mask can close because people wearing masks are also otherwise hygienic behave differently. For example, it is very likely that mask-wearing Individuals also wash their hands more frequently, so an observed effect instead the mask can also be due to frequent hand washing.

There are also studies in which the filter effect of the mask is examined in the laboratory.

The problem with these types of studies is that you can get out of such laboratory experiments Findings do not suggest the spread of the virus in real life. The reason is,

that only a single transmission path is experimentally tested in such studies. in the In real life there are other ways of transmission through which wearing a

Mask may have a negative effect, so that in the total masks may even

can have negative effects on virus spread, although there is a positive effect on it the transmission via the air flow can be proven experimentally. For example show

Studies show that while masks reduce the viral load in exhaled air, they do but more viruses accumulate on the outside of the mask [1]. This means that a

Mask reduces the transmission path through the air, but the

Transmission path reinforced by touching the mask with your hands. From the

Investigation of a single transmission path in the laboratory for virus spread in the

Closing real life is a familiar one from an application research perspective

Wrong conclusion, because in practice it is the interaction of all transmission paths that counts.

Finally there are studies in which it is attempted on the basis of modeling

the spread of the virus in the population the effect of the prescription of mask requirements

to estimate. The result of modeling studies depends fundamentally on the ins

Model built-in parameters. For example, in many models

ignores that the virus spread is strongly influenced by seasonal effects, what then

can be wrongly assigned to an effect of prescribed measures [2].

Furthermore, some parameters cannot be estimated from the empirical data,

but must be determined with certain theoretical assumptions. So varied

For example, the time between infection and reporting a test result to the

Health Department substantially from person to person, as evidenced in several modeling studies

is not adequately mapped [3]

In order to really scientifically investigate the effect of wearing a mask, you need to

Studies are actually necessary in which people happen to be part of a group in everyday life

or without a mask and the infection process in both groups over

is observed for a longer period of time (so-called randomized controlled trials), which is called

Gold standard of effectiveness research can be considered.

Recommendations of the RKI on measures in the school sector

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On October 12th, the RKI issued a recommendation on preventive measures in schools

published [4]. There it is recommended to wear everyday masks if one
A minimum distance of 1.5 m cannot be maintained. Depending on the incidence
and the grade level is advised to put masks not only on the school grounds but
also to be worn in the classroom - for elementary schools from a 7-day incidence in the
Population of 50 per 100,000 and for secondary schools already from a 7-day
Incidence in the population of 35 per 100,000.

From an evidence-based perspective, it should be noted negatively that these recommendations
of the RKI no reference is made to any studies on the effectiveness of mask wearing. in the
It simply states the corresponding paper - without relying on a single supporting empirical
Reference study (p. 3):

"The recognized infection protection measures are also in children and adolescents
effective, at least easy to implement for older children and an important component
dealing with the pandemic".

Furthermore, it is explicitly pointed out that with these recommendations possible
Damage to wearing masks in children has been completely ignored. So writes
the RKI explicitly in the corresponding paper (p. 4):

"Psychosocial and other aspects like avoiding stigma are
not part of this recommendation, the focus is on infection prevention. "

From the perspective of evidence-based medicine, where both benefit and
also the cost of a measure against the background of the existing empirical
To weigh up studies, this paper of the RKI is on the recommendations of
To classify prevention measures in schools as questionable: The alleged benefits of the
Wearing masks in children is not proven by empirical studies, possible harm
were even explicitly ignored when drawing up the recommendations.

Recommendations according to the S3 guideline as a recommendation for action for schools

At the beginning of February, an S3 guideline on "Measures for the prevention and control of
SARS-CoV-2 transmission

in
Schools"
the
Scientific
Medical

Professional societies presented [5]. The recommendations for action formulated there were approved by
a representative group of experts in scientific

Specialist societies - in the lead were the German Society for Epidemiology, the
German Society for Public Health, the German Society for Children's and
Adolescent Medicine and the German Society for Pediatric Infectious Diseases - as well as on
School events for those involved and decision-makers. In relation
The recommendation for wearing masks is (p. 5):

2.2. Evidence-based recommendation

Appropriate wearing of masks by students, teachers and others
School staff should be implemented in schools.

Quality of evidence : Low ⊕⊕⊙⊙

Recommendation grade : Strong recommendation A

Strength of consensus : Strong consensus (100%); Yes-votes 24, against-votes 0,
Abstentions 1

Literature : Chu et al. (2020); Krishnaratne et al. (2021); Li et al. (2020)

2.2 Evidence-based recommendation

If there is a high incidence of infection, medical mouth and nose protection should be used
Use.

Quality of evidence : Low ⊕⊕⊙⊙

Recommendation grade : Strong recommendation A

Strength of consensus : consensus (86%); Yes-votes 18, no-votes 3, abstentions 4

Literature : Chu et al. (2020); Krishnaratne et al. (2021); Li et al. (2020)

With regard to the evidence on which the recommendations are based, the guideline states specifically (p. 6; emphasis by the author of the expert report):

Evidence base

□ The evidence on the effects of the measure with regard to SARS-CoV-2 Transmission was systematically recorded using a Cochrane Rapid Review [1]. The knowledge gained is based to a large extent on Modeling studies with quality defects. **The trustworthiness of this Evidence is very low or low .**

□ Indirect evidence on the transmission of SARS-CoV-2 when using Masks in the general population have **low trustworthiness .**

□ Health outcomes beyond COVID-19 **have not been systematic sighted** and based on indirect evidence, individual studies and / or Expert consensus.

□ Evidence on other criteria (acceptance, health equality, social and ecological consequences, financial and economic consequences, Feasibility) was not sighted, ie **no systematic search was carried out and evaluation of scientific studies carried out .** All Assessments of these criteria are based on expert consensus. A Restriction of fundamental rights by the measure was respected, too regarding the proportionality of the measure. A legal test was not made.

As the highlighting shows, the evidence base on which the recommendations for Wearing masks in children were consistently low to very low, one based systematic search and evaluation of scientific studies has partly not took place. Even so, the following are subsequently in terms of benefits Assertions made - without concrete empirical evidence for the to name the assertions made (p. 6):

"Wearing a mask reduces the transmission of SARS-CoV-2. Wearing a mask in Schools reduce infection rates as part of a package of measures ”.

It should also be noted critically that the same applies to those listed under “Literature” Meta-analyzes - Chu et al. (2020), Krishnaratne et al. (2021) and Li et al. (2020) - is exclusively a meta-analysis of observational studies. For example, Li et al. explicitly in the conclusion in the abstract:

"Robust randomized trials are needed in the future to provide better evidence for these interventions. "

Likewise, Chu et al. when interpreting in the abstract:

"Robust randomized trials are needed to better inform the evidence for these interventions. "

In addition, most of the studies analyzed in the meta-analyzes are are studies from the field of hospitals, which with regard to the Infections cannot simply be transferred to schools.

For example, only one of the six studies included in the meta-analysis by Li et al. were included, not in the hospital setting, but in the normal Population, and interestingly this study showed up for people outside no significant effect of wearing a mask in hospitals.

In fact, there are now relatively extensive observational studies on the Infection events outside of hospitals, which are mentioned in the meta Analyzes are not yet included, but point in a similar direction. So is recently an extensive study from Spain appeared in the Lancet [6], in the 282 Infection clusters in households were examined, with regard to factors that cause the Have influenced the incidence of infection. One factor was whether or not masks were worn Not. Between the groups “never wearing a mask” and “always wearing a mask” there was there is no significant difference in the infection rate, the authors write:

"We observed no association of risk of transmission with reported mask usage by contacts. "

The recommendations for action in the S3 guideline are therefore not convincing scientific evidence, as is actually the case with high-quality S3 guidelines Should be case.

It is particularly noteworthy that possible damage is almost completely ignored. As can be seen in the section cited above from the S3 guideline on the evidence base, the health consequences of wearing a mask beyond COVID-19 did not systematically sighted. Regarding the assessment of the possible harm caused by the The guideline says wearing masks - mind you, although the evidence is not systematic was sighted (p. 6):

"There are few health side effects associated with wearing masks. There are no evidence of possible damage from wearing a mask. "

Overall, the S3 guideline meets the actual expectations of such Guideline does not do justice to the scientific quality. The claimed benefit is not justified with high quality scientific evidence, but is based to studies that only provide very low to low evidence and from more recent ones Studies are also questioned. Regarding the damage, it is claimed that it there would be no evidence for possible damage, although the study situation does not even exist systematically spotted. As will be described in more detail in a moment, would have In this regard, just a look at the official WHO recommendation is enough where the

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possible damage is at least partially listed with appropriate references.

With regard to damage in particular, the S3 guideline almost borders on one Mislead the users of such guidelines.

WHO recommendations for wearing masks

The WHO's general recommendations for wearing masks were last updated on Jan. Updated December 2020 [7]. On the one hand, there is explicitly between the settings within and differentiated outside of hospitals. On the other hand, it says there in relation to Settings outside of hospitals explicitly (p. 8):

"At present there is only limited and inconsistent scientific evidence to support the effectiveness of masking of healthy people in the community to prevent infection with respiratory viruses, including SARS-CoV-2. "

Despite this body of evidence, wearing masks is essential when the virus spreads recommended if a distance of 1 m cannot be maintained. However, will explicit reference to the numerous possible damages, with reference to the corresponding Scientific evidence, which is included in decisions about wearing a mask should be (p. 10; the references given relate to the numbering in of the WHO recommendation):

The potential disadvantages of mask use by healthy people in the general public include:

- headache and / or breathing difficulties, depending on the type of mask used (55);
- Development of facial skin lesions, irritant dermatitis or worsening acne, when used frequently for long hours (58, 59, 127);
- Difficulty with communicating clearly, especially for persons who are deaf or have poor hearing or use lip reading (128, 129);
- discomfort (44, 55, 59)
- a false sense of security leading to potentially lower adherence to other critical preventive measures such as physical distancing and hand hygiene (105);
- poor compliance with mask wearing, in particular by young children (111, 130-132);
- waste management issues; improper mask disposal leading to increased litter in public places and environmental hazards (133);
- disadvantages for or difficulty wearing masks, especially for children,

developmentally challenged persons, those with mental illness, persons with cognitive impairment, those with asthma or chronic respiratory or breathing problems, those who have had facial trauma or recent oral maxillofacial surgery and those living in hot and humid environments (55, 130).

On August 21, 2020, the WHO also issued a recommendation to wear a mask published specifically for children [8]. There, too, the lack of empirical evidence is explicitly referred to Referenced evidence. It says (p. 2):

"Evidence on the benefits and harms of children wearing masks to mitigate transmission of COVID-19 and other coronaviruses is limited. "

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Studies are also cited which indicate that masks are less effective in children are more effective than in adults. It says (p. 2):

"One study, conducted under laboratory conditions and using non-betacoronaviruses, suggested that children between five and 11 years old were significantly less protected by mask wearing compared to adults, possibly related to inferior fit of the mask. "

With regard to the recommendation whether children should wear masks, it is then explicitly stated advised that the possible damage should be given priority. So

it says in the *Main Conclusions* (p. 2):

"The benefits of wearing masks in children for COVID-19 control should be weighed against potential harm associated with wearing masks, including feasibility and discomfort, as well as social and communication concerns. "

And in the *Overarching Guiding Principles*, the first two points are:

Do no harm: the best interest, health and well-being of the child should be prioritized.

The guidance should not have negative impact development and learning outcomes. Even so, then, surprisingly, the wearing of masks for children is starting Recommended for six years, but only if (among other things) a higher virus spread in of the population and a higher risk of infection in the corresponding age group is given and possible negative influences on learning and psychosocial Development must be weighed.

In summary, the WHO recommendations explicitly point to the lack of quality high quality scientific evidence on the overall effectiveness of mask wear and especially in relation to children. At the same time, numerous of the possible Damage, and it is explicitly recommended that children to consider and, if necessary, prioritize psychological and social damage.

Randomized controlled studies on the effect of the mask on virus spread

As mentioned at the beginning, are for a high quality scientific investigation the effect of masks on virus spread is actually randomized controlled Studies needed. Since such studies are very complex, such studies were relatively up to now recently with regard to the SARS-CoV-2 virus. However, there are several of them Studies on the already known respiratory viruses. The situation there is relative clear: In two different meta-analyzes from 2020 on the existing ones randomized controlled trials, the results are consistent:

Cochrane Review from April 2020 [9]: "Compared to no masks there was no reduction of influenza-like illness (ILI) cases (risk ratio 0.93, 95% CI 0.83 to 1.05) or influenza (Risk Ratio 0.84, 95% CI 0.61-1.17) for masks in the general population, nor in healthcare workers (risk ratio 0.37, 95% CI 0.05 to 2.50). There was no difference between surgical masks and N95 respirators: for ILI (Risk Ratio 0.83, 95% CI 0.63 to 1.08), for influenza (Risk Ratio 1.02, 95% CI 0.73 to 1.43). "

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Policy Review of the American Center for Disease Control and Prevention

[10]: "We did not find evidence that surgical-type face masks are effective in reducing laboratory-confirmed influenza transmission, either when worn by infected persons (source control) or by persons in the general community to reduce their susceptibility".

Accordingly, it is not surprising that the RKI Vice President Lars Schaade is up At a press conference on February 28, 2020, the RKI stated that the wearing of masks I expressly do not recommend it in everyday life. Literally he made it clear when asked [11]: "It has been investigated several times: there is simply no scientific one Evidence that there was some point in [wearing masks]."

At the beginning of the SARS-CoV-2 pandemic, there was therefore no scientific evidence from randomized controlled trials for the spread of respiratory viruses could contain in a relevant way using masks. That was meanwhile also in the first larger randomized controlled study on the effect of wearing a mask SARS-CoV-2 infections confirmed. In a Danish study [12] there were 4,862 people randomly assigned to either a group that left the house for a month high-quality surgical masks (filter rate 98%) should, or a group, which in the same Period should not wear masks. At the time of the study, there was no mask requirement Denmark and wearing masks was unusual.

The result was that there was no significant difference ($p = 0.18$) in the infection rate between the mask group (infection rate: 1.8%) and the control group (infection rate: 2.1%) was observed. If only the people in the mask group were left, who really wore the mask properly, then the effect disappeared of wearing the mask almost completely (infection rate mask group: 2.0% versus Infection rate control group: 2.1%, $p = 0.82$). The first extensive randomized Controlled study on the effect of wearing a mask on SARS-CoV-2 infections confirmed that is, those observed in previous studies on other respiratory viruses lack of effect of wearing a mask. It should be noted that in this study the effect of the Mask wearing was examined for self-protection. With regard to third-party protection - So to what extent masks prevent an infected person from infecting other people - there are no randomized controlled trials to date.

At the end of November an update of the already mentioned *Cochrane Review* was published [13], which includes the studies that have been added up to then. The result is unchanged:

"The pooled results of randomized trials did not show a clear reduction in respiratory viral infection with the use of medical / surgical masks during seasonal influenza. There were no clear differences between the use of medical / surgical masks compared with N95 / P2 respirators in healthcare workers when used in routine care to reduce respiratory viral infection. (...) Harms associated with physical interventions were underinvestigated."

There is therefore still no evidence from randomized controlled trials that Masks could prevent the spread of infection. In terms of wearing

In fact, cotton masks are the only ones that have been randomized to date controlled study [14] shows that wearing cotton masks increases the risk of infection not only does it not contain it, it actually increases it significantly. In the study, the effect of the Masked wear checked on 1,607 hospital employees, a third of whom Cotton masks and a third wore surgical masks, the remaining third should be like that behave as they usually do (in this condition almost all individuals also wore either medical masks or cotton masks). The authors summarize the results in the abstract as follows:

"The rates of all infection outcomes were highest in the cloth mask arm, with the rate of ILI [Influenza-like Illness] statistically significantly higher in the cloth mask arm (relative risk (RR) = 13.00, 95% CI 1.69 to 100.07) compared with the medical mask poor. Cloth masks also had significantly higher rates of ILI compared with the control poor."

The risk of infection was significantly higher than in the group with cotton masks. In the group with the medical mask the risk of infection was compared to the control condition reduced. However, this should not be taken as an indication that medical masks could actually have had an effect. In the control group, the people wore not no masks, but either cotton masks or medical masks.

Therefore, the risk of infection in the control group is exactly in the Middle between cotton mask group and medical mask group.

Interestingly, there are two other studies from the same researchers with a very similar design in which medical masks with a real control condition without Mask were compared. There was no difference in the risk of infection between the Groups. The authors use these results to provide the findings from the study Interpret and write cotton masks:

"The magnitude of difference between cloth masks and medical masks in the current study, if explained by efficacy of medical masks alone, translates to an efficacy of 92% against ILI, which is possible, but not consistent with the lack of efficacy in the two previous RCTs. Further, we found no significant difference in rates of virus isolation in medical mask users between the three trials, suggesting that the results of This study could be interpreted as partly being explained by a detrimental effect of cloth masks. This is further supported by the fact that the rate of virus isolation in the no-mask control group in the first Chinese RCT was 3.1%, which was not significantly different to the rates of virus isolation in the medical mask arms in any of the three trials including this one. "

So the authors conclude that the findings are presumably to be interpreted in such a way that too medical masks do not reduce the spread of the virus, cotton masks do

But also increase the risk of infection. Specifically, this is the one derived from the study Main conclusion in the abstract:

"The results caution against the use of cloth masks."

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This is particularly interesting with regard to the question of how children wear masks the authors' explanation of the increased risk associated with cotton masks. the authors write:

"The physical properties of a cloth mask, reuse, the frequency and effectiveness of cleaning, and increased moisture retention, may potentially increase the infection risk for Health Care Workers. The virus may survive on the surface of the facemasks, and modeling studies have quantified the contamination levels of masks. Self-contamination through repeated use and improper doffing is possible. For example, a contaminated cloth mask may transfer pathogen from the mask to the bare hands of the wearer. We also showed that filtration was extremely poor (almost 0%) for the cloth masks. Observations during SARS suggested double-masking and other practices increased the risk of infection because of moisture, liquid diffusion and pathogenic retention. These effects may be associated with cloth masks. "

The authors therefore suspect that cotton masks soak through faster and viruses can remain in the mask and, if handled incorrectly, the May increase the risk of infection. Interestingly, these are the ones mentioned Problems - long wearing time, higher moisture penetration, long-term use of the same Mask without adequate cleaning and problematic handling - by exactly that Problems with schoolchildren when wearing masks in class are typically observed.

The factor of correct handling of the masks when wearing them

It should be noted here that correct handling of masks in general The decisive factor is that masks can have an effect at all. Is called it in the mentioned recommendation of the WHO on the wearing of masks for the correct Handling [7]:

WHO provides the following guidance on the correct use of masks:

- Perform hand hygiene before putting on the mask.

- Inspect the mask for tears or holes, and do not use a damaged mask.
- Place the mask carefully, ensuring it covers the mouth and nose, adjust to the nose bridge and tie it securely to minimize any gaps between the face and the mask. If using ear loops, ensure these do not cross over as this widens the gap between the face and the mask.
- Avoid touching the mask while wearing it. If the mask is accidentally touched, perform hand hygiene.
- Remove the mask using the appropriate technique. Do not touch the front of the mask, but rather untie it from behind.
- Replace the mask as soon as it becomes damp with a new clean, dry mask.
- Either discard the mask or place it in a clean plastic resealable bag where it is kept until it can be washed and cleaned. Do not store the mask around the arm or wrist or pull it down to rest around the chin or neck.
- Perform hand hygiene immediately afterward discarding a mask.
- Do not re-use single-use mask.

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- Discard single-use masks after each use and properly dispose of them immediately upon removal.
- Do not remove the mask to speak.
- Do not share your mask with others.

As this list makes clear, the correct wearing of masks is very important Requirements for the person wearing the mask. Just considering that Pupils with a mask requirement in class have masks relatively consistently up to 10 Hours a day (school bus, school grounds, morning and Afternoon classes), correct handling in schools can hardly be implemented. In addition When younger students come about that correct handling of cognitive requirements which are not given in younger children due to developmental reasons. There For example, the prefrontal cortex does not yet exist until around the beginning of adolescence is fully mature [15], children's behavior is highly automated Behavioral tendencies controlled, which are only partially regulated by the child himself can. Requirements such as not touching the mask by children are hardly any to implement. There is therefore a risk that when children wear a mask, the Incorrect handling caused increased risk of infection according to the randomized controlled studies have little to no benefit.

From the perspective of evidence-based medicine, it should be noted critically, in particular, that wearing masks in schools has no effect on the spread of the virus randomized controlled trials there. Given the situation described, it is it is questionable to what extent it can be justifiable to have a comprehensive mask requirement prescribe without a real scientifically proven benefit. The is all the more the case as long-term wearing of masks with possible damage on a physical, psychological and social level - perhaps even more intensely Virus spread beyond - may be linked (see below).

The extent to which the risk of infection is reduced by wearing masks schools

It is important to note that the effect of a measure on virus spread in the Population does not depend solely on the effectiveness of a measure. The effect of a Measure also depends on how many infections are in the setting in which the Measure is used, can be prevented at all. Is there in one certain setting, for example, hardly any infections in itself, so even with a high effective measure hardly influences the infection rate in the population because there are hardly any infections that can be prevented by the measure can.

This point is particularly relevant when potential measures are involved Side effects are associated. You can do this using the so-called *Number Needed*

to Treat - i.e. the number of people who with a measure must be treated to prevent a single case of illness. If for example, very many people treated with a drug and under potential Side effects must suffer in order for a single person to get better cause, the use of the drug is to be classified as questionable.

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With regard to the question of wearing masks in schools, this point is because of it particularly relevant because virtually all of the available data suggest infections occur comparatively rarely in schools. That is the case simply because extensive meta-analyses indicate that in particular children under 12 years become infected less often and pass the virus on less often than adults [16,17]. On top of that, already by taking action that children with symptoms at home remain, the number of infectious children in schools is significantly reduced. How Extensive meta-analyses show, on the one hand, asymptotically infected people are stuck - i.e. people who have received a positive SARS-CoV-2 test result, but develop no symptoms of illness - hardly any other people. A meta Analysis of studies on infections among people living together in the same household Individuals [17] that have the likelihood of meeting an asymptotic person to infect (secondary infection rate), is only 0.7 percent, according to the statistical analysis showed that the value was not significantly different from zero. A comparable finding can be found in another recently published extensive meta-analysis Contact follow-up studies [18]. There the estimated secondary infestation rate was 1.0 Percent and was also not statistically significantly different from zero. Both meta-Analyses show very clearly that asymptomatic infections play practically no role. Asymptotically infected children do not pose a relevant risk of infection. In the case of infected children with symptoms, it is about a maximum of two days before Contagion can occur on the onset of symptoms [19]. When children with symptoms too So staying home there is only a two day window of time in which to experience symptoms Developing children can infect other people, which significantly increases the risk of infection reduced.

In fact, numerous data confirm that there are hardly any infected children or children in schools. There are contagions. Interesting in terms of wearing masks are here in particular the current figures from Austria, because there is no mask in primary schools and at the same time tested extensively with rapid tests three times a week. This allows you to estimate the number of infected students relatively well. In the Week 22-28 February (latest available dataset) were in elementary schools only 0.08 percent of the rapid tests were positive [20]. Assuming that the number False-positive and false-negative results are roughly balanced, would therefore the likelihood that a student will develop an infection within a week, be only 0.08 percent. The likelihood of an infected student at close contacts without wearing a mask in schools another person is infected, also very small and, according to extensive contact follow-up studies, is in the The order of magnitude is only about 0.5 percent [21,22]. On the basis of these numbers, an example can be used to illustrate this using a calculation example how big the risk reduction is that can be achieved by wearing masks can. The risk of having one in a class of 25 children over the course of a week Contagion occurs is therefore 0.08 percent times 25 (probability of infected child in a class) times 25 (number of contacts including teacher) times 0.5 Percent (probability of infection per contact) = 0.25 percent.

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This number would correspond to the risk of contagion that one is potentially having Can reduce measures in schools. The extent of the reduction depends on the

Effectiveness of a measure. If one interprets the insignificant effects from the Randomized controlled trials as zero effects, could be with the mask wearing Schools do not achieve any risk reduction.

If one proceeds from the insignificant effect sizes in the current Cochrane Review mentioned from (see above), according to which the likelihood of infection when wearing medical masks would be reduced by a maximum of about 10 percent

Risk of infection at the level of a school class from 0.25 percent to 0.225 percent decrease, which would correspond to an absolute risk difference of 0.025 percent.

Extrapolated to the *Number Needed to Treat*, the students would have to 4,000 primary school classes wear a mask for a week to avoid a single infection prevent. That is an extremely small effect size and it would have to be just under 100,000 Elementary school students face the potential side effects of wearing a mask to avoid a only one infection per week to prevent.

Assuming that masks reduce the likelihood of infection in the Order of magnitude of 80 percent (result mentioned in the S3 guideline Meta-analysis by Chu et al. on observational studies with low quality evidence, see [23]), the risk of infection at the level of a school class would be 0.25 Percent to 0.05 percent, which is an absolute risk differential of 0.2 percent would correspond. Extrapolated to the *number needed to treat* would therefore have to be the students in 500 primary school classes still wear a mask for a week and thus almost 12,500 primary school students the possible side effects take to prevent a single infection per week.

To evaluate such a relationship, an example is from the field of Drug approval helpful. Here it would be difficult to imagine a drug being positive rate if this means 100,000 (reduction of the likelihood of infection through masks by 10 percent) or 12,500 (reduction in the likelihood of infection through masks around 80 percent) people treated and suffer from side effects in order to with to have a positive effect on a single person.

In summary, it can be concluded that the achievable extent of the reduction in The risk of infection by wearing a mask in schools is very low, because at In schools, even without masks, infections very rarely occur. It's intuitive, that with an absolute risk reduction of 0.025 percent (reduction of the Probability of infection through masks around 10 percent) and also with an absolute one Risk reduction of 0.2 percent (reduction in the likelihood of infection through Masks by 80 percent) a pandemic cannot be combated in a relevant way.

On top of this, there are numerous possible side effects related to this minor benefit oppose the physical, psychological and social well-being of children, from which numerous children would have to suffer in order to prevent a single infection (see below).

The currently observed increase in reported infections in children

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Finally, due to the current situation, we should refer to the previous ones Calendar weeks observed increase in the number of reported positive SARS-CoV-2 test results in children and the relevance of the new virus variant B.1.1.7 To be received. The RKI and the media interpret this increase in such a way that the Infection numbers among children would rise sharply, something with the new virus variant B.1.1.7 could have to do with. Both of these are used as arguments in favor of schools more stringent measures would be necessary.

However, the RKI overlooks a serious aspect here: in the previous ones Calendar weeks, the number of corona tests (PCR tests) carried out in the Children roughly quadrupled (see the numbers published by the RKI on the number of tests carried out: [24]). An expansion of the tests is possible with an existing one The number of unreported cases of infected but previously undiscovered people is automatically assigned a increased number of infections found, without the infection process must have changed. The increase in the number of cases among children assumed by the RKI

could therefore only go back to the fact that the number of tests in the children quadrupled and the number of unreported cases has thus increasingly been uncovered. If one looks at the proportion of positive test results obtained, however, it shows that in the 5-14 year old children no increase in the previous calendar weeks can be seen. Instead, the percentage of positive test results has been falling for several weeks. Unlike the RKI mediated and distributed in the media, is - based on the proportion positive test results - instead of an increase, a decrease in the values is recorded. There is actually only one single case when an increase in the number of people discovered Infections while increasing the number of tests made to a real one Indicates an increase in the number of infections. That would only be the case if the increase in The number of tests is driven by the fact that there are more and more people with corona-specific Symptoms observed, which are then tested with targeted tests. But that is with them current corona tests with the children are highly unlikely to be the case. This is indicated by the fact that over 90 percent of the tests carried out at the children are negative. So the question of which children to test seems to a large extent regardless of whether or not children have corona-specific symptoms. In fact, there has been a strong campaign for widespread testing of children for weeks Schools and day care centers advertised regardless of symptoms. Through the The number of unreported cases is increasing with increasing mass tests regardless of symptoms of infected, but so far undiscovered people revealed what the number of cases increases due to the test. At the same time, the number of PCR tests is increasing in general regardless of symptoms. According to RKI calculations [25], in mass tests with Rapid tests regardless of symptoms the likelihood of getting a positive Result of actually being infected, with an incidence of 50 (test specificity 80%, Test sensitivity 98%) only two percent. That would mean: to two really positive ones Rapid test results would be 98 false-positive rapid test results, which one then would all have to retest with a PCR test. In addition, there is currently a sharp increase in respiratory diseases by rhinoviruses and the coronavirus hCoV in particular. According to the current

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Influenza weekly report of the RKI [26], according to the in the course of the flu surveillance examined sentinel samples the number of rhinovirus-related and hCoV-related Respiratory illnesses more than tripled in the last four weeks. The in the same Graphic published weekly report on age-dependency of virus outbreaks shows that the rhinovirus in particular is particularly common among children and adolescents spreads Since, according to RKI guidelines [27], if acute respiratory symptoms are present, everyone Severity testing for SARS-CoV-2 leads to the current increase in rhinovirus and hCoV-related respiratory diseases mean that more and more people respond to SARS CoV-2 will be tested, although the majority of respiratory diseases are due to another Virus. In turn, PCR test results take weeks and sometimes even Months after a SARS-CoV-2 infection can be positive [19], this leads Rhinovirus and hCoV-related increase in the number of SARS-CoV-2 tests, that the unreported number of actually past but not yet discovered Infections is increasingly being revealed. Taken together, from a diagnostic perspective, it can be said that it is extreme unlikely that the increase in the number of tests caused by the increase in coronary specific symptoms in children. Instead, the increase goes The number of tests with a high probability mainly depends on the mass tests advertised of children and the increasing number of rhinovirus and hCoV-related Respiratory illnesses among children. Both of these lead to the fact that the Unreported number of children infected with SARS-CoV-2 but not yet discovered is uncovered, which leads to an increase in the number of infections caused by the number of tests. Interestingly, the results from the sentinel samples confirm the Flu surveillance, which by increasing the number of tests in the population does not

be distorted that the new coronavirus SARS-CoV-2 is currently not stronger spreads than in the previous weeks. As the virus evidence for the sentinel samples shows, is the number of SARS-CoV-2 infections detected in the sentinel samples since the 4th calendar week at a comparatively low level, a “third wave” is here practically undetectable.

The relevance of the virus variant B.1.1.7

The argument for action in school often refers to what is supposed to be in children prevailing higher risk of infection with the new mutations referenced B.1.1.7.

More recent extensive studies could not confirm this fear. That is the conclusion of a very extensive study from England [28]:

"Our findings of no evidence of difference in SGTF growth rates between children and adults do not support B.1.1.7 being particularly adapted to transmit more in children. "

There are comparable findings from a similarly extensive study from Portugal [29].

In summary, the German Society for Pediatric Infectious Diseases and the German Society for Hospital Hygiene in a recent statement [30]: "

Initial media reports increased compared to adults

The risk of infection or transferability for children has not been confirmed. "

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It is important to point out that there is a frequent statistical misinterpretation. Statements like “The new variant is 50 percent more contagious” intuitively sounds like a lot. In reality the resulting threat depends on how high the

The probability of infection with the old virus variant is: The percentage value says yes, by what percentage of the old probability of infection the new one

The likelihood of infection is higher. If the old probability of infection is low, so is the new probability of infection with a 50 percent increase still small as before.

An illustrative example, which is particularly suitable for those starting out with children

Risk of contagion

relevant

is:

According to

the

mentioned

extensive

Contact follow-up studies in schools is the likelihood of a

infected child infects a contact in school (without masks in schools) only in

about 0.5 percent. With an increase of 50 percent that would be

The probability of infection is still only 0.75 percent. Extrapolated to 100

Contacts would mean that despite one, they increased by 50 percent

The likelihood of infection is still less than a single other person

infect

would.

Self

at

one

50 percent

increase

the

The likelihood of infection is still very high in schools

low, so that a tightening of the measures from scientific

Perspective cannot be justified.

Summary evaluation

In summary, it should be noted that so far there has been no high-quality scientific

There is evidence that wearing face masks increases the risk of infection

can be significantly reduced. The recommendations of the RKI and the S3 guideline of

Professional societies are based on observational studies, laboratory tests for Filter effect and modeling studies that provide only low and very low evidence, because none of these studies are really valid due to the underlying methodology. Conclusions can be drawn about the effect of masks in everyday life and in schools. In addition, the results of the individual studies are heterogeneous and more recent Observational studies also provide contradicting findings.

The existing randomized controlled studies on the effect of the Mask wear shows no effectiveness of masks, the observed effects are consistently small and meta-analytically insignificant. Rather, it points so far only large-scale randomized controlled trial on the wearing of cotton masks point out that cotton masks can actually increase the risk of infection. A role The main factor here is the handling of the mask, which can be avoided if it is handled poorly can have a negative impact on the risk of infection. This point is especially for the Interesting area of the school because handling problems in the school setting and can hardly be avoided, especially in the case of younger students. In addition, the achievable extent of the reduction in the risk of infection through the wearing of masks in schools is very low, because in schools without masks infections occur very rarely. Accordingly, the absolute risk reduction is like this little that a pandemic cannot be combated in a relevant way with it. In addition

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That comes as a result of this minor benefit related to numerous possible side effects oppose the physical, psychological and social well-being of children (see below), from which numerous children would have to suffer in order to receive a single infection prevent.

The currently allegedly increasing numbers of infections in children are going with higher Probability is actually due to the fact that the number of tests in the children in the has increased significantly in the previous weeks. As the risk of infection in schools is very small, even if there is a possible increase in the infection rate new virus variant B.1.1.7 in the order of magnitude assumed in studies expect the virus spread in schools to increase significantly.

2. What physical, psychological and educational damage can be caused by Does the wearing of masks arise especially among children?

In order to answer this question, the already mentioned one will first be given for an overview List of damage to mask wear from the official WHO recommendation and as a supplement, the overviews from two specialist publications on damage to the Wearing a mask. The results are then sent to an online register the physical and psychological side effects of wearing a mask in children which were recently published. After that it will be more detailed on various physical and psychological damage in particular in relation to the Special features in children received. In conclusion, it is questionable Arguments of plausibility received, which are often quoted.

Overview studies on the damage caused by wearing a mask

As already explained in the elaboration on question 1, in the on 1. December 2020 updated recommendations of the WHO on wearing masks [7] numerous possible damages mentioned with reference to corresponding empirical evidence. These are shown again in the following list, the corresponding ones empirical evidence is linked in the bibliography at the end (see WHO recommendation, P. 10):

- headache and / or breathing difficulties, depending on the type of mask used [31]
- Development of facial skin lesions, irritant dermatitis or worsening acne, when used frequently for long hours [32,33,34]
- Difficulty with communicating clearly, especially for persons who are deaf or have poor hearing or use lip reading [35.36]
- discomfort [13,31,33]

- a false sense of security leading to potentially lower adherence to other critical preventive measures such as physical distancing and hand hygiene [37]
- disadvantages for or difficulty wearing masks, especially for children, developmentally challenged persons, those with mental illness, persons with cognitive impairment, those with asthma or chronic respiratory or breathing problems, those who have had facial trauma or recent oral maxillofacial surgery and those living in hot and humid environments [31, 38]
- waste management issues; improper mask disposal leading to increased litter in public places and environmental hazards [39]

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In the peer-reviewed journal *Medical Hypothesis* is a January 2021 Comprehensive overview article on the state of the art on the damage of the Wearing masks on a physical and psychological level and the resulting Health consequences appeared [40]. Like the following overview table from the Article shows (see Table 1), there are additional references to further - in particular psychological damage that has not yet been mentioned in the WHO recommendation:

Table 1

Physiological and Psychological Effects of Wearing Facemask and Their Potential Health Consequences.

Physiological Effects

Psychological Effects

Health Consequences

- Hypoxemia
- Hypercapnia
- Shortness of breath
- Increase lactate concentration
- Decline in pH levels
- Acidosis
- Toxicity
- Inflammation
- Self-contamination
- Increase in stress hormones level (adrenaline, noradrenaline and cortisol)
- Increased muscle tension
- immunosuppression
- Activation of "fight or flight" stress response
- Chronic stress condition
- Fear
- Mood disturbances
- Insomnia
- Fatigue
- Compromised cognitive performance
- Increased predisposition for viral and infection illnesses
- Headaches
- Anxiety
- depression

- hypertension
- Cardiovascular disease
- Cancer
- diabetes
- Alzheimer's disease
- Exacerbation of existing conditions and diseases
- Accelerated aging process
- Health deterioration
- Premature mortality

An article in the British Medical Journal in August 2020 on the possible psychological, biological and immunological risks especially for children and students long-lasting mask wear appeared [41]. In summary it says there (the corresponding empirical evidence is linked in the bibliography at the end):

"Aside from the highly variable protective effects, WHO mentions several negative aspects of frequent / long-term use of facemasks, fueling the debate as to whether the benefits outweigh the drawbacks [7]. Many people report claustrophobic experiences and difficulty getting sufficient oxygen due to the increased resistance to inhaling and exhaling. This can lead to an increased heart rate, nausea, dizziness and headaches and several other symptoms [42,43]. In an inquiry among Belgian students wearing mouthmasks for one week, 16% reported skin problems and 7% sinusitis, also problems with eyes and headaches and fatigue were frequently mentioned [44]. Furthermore, face masking can provoke an increase in stress hormones with a negative impact on immune resilience in the long term [45]. Facemasks prevent the mirroring of facial expressions, a process that facilitates empathetic connections and trust between pupils and teachers. This potentially leads to a significant increase in socio-psychological stress. During childhood and puberty the brain undergoes sexual and mental maturation through hormonal epigenetic reprogramming [46-49]. Several studies show that long-term exposure to socio-psychological stress leaves neuro-epigenetic scars that are difficult to cure in young people and often escalate into mental behavioral problems and a

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weakened immune system [50-54]. A recent study by the CDC concludes that in young adults (18-24 years), the level of anxiety and depression has increased by 63% (!) since the corona crisis. A quarter of them think about suicide. As a result, the use of antidepressants has increased by 25% [55]. Several researchers have shown a relationship between the increase in stress experiences and the risk of upper respiratory tract infections and mortality [56-59]. "

The cited overview articles already show how numerous the possible damage of wearing a mask. In particular, a few more are missing here on the one hand possible harm to such as the risk of discrimination against children medically Cannot wear masks, or development-related impairments. To the Others add that children are due to their developmental immaturity are more prone to many of the listed side effects.

Results of a registry on side effects of wearing masks in children

A clear and impressive proof of the range and numerical magnitude The side effects of wearing masks in children represent the results of the the world's first register in which - comparable to the collection of side effects of medication through the Paul Ehrlich Institute - parents, doctors, educators and others share their observations on the side effects of wearing a mask on children and young people can register. On the one hand, there is a checklist various possible symptoms are queried (see the following table from the article) for others can be given further symptoms in a free text field.

The first results were recently published in the journal *Kinderheilkunde* published [60]. Within a week of the start of the register, there were already 20,353 people Entries made, the group of parents alone entered data on 25,930 children. The article reports the results from the parent entries. The specified

the average wearing time of the mask was 270 minutes per day. Overall, the report 68 percent stated that children were impaired by wearing a mask complain. For example, 13,811 of the children suffered from headaches and 12,824 from Difficulty concentrating, 9,460 with drowsiness, 7,700 with shortness of breath, 6,848 dizziness, 5,365 fainting, and 4,292 nausea. The following Table from the article shows the frequency of information for all symptoms of the symptom-Checklist (see table 3 in the article):

Symptoms

total

n (%)

Age 0 to 6

n (%)

7 to 12 years

n (%)

Age 13-17

n (%)

a headache

13,811

(53.3)

960

(24.0)

7863

(54.6)

4988

(66.4)

Difficulty concentrating

n

12,824

(49.5)

961

(24.0)

7313

(50.8)

4550

(60.5)

malaise

10,907

(42.1)

1040

(26.0)

6369

(44.2)

3498

(46.5)

Impairment in learning

9845

(38.0)

621

(15.5)

5604

(38.9)

3620

(48.2)

Drowsiness / tiredness

9460

(36.5)

729

(18.2)

5163

(35.8)

3568

(47.5)

Tightness under the mask

9232

(35.6)

968

(24.2)

5427

(37.7)

2837

(37.7)

Feeling short of breath

7700

(29.7)

677

(16.9)

4440

(30.8)

2583

(34.4)

dizziness

6848

(26.4)

427

(10.7)

3814

(26.5)

2607

(34.7)

Dry throat

5883

(22.7)

516

(12.9)

3313

(23.0)

2054

(27.3)

Powerlessness

5365

(20.7)

410

(10.2)

2881

(20.0)

2074

(27.6)

Reluctance to move, reluctance to play

4629

(17.9)

456

(11.4)

2824

(19.6)

1349

(17.9)

Itching in the nose

4431

(17.1)

513

(12.8)

2550

(17.7)

1368

(18.2)

nausea

4292

(16.6)

310

(7.7)
2544
(17.7)
1438
(19.1)
Feeling weak
3820
(14.7)
300
(7.5)
2020
(14.0)
1500
(20.0)
stomach pain
3492
(13.5)
397
(9.9)
2292
(15.9)
803
(10.7)
Accelerated breathing
3170
(12.2)
417
(10.4)
1796
(12.5)
957
(12.7)
Feeling sick
2503
(9.7)
205
(5.1)
1328
(9.2)
970
(12.9)
Chest tightness
2074
(8.0)
161
(4.0)
1122
(7.8)
791
(10.5)
Eye flicker
2027
(7.8)
149
(3.7)
1047
(7.3)
831
(11.1)
Loss of appetite
1812
(7.0)
182
(4.5)
1099
(7.6)
531

(7.1)
Palpitations, palpitations
Heart stitches

1459

(5.6)

118

(2.9)

766

(5.3)

575

(7.6)

Rushing in the ears

1179

(4.5)

107

(2.7)

632

(4.4)

440

(5.9)

Short term

Impairment of consciousness

g / fainting spells

565

(2.2)

39

(1.0)

274

(1.9)

252

(3.4)

Vomit

480

(1.9)

40

(1.0)

296

(2.1)

144

(1.9)

Further health problems were indicated in the free text field:

- 269 entries on deteriorated skin, v. a. increased pimples, and rashes allergic symptoms around the mouth area through to fungal infections and around the mouth
- 151 entries on nosebleeds
- 122 entries on reluctance to go to school through to fear of school / refusal to attend
- 64 entries on increased sweating

128

- 52 entries on pressure points and wounds behind the ears
- 46 entries to sore or cracked and z. T. bloody lips
- 31 entries on increased migraine attacks in frequency and severity
- 23 entries on impaired vision
- 13 entries on aphthous ulcers

As the authors note, this resulted in more children and

Adolescents with mask-related physical complaints reported as up to

At that time, a total of children and adolescents with positive SARS-CoV-2

Test results were reported.

In addition to the physical side effects, there were also numerous psychological ones

Side effects listed in the following table (see table

4 in the article):

**Mental
Side effects
total**

***n* (%)**

Age 0 to 6

***n* (%)**

7 to 12 years

***n* (%)**

Age 13-17

***n* (%)**

The child is irritable more often
than usual

11,364

(60.4)

1041

(40.0)

6566

(62.1)

3757

(66.5)

The child is less cheerful

9286

(49.3)

959

(36.9)

5640

(53.3)

2687

(47.6)

The child no longer wants
to

School

the

Go to kindergarten

8280

(44.0)

824

(31.7)

5168

(48.9)

2288

(40.5)

The child is more restless than
otherwise

5494

(29.2)

773

(29.7)

3515

(33.2)

1206

(21.4)

The child sleeps worse
than usual

5849

(31.1)

633

(24.3)

3507

(33.2)

1709

(30.3)

No other abnormalities

7103

(27.4)

1400

(35.0)

3834
 (26.6)
 1869
 (24.9)
 The child has new fears
 developed
 4762
 (25.3)
 713
 (27.4)
 2935
 (27.8)
 1114
 (19.7)
 The child sleeps more than
 otherwise
 4710
 (25.0)
 319
 (12.3)
 2183
 (20.6)
 2208
 (39.1)
 The child plays less
 2912
 (15.5)
 400
 (15.4)
 1998
 (18.9)
 514
 (9.1)
 The child has a bigger one
 Urge to move than usual
 1615
 (8.6)
 253
 (9.7)
 1124
 (10.6)
 238
 (4.2)

The fears that occurred were further specified in the free text:

- In addition to a general fear of the future, there are also fears of even wearing a mask suffocate as well as before the death of relatives from Corona, most often represented.
- Added to this is the fear of stigmatization both from wearing and by not wearing a mask in social surroundings.
- Many parents also report having nightmares and anxiety disorders that arise masked people relate their facial expressions and identity to the children not is recognizable.

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On the one hand, it should be noted that the entries have not been fully validated could become. The authors write about the limitations of the study:

“Naturally, an openly accessible register can never have all entries made by a doctor validate. The register entries increase daily in the multi-digit range, and additional validity checks will take place in order to make further more reliable ones in the foreseeable future

Data on the health situation of children in Germany with regard to the
 To be able to present wearing a face mask. "

As an argument for the credibility of the data, the authors cite:
“With a few exceptions, the data records in the free text entries show a lot differentiated approach and result in a balanced overall picture Overall picture with a plausible spectrum of symptoms and an easily comprehensible one Description of the impairments associated with the mask in children to be watched. Answering hundreds of incoming emails through the Study initiators with answers to questions about the existence of the register, specification and supplementing the entries made by participants in detail Case descriptions and suggestions for further research are another indication of that high relevance of the topic and for the honesty with which many participants feel about the Dedicate the question. ”

The authors also note that the reporting is biased with respect to the preferential documentation of particularly severely affected children or the In principle, protective measures do not exclude people who are critical of each other leaves.

Overall, this study shows the world's first register for possible Side effects of wearing masks by children are very impressive that it is a very large one Range of physical and psychological side effects. The central one The authors' conclusion is:

“The frequency of use and the spectrum of symptoms indicate the importance of the Topic back and forth for representative, randomized controlled surveys Studies with different types of masks and after a risk-benefit analysis of the Mask requirement for the vulnerable group of children. ”

This confirms the descriptions of children wearing masks for long periods of time Complaints also from further studies on other groups of people, which also long Must wear masks. There are now several studies on the symptoms of People who work in the health sector and who also wear masks for a long time must, whereby it should be noted here that, unlike in the school area, in addition to masks for Part of the need to wear additional protective equipment (e.g. protective goggles, Protective suits). In a meta-analysis recently published as a preprint on the existing That was studies with a total of 11,746 participants on the physical side effects Result [61]:

“The most frequent adverse events were headache (55.9%), dry skin (54.4%), dyspnoea (53.4%), pressure injuries (40.4%), itching (39.8%), hyperhidrosis (38.5%), and dermatitis (31.0%). ”

The studies described clearly show that wearing masks is a wide range of side effects can be associated. The following is still

went into more detail on some side effects that have not yet been mentioned have been or are associated with particularities in relation to children.

Physiological side effects

Studies in adults show that wearing masks has physiological effects Level, especially under physical exertion. Already after a few minutes in some studies there is a slightly higher CO₂ concentration in the Blood, a faster heartbeat, and faster breathing [62,63]. For hours Wearing surgical masks also shows a decrease in oxygen saturation in the blood [64]. On the one hand, it is important to note that there are also studies in which such effects cannot be observed [65]. For another, it is important to note that the values when wearing masks based on the average values over the examined Move the test subjects away in an order of magnitude, which according to the current guidelines no clinical relevance achieved.

However, it should be noted that it still applies to undetected previous illnesses more extreme side effects such as panic, seizures, and impaired consciousness can come [66]. In this regard, there is an important methodological aspect in the Interpretation of studies on possible side effects of masks to be noted: Alone

from the observation that there was no statistically significant difference in the average physiological values between the conditions with and without a mask there, it cannot be concluded that there are no side effects.

The first problem is that in the case of small samples, there are mean differences only become statistically significant if the differences are very large. In the medicine but even small effects can be relevant. The second problem is that even with insignificant effects at group level for individual persons Extreme values can occur which are severely impairing for the persons concerned are.

A negative example in this regard is a study by a research group led by Michael Campos [67], which has been widely used in the media and allegedly shows that himself people with lung disease would not show any physiological effects of wearing a mask. However, on the one hand, the sample examined is very small - in this study were only 15 healthy or lung sick people tested - so that with this study only statistically extremely large effects can be discovered. Second, occurred despite the lack of significant effect at the group level in individual persons to extreme values. Is called in the study for the group of people with lung disease:

"With the 6-minute walk, subjects with severe COPD decreased oxygenation as expected (with two qualifying for supplemental oxygen). However, as a group, subjects with COPD did not exhibit major physiologic changes in gas exchange measurements after the 6-minute walk test using a surgical mask, particularly in CO₂ retention. "

So in two of the lung disease patients there were more fundamental ones

Side effects, only at the mean value level, are shown on average for all patients

away no effect. Would that be the case, for example, with drug approval for

As a rule, you would no longer have to pay attention to rare side effects from now on - which is questionable.

In summary, it says in a mini review published in February 2021 about the existing studies [68]:

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“The few existing studies suggested that surgical and cloth masks did not significantly compromise ventilation and oxygen supplies in healthy individuals and may, therefore, be considered as not harmful. Physical exercise and pre-existing respiratory problems may cause hypoxemia and hypercapnia. As using face masks could be a long term preventive measure in the COVID-19 era, further studies are needed, particularly to explore the impact on pre - existing respiratory problems in children and adults. ”

Regarding the possible physiological harm of wearing a mask in children is a fundamental problem that so far there have been hardly any studies on the effects in children.

This is particularly problematic because of the effects described in children could be stronger because the oxygen consumption in children is higher and the Breath reserve is lower, the percentage of the dead space volume in children Mask at the total respiratory volume is larger and the flow resistance of the Mask can have a stronger effect due to the weaker respiratory muscles.

In the aforementioned mini review, a

only study discovered in which the physiological consequences of the five-minute

Wearing N95 masks in 7-14 year old children has been studied once when

Reading and once during light physical exertion [69]. It turned out that the CO₂

Concentration (end-tidal carbon dioxide and fractional inspired carbon dioxide) when wearing the

Mask increased by up to 34 percent (light exercise) in both cases, with

the values still did not reach clinical relevance.

The problem, however, is that in the course of the mask requirement in the classroom not only children Wear masks for five minutes, but up to ten hours a day, five days a week.

There are no studies on such long wearing times. This is especially so as

highly problematic to assess because it is in the state regulation of mandatory measures for millions of children from a medical ethical perspective

It is really imperative to consider possible risks before prescribing the measure

examine and exclude based on evidence or at least quantify the risk.

Oral diseases - the so-called "mask mouth"

Wearing masks can be associated with a number of oral conditions, such as:

Tooth decay, bad breath, inflammation of the gums and inflammation of the mouth region - here the term "mask mouth" was coined [70].

Deformation of the auricle

Children before puberty have undeveloped ear cartilage with less resistance against deformation. A longer pressure through the elastic loops of the mask can do that correct growth and angulation of the outer ear and affect the angle of the increase the outer auricle [71].

Virus and bacteria build up on the mask

Viruses, bacteria and fungi can accumulate on the masks, some of them again and again inhaled and can cause disease, such as studies on

Show wearing surgical masks [72]. While exhaled droplets and aerosols

usually released into the surrounding air on exhalation and quickly

dry, they remain in the mask when wearing masks, with the effect that

Bacteria and fungi can multiply again in the constantly moist environment of the mask can be inhaled and put a strain on the body.

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Possible contained toxins in masks

Problematic side effects can also occur if worn masks release toxins contain. In an article in the *Frankfurter Rundschau*, the results of a Investigation by the private Hamburg Environmental Institute (HUI) reports [73]. There were sometimes considerable amounts of pollutants in the masks currently in use detected, including volatile organic hydrocarbons and formaldehyde. In addition showed that when worn for several hours and with multiple use - as shown in the case in schools - microplastics are inhaled. The HUI chairman, professor Michael Braungart, is quoted as follows:

“In tests we found up to 2000 fibers per day, some of them with the Breathing air into the lungs ”.

A current article by the German Allergy and Asthma Association (DAAB) states [74]:

“During the corona pandemic, the DAAB has sent some inquiries about smells Receive protective masks. Especially at the beginning of the pandemic were certainly also more and more products on the market that contain harmful substances. But even now you can this may still be the case in isolated cases, as the WISO magazine has recently checked.

Pollutants in masks can get directly into the lungs through breathing ”.

Since in the certification of medical masks only the filter performance and the Bioburden, but not necessarily the presence of toxic components

must be checked (see DIN EN 14683, 5.2.7 summary of the

Performance requirements), that could indeed be an issue with some medicals

Represent masks. Should it be true that medical masks are problematic

May contain ingredients that children would wear medical masks

exposed to a health risk. Since the masks in class, on the

It is mandatory to carry the school premises and the school bus, it becomes a wearing time at which such risks would be particularly great.

Psychological side effects

As already with the entries in the register for the side effects described above of wearing masks in children is longer on a psychological level

permanent mask requirement in schools with far-reaching negative effects in terms of

to be expected of the development and maturation of children. In a current

Overview work on the side effects of wearing a mask on the emotional experience

and the neuroscientist Manfred Spitzer points out the three in terms of social communication the following problems [75]:

Restricting non-verbal communication

Wearing masks makes non-verbal communication extreme

restricted, which is one of the most important channels for the
Represents the emergence of a sustainable social relationship. Furthermore, the
Facial expression one of the central signals through which we our own
Communicate emotional state and the emotional state of the other person
tap into what is one of the fundamental building blocks of developing a high
represents emotional and social competence. Children in particular have yet to do it
learn to reliably interpret these signals on the faces of others.

Negative distortion of emotional experience

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In addition, there is another negative effect: According to studies, fear and grief are more likely to end
read from the eyes and joy rather from the mouth region. Continue to be without that
Signal from the mouth region misinterpreted emotional facial expressions. One actually
A happy expression is often referred to as a skeptical expression
Misinterpreted, a surprised facial expression is often referred to as anger or sadness
misinterpreted. So wearing masks could lead to being in the
Faces of others are less likely to perceive positive and more negative emotions.

Impairment of empathy

Furthermore, the empathy - the sympathy for the emotional state of the other -
impaired by wearing masks. As studies show, you take with
unconsciously communicate with each other the facial expression of the other person and
feels the inner state of the other person, which is achieved by wearing a mask
is prevented.

In summary, Manfred Spitzer writes one of his overview work:

"However, covering the lower half of the face reduces the ability to communicate,
interpret, and mimic the expressions of those with whom we interact. Positive
emotions become less recognizable, and negative emotions are amplified. Emotionally
mimicry, contagion, and emotionality in general are reduced and (thereby) bonding
between teachers and learners, group cohesion, and learning - of which emotions
are a major driver. The benefits and burdens of face masks in schools should be
seriously considered and made obvious and clear to teachers and students. The
school's specific situation must also inform any decision regarding face mask use. "
Interestingly, the mentioned psychological side effects of wearing a mask
also in the Bavarian law for the education, upbringing and care of children in
Kindergartens, other day-care centers and day care (BayKiBiG)
picked up. There it is about kindergarten children, but the corresponding content
can also be carried over to primary school age. There you can find in part 3 for
Ensuring the best interests of the child of the following articles [76]:

Article 9a: Prohibition of covering the face

Employees in day-care centers are allowed to face their faces during visiting hours
Do not cover up, unless there are reasons related to supervision. Sentence 1
applies accordingly to day care workers.

On the official website of the Bavarian State Ministry for Family, Labor and Social Affairs
there is a more precise interpretation. There are the various educational
Reasons given for the ban on face covering [77]:

Excerpt from the explanatory memorandum for Art. 9a BayKiBiG:

The aim of day care centers and day care is among other things, cooperation and
To impart communication skills and to enable the children to integrate.
Especially in the area of young children, it is with a view to the development of a child
it is essential that good educational work is done. This would be seriously endangered
if the child is a carer or another in the day-care center
person who does not reveal their face.

The facial expression is important to the various possibilities of expression
to get to know and understand. It also prevents a veiled

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Face especially communication and interaction between children and educators and thus affects what is indispensable for the education and upbringing of children Building bond and relationship. After all, it's just the personal and familiar Contact between child and staff is extremely important for early childhood education. It is therefore necessary that employees in day-care centers during the Visiting times as well as your face at events of the facility (between chin and Forehead). (...) The prohibition does not apply if there are childcare-related reasons for the oppose. Care-related reasons would be, for example, a disguise in one Role play or at a carnival party.

Given that the aforementioned negative effects of wearing a mask on the The development of children at BayKiBiG is felt to be so important that there a It is all the more surprising that the ban on wearing masks is prescribed by law none of the side effects mentioned under the current prescription one Mask compulsory in elementary school - and also not for the educators in the Kinds of children - attention.

There are also a number of other possible psychological side effects:

Restriction of voice transmission

Wearing masks continues to have negative effects on speech transmission along with [78]. On the one hand, higher frequencies are attenuated, on the other hand, the visual Signal from the lips completely obstructed, which interferes with verbal communication and is associated with the risk of misunderstandings. Has a particularly negative effect focus on learning a new language, so that language acquisition and children with a migration background are particularly affected.

Risk of discrimination

Finally, there are negative side effects on a psychological level for children, which are not allowed to wear a mask for medical reasons. There is a risk here that such children - justified with hygienic arguments - discriminated and out of the social class group are excluded, with negative consequences for the psychological and social wellbeing. I am aware of cases where children who made medical For reasons of not being able to wear a mask, wear yellow armbands throughout the school day have to. In another case, there is a corner in the classroom and in the playground masked, in which children who cannot wear a mask for medical reasons, have to stop. The risk of discrimination is also evidenced by the fact that in the above described register on the side effects of mask wearing in children as one of fears the fear of stigma from both wearing and the Not wearing a mask in social surroundings is called.

The risk of such discrimination is increased by questionable statements by Experts in the media. So said the youth psychiatrist Dr. Biskup-Meyer in a SZ- Interview on the mask requirement in primary school [79]:

"If the teachers wear a mask and the students are shown to be believable, that this is precisely what is needed, then elementary school children are certainly the ones who most willingly adhere to it. This also includes having a unit in the Great because everyone wears a mask. "

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The teachers strongly convey the necessity of wearing a mask to children and if there is corresponding group pressure due to social dynamics, the danger is all the more so that some children are discriminated against.

In addition, children who are not allowed to wear a mask for medical reasons, thereby come into a psychological situation that cannot be positively resolved for the child. No matter how the child behaves, there are negative consequences: If the child does not wear them Mask, if it becomes socially excluded, does the child wear the mask, physical suffering occurs. Such a situation can be associated with very negative psychological consequences

towards the development of mental disorders.

**The
Trigger
and
Sustained
of
developmental psychology
inappropriate fears**

With regard to the Corona measures in primary schools, there is also the problem that with Measures such as wearing a mask or keeping a distance from the children permanently it is conveyed that there is a great danger for themselves from others as well as by themselves for others. This can be accompanied by fears and feelings of guilt, with which a child cannot handle due to their developmental immaturity. Is If this is the case, anxiety disorders develop, which the child develops in its development affect.

Prolonged anxiety has problematic effects on different levels of the psyche out. For example, thoughts begin to revolve around the fearful event, like this that the child can no longer concentrate on other things. At the level of the Motivation, the avoidance-related behavior system is chronically activated, what to do with it leads to the fact that the child no longer strives for things that it wants to achieve, but rather those The world is increasingly viewed through the glasses of possible impending events, which it want to avoid. The consequence is that the child is increasingly developing stops and increasingly withdraws. In extreme cases it can go so far that depression is developed. It can be at the level of brain development too "Biological scars" come, which translates into increased vulnerability for life can affect physical and psychosocial stressful situations [80].

There is also another important point: The fears caused by the coronavirus Measures can be triggered in schools, do not relate to an aspect which has little meaning for us humans. With a fear of snakes it is for example, in such a way that it does not necessarily have to be severely impairing, because Snakes are not a relevant part of our human life. The fears, which Corona measures in schools can be triggered, however, affect one of the most central aspects of human life: contact with others People. Man is genuinely a social being, the need for closeness and good Social relationships is a basic human need, just like eating, drinking or eating Sleep [81].

With the measures taken in schools such as wearing a mask and keeping your distance thus violated the basic social needs of children. There is also the fact that children Develop a fear of the other person, there is a risk of mental disorders can be acquired in the social field and the social health of children - and with it the overall psychological development - is permanently impaired.

In fact, there is now ample empirical evidence that mental health problems occur Children gain weight, although it is important to note that this is not the case

can be causally traced back to wearing a mask, but rather a product of problematic overall situation.

The so-called Copsy study by the University Medical Center Hamburg-Eppendorf [82] that at the time of school closings in spring [2020](#) 71 percent of children and Young people felt burdened by the contact restrictions. In 39 percent of the children and the relationship with friends worsened through the youth limited personal contacts, which burdened almost all respondents. The proportion of Children and adolescents with reduced health-related quality of life rose from 15 to 40 percent, the risk of mental health problems from around 18 to 30 percent. Current studies also point to the dramatic situation. So summed up the children's and Youth psychologist Prof. Dr. Julian Schmitz from the University's Department of Psychology

Leipzig summarized its current findings as follows in a current interview [83]:

"We are currently not seeing an increase in just one group of faults, but rather a sharp increase in mental stress across the spectrum such as depression, anxiety, obsessive-compulsive disorder, and behavioral disorders. There On the one hand, the children and adolescents who already have one suffer mental disorder have gone into the pandemic and their location changes frequently has deteriorated very much. On the other hand we also see that many children who were mentally healthy before the crisis, now at this time - especially the Lockdowns - have become mentally ill. (...) Our research data show It is very clear that the majority of mental disorders do not resolve themselves again, but these disorders often take a chronic course and over the time more disturbances are added. So we cannot assume that after the end of the pandemic, the psychological situation got sick Children, adolescents and adults simply complete again on their own relaxed."

The Austrian psychology professor Manuel Schabus summarizes the results of his current surveys in an interview as follows [84]:

"FOCUS Online: Mr. Schabus, how do you rate the effects of the Lockdowns lasting for months, especially on children and young people? They will be lost under this year - maybe it will even be lost a year and a half or two - suffer a lot. We see that in our data Survey. The main fear of 6 to 18 year olds is that their lives will never be like this again becomes like it was before the pandemic and lockdowns. You assume that their future is negatively affected in the long term. An example: three quarters of the surveyed children and adolescents assume that Corona will not occur until 2022 or 2023 will be "over". We have to assume that the youth are in theirs psychological development will get a big problem with the subject of anxiety. Psychotherapists tell me that the children don't have very diffuse fears only because of Corona. Fears come from all corners to which they respond because they are literally conditioned to be afraid and under that pressure to live. We have to assume that this will lead to more psychosomatic excesses and physical illness. If you are permanently exposed to increased stress, the immune system naturally suffers underneath and every infection and disease has an easier time. It is not

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rule out that therefore in the coming years even Cancers will increase because this connection is scientifically good is known. "

Questionable plausibility arguments

As an argument for the alleged harmlessness of wearing masks there is one Set of plausibility arguments that do not stand up to closer examination. A first argument that one often hears is the comparison with operating room doctors, who also do wearing masks for hours during operations without allegedly looking at them Would show impairments. For one, there are also physiological ones Detected side effects such as a drop in oxygen saturation in the blood [63]. On the other hand, wearing masks in the classroom is not comparable to that Wear of Masks in Operating rooms. Operating rooms are With

Equipped with high-performance ventilation systems that maintain positive pressure and increase the oxygen content of the room air [85]. In addition, the masks are there at Moisture penetration changed immediately, something in the classroom due to the limited number the masks per child is not possible. Furthermore, operating room doctors are hygienic sensible use of the mask highly trained, so that contagion through the Accumulation of germs on the mask over the hands can be minimized, which is the case Is impossible for elementary school students due to their level of developmental maturity. Another questionable argument comes from the spokesman for the professional association of children's and adolescent doctors (BVKJ), Dr. Jacob mask. He spoke to the German press Agency stated as follows (quoted from Die Welt [86]):

“Even small children could wear a face mask. 'That is absolutely no problem', explains the expert. Suppose a child actually becomes insufficient If you inhale oxygen or too much CO₂, then it would get tired and yourself Feeling beaten, so the doctor. In this case the child would take off the mask of its own accord ”.

In view of the fact that there are no empirical studies on this, it is this statement is a mere hypothesis. When strict rules from social authorities are given and there is social pressure in the class, but it's over From a psychological perspective, it is not to be expected that smaller children in particular will in such a case will take off the mask on their own initiative.

A third questionable argument is that children cannot get out of wearing masks themselves Would cause disaster and get used to it quickly. From the Observation that children would not make a disaster out of wearing masks, too conclude that children would not mind, is highly negligent. Even if a Child being abused doesn't necessarily make it a disaster because a child still lacks the rational standards of assessment. To conclude that the then yes would be ok, would be absurd. This is exactly why our children are not yet of age, and it takes adults to evaluate situations for children. In addition, the Side effects of the mask can not be noticed for a long time, because children simply become quieter and therefore less noticeable. What you need here is a very good eye on the part of teachers and parents.

Summary evaluation

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In summary, there is ample evidence of the range of possible damage physical, psychological and social level, which especially with the longer Mask wearing in children can be connected. On the one hand, these are occupied by several studies mainly related to the various side effects Adults, on the other hand through the existing registry on the side effects of the Child wearing of masks. There are also from a psychological perspective the fear that with a longer-lasting mask requirement in schools very much sustained psychological impairments in the development of children are associated that can not yet be clearly proven, but loud different psychological theories are to be expected with a high degree of probability. It is particularly problematic that it is to be feared in spite of the numerous There is no single randomized controlled trial in which the Side effects of prolonged use of masks by children were investigated. Before mandatory measures are even prescribed for millions of children, From a medical ethical perspective, it would be imperative to consider possible risks before the To check the regulation of the measure and to exclude it based on evidence or the risk at least to be quantified and weighed against the benefits. Than is problematic In particular, it should also be appreciated that in view of the existing evidence for numerous possible side effects these are neither in the recommendations of the RKI nor in the S3-Guideline is still mentioned or taken into account in the relevant government statements become.

3. Is there any risk of infection from wearing face masks?

(or other measures) could be lowered?

This question has already been answered in the course of answering question 1 (see Section “The extent to which the risk of infection is reduced by wearing masks at schools ”on p. 10 ff).

4. Can reduce the risk of infection by observing distance regulations be lowered especially in children?

A recently published study is relevant to this question [87]. There was based a very large sample (537,336 students and 99,390 school employees) and of a large period (September 24th to January 27th) examined the extent to which there is one It makes a difference whether a distance of three or six feet was required in schools. The results show that the size of the gap was neither in the pupil infections made a difference in teacher infections. So at least it shows from a distance of 90 cm there is no effect of further increasing the distance. It should be noted is that from the secondary level onwards, a universal mask requirement in the schools examined The rule was that in primary school, wearing a mask was compulsory in 70 percent of the cases. Also The results of this extensive study also confirm once again that infections occur in the school staff appear far more often than the pupils, what a is further convincing evidence that students have a lower Risk of infection.

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5. May even offer children a “protective function” from spreading the coronavirus SARS-CoV-2 in the sense that it is spreading the virus rather slow down and protect against severe Covid-19 diseases?

To answer this question, extensive studies are presented first, which show that the risk of developing severe COVID-19 is lower when adults have a lot of contact with children. Current findings are then discussed that show that children - contrary to what was initially assumed - have a lower viral load, what that Risk of infection and the resulting severity of the disease according to current findings can reduce. Finally, the findings from sick leave become critical illuminates that professional groups that have to do with the upbringing and care of children most often would have been on sick leave due to COVID-19, which is often called The argument used is that children pose a particular threat.

The lower risk of developing severe COVID-19 in close contact with children get sick.

In one of the most extensive studies to date on the factors influencing the risk of Developing severe COVID-19 disease were all of those in Scotland analyzed corona cases that occurred [88]. It turned out that teachers (no Mask wear by students up to around 15 years of age) compared to others Occupationally have a 64 percent reduced risk of seriously contracting COVID-19 (rate ratio of 0.36, 95% CI 0.19 to 0.69). It was also shown that the risk of severe COVID-19 illness in adults was reduced by 28 percent when Children lived in the same household (rate ratio of 0.72, 95% CI 0.63 to 0.82). This effect of Children showed up even when adults belonged to a high-risk group (e.g.

Cancer,
difficult
asthma
and
other
heavy
chronic

Respiratory diseases, high blood pressure, immunosuppression, etc.). Comparable findings there is also from Sweden, where teachers were at risk of getting seriously ill Reduced by 57 percent compared to other occupational groups (relative risk of 0.43, 95% CI, 0.28 to 0.68) [89].

The authors of the study suspect that this could be due to the contact with

Children the pre-existing immune protection due to cross-reactions with others
Coronaviruses increased. They write:

"The inverse association of severe COVID-19 with past exposure to children is
consistent with evidence that other coronaviruses generate cross-reactive T-cell
responses that may confer some resistance to SARS-CoV-2. "

The lower viral load in children

There is a second possible explanation, which is based on the fact that in the meantime as
It has been proven that the viral load in children is lower than in children
Adult. Initially there was one in particular based on a study
Research teams led by Christian Drosten have suspected that children have the same viral load as
Adults would have and therefore a similar risk emanated from children. Indeed
this study contained an actually very classical and fundamental methodological approach

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Mistakes, such as the renowned statistician David Spiegelhalter from the University
of Cambridge [90].

Due to the small sample size in childhood and the division into numerous
Age groups in adulthood and the subsequent correction for multiple testing is
the power of the study - that is, the likelihood of an existing difference
statistically significant between the children and adult groups - see above
It is small that the study showed no statistical differences in principle in principle
can. In the case of an insignificant effect on the null hypothesis, it is at
a low power methodologically absolutely inadmissible. This is actually about
Basic statistical knowledge (the so-called "Type 2 error", see, for example, [91]).
Interestingly, as David Spiegelhalter proves, the study by the research team shows
about Christian Drosten in reality - if they had been correctly evaluated - even that
the viral load in children is lower. In descriptive terms, in the study the
Viral load in 0-10 year old children is only 27 percent of the viral load in adults over 20
Years (this is the actual comparison group, the artificial division in the
Adult age in the article in 10-year increments is given the actual
Research question - viral load in children versus adults - difficult to understand because
such a division only substantially reduces the power). In fact, that is made possible by a
Study recently published as a preprint with much larger samples (2,654 children and
Adolescents) than in the study by the research team around Christian Drosten (117 children and
Adolescents) [92].

As current studies again show [93], the viral load of the person from whom the
Contagion emanates, the risk of severe COVID-19 illness. That could make the
lower viral load in children in the event of infection a protective function against the
Developing more severe COVID-19 illness. It should be noted, however, that
direct scientific evidence that the lower viral load has the positive effect of the
frequent contact with children suggests the lower disease severity, not yet
is provided.

Common COVID-19 Diagnoses Among Occupational Groups To Do With Childcare to have

Finally, it is important to mention a misleading representation in the media.
The AOK Scientific Institute published the results at the end of 2020
an analysis [94] which occupational groups from March to October most frequently with the
Diagnosis "COVID-19" were written off sick. Amazingly, ranked first
Professional groups that have to do with the upbringing and care of children. In the
The media concluded that allegedly educators at the
would most often contract COVID-19.

A closer look at the study reveals, however, that this is a misleading representation.
With regard to the "COVID-19" diagnosis, there are two different diagnosis codes [95]:
Once a diagnosis is confirmed by a positive PCR test (diagnosis code
U07.1!) And once a mere suspected diagnosis without confirmation by a positive one
PCR test (diagnosis code U07.2!). Since people with a suspected diagnosis do not have

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have a positive SARS-CoV-2 test result, it is very likely that it is in
Such cases are really just a harmless cold.

It is a common practice in day-care centers for educators to take care of light
Always have cold symptoms tested immediately and then until you receive the
Test results must be written off sick. On the sick note, the

Suspected diagnosis U07.2! noted. If the test result then shows that in

In reality, there is no SARS-CoV-2 infection, it is the initial one

Suspected diagnosis U07.1! thus actually a wrong COVID-19 diagnosis.

The problem with the analysis of the AOK is that there is no distinction between whether it is with
a "COVID-19 diagnosis" on a sick note may only be a mere

Diagnosis is suspected. So it could be that people working with children
just have it tested particularly often for a suspicion (diagnosis U07.2!), but
in reality don't get COVID-19 more often (U07.1!).

This is indeed proven by a more precise evaluation of the AOK data, which recently appeared
is [96]. Accordingly, professions in child rearing and childcare are related

on the total of diagnoses "COVID-19" received in first place. However, it does

48.0 percent of the cases are merely suspected diagnoses. Professions in geriatric care or
Health and nursing care lie in relation to the total received

Diagnoses "COVID-19" only in second and third place. However, it is only there in

31.8 and 28.9 percent, respectively, are suspected diagnoses. In terms of actually confirmed

COVID-19 diseases, on the other hand, are the occupational groups in geriatric care (22.9 percent
more cases) or healthcare and nursing (25.7 percent more cases) well ahead of the

Occupational groups in child-rearing and childcare. In reality get sick

So educators are significantly less likely to be affected by COVID-19 than those employed in the elderly,
Health and nursing.

Summary evaluation

In summary, there is indeed reliable evidence from very extensive

Scientific studies suggest that frequent contact with children may actually be
represent a protective function against the development of severe COVID-19 disease

can. In particular, an extensive study now shows that children do indeed have a

have lower viral loads than adults, which is one of the explanations for this

Could represent protective function.

6. Which methodological level and, if applicable, which methodological shortcomings have existing studies on infection rates in schools and their effectiveness of measures such as wearing masks and keeping your distance in schools?

This question has already been answered in the course of answering question 1 (see

Section "Evaluation scheme for classifying the quality of the evidence from studies" on p. 1
ff).

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X. Expert opinion by Prof. Dr. rer. biol. hum. Ulrike Kämmerer

Prof. Dr. rer. biol. hum. Ulrike Kämmerer represents at the University Hospital Würzburg, Women's clinic, in particular the focus on human biology, immunology and cell biology.

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The reviewer has her molecular biology expert report, this one is fully inserted, reimbursed as follows:

As to the question of evidence “What is the significance of the detectability of an infection with the Coronavirus SARS-CoV-2 is provided by the RT-qPCR test and those currently used Rapid tests ”

1. The nucleic acid detection using the RT-qPCR test

R reverse- **T** ranskriptase- **q** uantitative **P** olymerase **C** hain **R** eAction (**RT-qPCR**) tests are as Diagnostic tool for active SARS-CoV-2 infection for numerous reasons unsuitable in the beginning.

1.1. Explanation of terms / basics

In a **polymerase chain reaction (PCR)** , the enzyme polymerase is used defined short (usually 100-1000 bases comprising) piece of the Deoxyribonucleic acid (DNA) amplified. The piece of DNA to be replicated becomes with the help of two very short single-stranded DNA sections, the "primers".

These **primers** usually consist of a defined sequence of 18-25

Nucleic acid bases (the primer sequence) that are specific to the regions on the DNA which flank the section to be reproduced. To determine the specificity of the PCR ensure that these primers are explicitly only allowed to this flanking area and to no further area of a DNA match. With the help of large gene databases and more appropriate

Software programs

(e.g.

Primer blast

<https://www.ncbi.nlm.nih.gov/tools/primer-blast/>) these primers can be used in the PCR design

be designed in a highly specific manner. In the case of specialized companies, the The primer sequences are then synthesized and sent to the PCR laboratory or the Supplied by PCR kit manufacturer. Here these primers have to be valid with positive and negative controls under various test conditions and tested in Use to be optimized. This ensures that the primer pair used only the DNA to be searched for is recognized and replicated, but no other similar stretches of DNA.

Once the primers have been found and specific, the to replicating DNA with the primer pair, various auxiliary chemicals as well as the Enzyme polymerase mixed and the chain reaction started.

Sequence of the PCR: This runs in cyclical repetitions of the following individual steps from:

1. The mixture is boiled (denatured) at over 90 ° C. This will make the DNA strands usually present as double strands separated into single strands in order to obtain the to allow later attachment of the primer.

2. During the subsequent cooling down to the so-called " **annealing temperature** ", the Attach primers to their appropriate regions on the separated strands of DNA. The Binding of the primers, the annealing, takes place only in a narrowly limited temperature range, the so-called melting temperature. This mainly depends on the base composition of the Primer off and therefore their sequence will ideally always be chosen so that both Primers have the same melting temperature of approx. 60 ° C. The attached primers form the starting point for the polymerase.

3. Starting from the primers, this polymerase supplements those resulting from the heating existing single-stranded DNA back to a matching double-strand (**elongation**) mostly at approx. 72 ° C.

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Due to the position of the two primers on the flanking sides of the DNA Section, the elongation reactions are opposite to the single strands, since the Polymerase only ever works in one direction. At the end of this step you are off a original double-stranded DNA now has two identical double-stranded DNA molecules emerged, which separated again by boiling, then with the help of the primer deposition and the polymerase are amplified into 4 identical DNA molecules, etc. Each PCR Cycle of boiling-annealing-elongation causes a doubling of the sought-after DNA Section, so that the duplication takes place in the 2-way logarithm and therefore very quickly there is an extremely high number of copies of the original starting material. Thus, after 10 PCR cycles, a DNA strand already turns into $2^{10} = 1,024$ DNA copies 20 cycles already over 1 million (1,048,576) and with 30 cycles over 1 billion (1,073,741,824) copies.

In the **quantitative PCR (qPCR)** technique, as it is currently used worldwide mainly for Detection of the genomic RNA of SARS-CoV-2 is used, one uses a third one short piece of DNA, similar to the two primers, which is located in the middle of the DNA-Section can suitably bind the "**sample**" (**probe**) . This is different from the two primers Probe still attached to two molecules, a fluorescent dye at one end and another molecule (quencher), which prevents the emission of fluorescence can, as long as both are working on the sample at the same time (i.e. in close proximity to each other) are located. During the elongation step, the polymerase now breaks down this probe. This will the quencher is separated and the fluorescent molecule can now emit its color signal. This color signal is recorded in the device performing the PCR (thermal cycler) and measured. With each PCR cycle, the number of

Copies release more and more fluorescence signals, the probe "glows" more and more. And the Color signal intensity curve increases with each cycle. Exceeds a certain value the curve then the background noise (threshold value) and is evaluated as positive. The The number of cycles at which the threshold value is exceeded is called the **CT value** (CT stands for "Cycle Threshold"). The faster the fluorescence increases (lower CT), the more initial copies of the The desired DNA was present in the PCR mixture. Since neither the primer nor the enzyme Polymerase always work 100% specifically, there will also be a fraction in every PCR approach unspecific DNA copied. And the more cycles the PCR goes through, the greater it is There is a risk that these few unspecific reactions will eventually exceed the threshold value exceed. From a CT value of 40, there is therefore a high probability of one false positive signal due to unspecific starting materials. A reliable PCR should therefore not require more than 30-35 cycles to achieve a distinct Generating a "positive" signal, in the case of active infections with the virus being sought, is from one A sufficient number of cycles of 25-30 can be assumed (see also point 3.2.).

The **reverse transcriptase reaction (RT)** is needed when the to be duplicated Starting nucleic acid is not present as DNA but as ribonucleic acid (RNA), like this is the case with SARS-CoV-2 as an RNA virus. Because in the PCR only DNA is reproduced an RNA has to be converted into DNA beforehand. This is done using the Enzyme "reverse transcriptase", which turns RNA into a complementary copy strand DNA is created, which then serves as the starting material for the PCR.

About the reliability of a result obtained by means of RT-qPCR or even just PCR To be able to evaluate, correct target genes are diluted with the help of defined samples (e.g. RNA of the virus sought) and very similar, but not sought target genes (e.g. closely related viruses) the sensitivity and specificity of the test system used rated.

The **sensitivity** indicates how sensitive the test is to even the smallest amount of the the target gene being sought, the **specificity** describes how reliable the test is

excludes that other, closely related genes also lead to a positive result (**false**

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positive) lead. The higher the specificity, the more reliably it can be ruled out that the PCR system itself can produce false positive results.

Unaffected by this, however, are still false positive events caused by

Laboratory contamination with target genes, **impurities of test chemicals** and **Contamination can arise directly when taking the sample** . These contamination-related false positive results can be carried out by rigorous Quality assurance and Standard Operating Procedures (SOPs) through the use of specially trained specialists as well as permanent external control in the form of Round robin tests are excluded.

1.2. Basic information on the diagnostic significance

The inventor of the PCR test, Nobel Prize winner Kary Mullis, who died in August 2019, has repeatedly pointed out that his test alone is suitable for an otherwise Molecule invisible to the human eye (deoxyribonucleic acid, DNA) or Make the fragment of the DNA visible by means of duplication (amplification). No but, to allow a statement as to whether what has been made visible is dangerous or makes you sick.

In particular, a PCR test - even if it is carried out correctly - cannot do anything Make a statement about whether a person is infected with an active pathogen or not.

Because the test cannot differentiate between “dead” matter *, such as one completely harmless genome fragment as a remnant of the struggle of the body's own Immune system against a cold or flu (find such genome fragments many months after the immune system has "dealt with" the problem), and “Living” matter, ie a “fresh”, reproductive virus.

For example, PCR is also used in forensics to extract hair residues or to reproduce residual DNA present in other trace materials by means of PCR in such a way that the genetic origin of the perpetrator (s) can be identified (“genetic fingerprint”).

Even if that means when performing the PCR including all preparatory steps (PCR design and establishment, sampling, preparation and PCR execution) everything Is done “correctly” and the test is positive, ie: a genome sequence recognizes which possibly also exists in one or even the specific "Corona" virus (SARS-CoV-2), Under no circumstances does this mean that the person who tested positive is with a replicating SARS-CoV-2 and consequently infectious for other people = could be dangerous.

Rather, more, and

specific diagnostic methods such as the isolation of viruses that are capable of replicating used (gold standard).

1.3. Factors influencing the reliability of the PCR test

In fact, the results of a PCR test depend on a number of parameters which, on the one hand, cause considerable uncertainties and, on the other hand, **specifically** so can be manipulated so that many or a few (seemingly) positive results are achieved become.

1.3.1. Number of independent target genes (" **targets** ")

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In the protocol “ **Diagnostic detection of Wuhan coronavirus 2019 by**

*real-time
PCR "*

(<https://www.who.int/docs/default-source/coronaviruse/wuhan-virus-assay-v1991527e5122341d99287a1b17c111902.pdf>) is the sequence of PCR detections of described three independent partial genes of the virus later renamed SARS-CoV-2. The order was based on the E gene, the RdRp gene, and then the N gene. Already at January 17th, 2020 a change followed by the WHO with the protocol "*Diagnostic detection of 2019-nCoV by real time PCR "*

(https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf?sfvrsn=a9ef618c_2) in which the N gene as evidence was removed and therefore only 2 targets are recommended instead of the original 3 targets were. On March 2nd, 2020, a test protocol of the WHO "*Laboratory testing for coronavirus disease 2019 (COVID-19) in suspected human cases "* (<https://apps.who.int/iris/bitstream/handle/10665/331329/WHO-COVID-19-laboratory-2020.4-eng.pdf?Sequence=1&isAllowed=y>) pointed out that "... *In areas where COVID-19 virus is widely spread a simpler algorithm might be adopted in which for example screening by RT-PCR of a single discriminatory target is considered sufficient.*"(page 3 below) whereupon the laboratories began to analyze only 1 target on a large scale, whereupon many laboratories only refer to the E gene introduced as the first target as a valid one PCR specialized, such as explicitly from the Augsburg Laboratory on April 3rd. described (only in the

Internet cache
available:

<https://www.oder-spree-piraten.de/wp-content/uploads/2020/05/Changed-findings-layout-of-SARS-CoV2-PCR-Results--Labor-Augsburg-MVZ-GmbH.pdf>

**The outstanding importance of the number of independent individuals analyzed by means of PCR
Target genes result from the following calculation:**

The three originally specified in the WHO protocol for the detection of SARS-CoV-2 E, RdRp, and N-Gen targets have been used expeditiously in many laboratory and commercial applications Test systems used. A round robin test by the Institut Instant eV ([https:// corona-ausue.de/wp-content/uploads/2020/07/Instand-Ringversuch-Virusgenom-Nachweis-SARS-CoV-2.pdf](https://corona-ausue.de/wp-content/uploads/2020/07/Instand-Ringversuch-Virusgenom-Nachweis-SARS-CoV-2.pdf)) resulted in a mean specificity of:

Target gene
of
SARS
CoV-2
Genome
number
checked
Testing
Specificity
just
Cell culture
(without
Virus rna)
Specificity
With
related
Coronavirus
(HCoV 229E)
%

Medium
 Specificity
 absolutely
 Medium
 Error rate
 (1-abs.
 Spec.)
 E gen
 24
 99.46%
 95.17%
 97.31
 0.9731
 0.0269
 RdRp gene 13
 97.80%
 90.66%
 94.23
 0.9423
 0.0577
 N gene
 21
 98.20%
 87.95%
 93.08
 0.9308
 0.0692

In a mixed population of 100,000 tests, none would actually become infected

Person based on the mean error rate result in:

For a pure e-genetic test: $100,000 \times 0.0269 =$

2690

not correct

positive

With E and RdRp test in sequence: $100,000 \times (0.0269 \times 0.0577) =$

155

not correct

positive

For all three genes (E, RdRp, N): $100,000 \times (0.0269 \times 0.0577 \times 0.0692) =$ **10** incorrect

positive

This means, according to the WHO specification, the number of target genes to be tested successively from Reducing SARS-CoV-2 from 3 to 1 resulted in an increase in false positives

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tested people in the above calculation example from 10 with 3 genes to almost 3000 with only

nor the E gene for every 100,000 tests performed. The 100,000 would be carried out

Tests are representative of 100,000 citizens of a city / district within 7 days

be carried out, the target genes used can be derived from this question alone

with regard to the "/-day incidence" a difference of 10 compared to 155 compared to 2690

and depending on this, the severity of the citizens' freedom restrictions.

Evaluation: The calculation example also shows how by "playing on the specifications" with regard to

of the targets to be verified for the laboratories, the daily case numbers are manipulated

can. Given the immense impact on political decisions,

which of the absolute numbers of positive tests and the "7-day

Incidence" is the stipulation of the WHO (and also the RKI) to reduce the

Target genes were clearly suited to artificially eliminating the "pandemic" through incorrect test

specifications

inflate by a factor of 300.

This is an evidence-free approach that is tremendously personal for one thing

Limitations of the quarantine / isolation, which the falsely "tested positive"

People have to suffer, on the other hand, about the "7-day incidence number"

willingly in enormous social and economic restrictions and damage

Purchase takes.

Would the correct number of targets of three or even better (e.g. in

Thailand) up to 6 genes had been used for the PCR analysis, the rate of

positive tests and thus the "7-day incidence" almost completely reduced to zero.

1.3.2. Number of cycles performed (**CT value**)

In addition to the number of detected target genes, especially with only one or at most

However, 2 genes represent the number of cycles of amplification in the qPCR up to the evaluation

"Positive" and the resulting CT value a crucial screw represents. **The**

The smaller the CT value of a sample in a qPCR, the higher the initial amount

the DNA in the sample . Under standardized conditions, this correlates with (in the case of

Viruses) the initial amount of viruses, the so-called **viral load** , which ideally as "number

viral copies "should be stated per ml of sample. This viral load also correlates in the

Case of SARS-CoV-2 with the ability to grow infectious viruses in cell culture as below

Participation of C. Drosten was already published in March 2020. (Figure 1e in Wölfel et

al., <https://doi.org/10.1038/s41586-020-2196-x>) Here was a minimum amount of 10^6 RNA

Copies / ml are necessary in order to be able to grow viruses from the sample, whereas

the RT-qPCR from the original [protocol](#) (Corman V et al., [10.2807 / 1560-](#)

[7917.ES.2020.25.3.2000045](#)) already with approx. 4 copies per sample preparation (5µl accordingly

approx. 10^3 copies / ml) can deliver a positive result, i.e. already by a factor of 1000

than in a sample with an actually infectious virus load.

Also

commercial PCR test systems , so-called kits, sometimes have

Detection limits of less than 10 copies / reaction, such as kits from TIB-

Molbiol

([https://www.roche-as.es/lm_pdf/MDx_53-0777_96_Wuhan-R-](https://www.roche-as.es/lm_pdf/MDx_53-0777_96_Wuhan-R-gene_V200204_09155376001%20%282%29.pdf)

[gene_V200204_09155376001%20%282%29.pdf](https://www.roche-as.es/lm_pdf/MDx_53-0777_96_Wuhan-R-gene_V200204_09155376001%20%282%29.pdf))

It is technically different here from a "settlement" of the pharynx with

a few, but not infectious, viruses and a real one

"Infection". The latter is accompanied by viruses capable of replication, which then a) become a

symptomatic disease and b) an infectiousness, ie the ability to treat others

Infesting people.

Christian Drosten already mentioned this aspect in an interview with Wirtschaftswoche in 2014

([https://www.wiwo.de/technologie/forschung/virologe-drosten-im-gespraech-2014-die-who-](https://www.wiwo.de/technologie/forschung/virologe-drosten-im-gespraech-2014-die-who-can-only-make-recommendations / 9903228-2.html)

[can-only-make-recommendations / 9903228-2.html](https://www.wiwo.de/technologie/forschung/virologe-drosten-im-gespraech-2014-die-who-can-only-make-recommendations / 9903228-2.html)) in connection with MERS

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described " *Yes, but the method (note: what is meant is the PCR) is so sensitive*

that they can detect a single genetic molecule of this virus. When such a pathogen

for example with a nurse for a day about them

Nasal mucous membrane scurries (note: that would be the above-mentioned "settlement") without them

falls ill or notices anything of it, then suddenly she is a Mers case. Where

previously terminally ill were reported, suddenly there are now mild cases and people who

are actually very healthy, included in the registration statistics. " [...] " Because what first

*interested are the real cases (note: these are the "infected") . **Whether symptomless***

or mildly infected hospital employees are really virus carriers, I think

questionable. It is even more questionable whether they can pass the virus on to others. "

The latter is a crucial statement also in relation to being very close with MERS

related SARS-CoV-2 viruses. But exactly this point of virus transmission (and thus

driving the pandemic) is the justification for the intervening measures such as

Quarantine / isolation orders, the "lockdowns" and the so-called AHA rules.

Further evidence for the relevance of the CT value

A Canadian study by Jared Bullard / Guillaume Poliquin in Clinical Infectious Diseases 2020, read under the link (<https://doi.org/10.1093/cid/ciaa638>) came in May 2020 to the result that above a CT value of 24 no reproductive Virus was found more - this means: An attempt to take from swab samples that were not found until a higher CT value resulted in a positive test, subsequently capable of reproduction Growing viruses failed. According to this study, above a CT value of 24 is the The amount of detectable viral genetic material is so small that the test is positive could no longer be interpreted in terms of an active infection. A great study from Jaffar et al. (Doi10.1093 / cid / ciaa1491) exposed the limit to the cultivability of SARS-CoV-2 Patient specimens at a CT value of 30.

In his NDR podcast from February 16, 2021, C. Drosten explicitly stated that an increase of the CT of 25-27 across the limit of 28 means that people of whom this Smears obtained with the higher CT are no longer infectious. *“ And here too a Ct value shift from 25 to 27 approximately, 27, 28 can be seen again. And this is an area where, in our opinion, the infectivity has really come to an end. If sees such a patient sample and one would ask, is the patient still infectious, because would I say: No, this is slowly no longer an infectious area. This can be correlate ”*

page
4th
(right
column
above
in:

<https://www.ndr.de/nachrichten/info/coronaskript270.pdf>

Unanimous scientific opinion (including from Dr. Fauci from the US CDC, but also a number of scholars quoted in the New York Times in August 2020, <https://www.nytimes.com/2020/08/29/health/coronavirus-testing.html>)

is
that
all

"Positive" results, which are only recognized from a cycle of 35, do not have any have a scientific (ie: no evidence-based) basis. The one with the help of the WHO RT-qPCR test for the detection of SARS-CoV-2, which was propagated worldwide, was (and him following also all other tests based on it as a blueprint) to 45 cycles set without defining a CT value for "positive".

Also in May 2020, the National Center for Infectious Disease in Singapore

a

Position paper
published

(<https://www.ncid.sg/Documents/Period%20of%20Infectivity%20Position%20Statementv2.pdf>), which indicates that

1. It is important that the detection of viral RNA by PCR is neither a Infectivity, still corresponds to a virus capable of replication (“it is important to note that viral RNA detection by PCR does not equate to infectiousness or viable virus ”)
2. The limit value (cycle threshold value CT) of the PCR shows as a surrogate marker for the Viral RNA content from a CT of 30 or more, viral RNA, not more, however, the presence of viruses capable of replicating and those affected People are not infectious.

Original text excerpt: *“ 6. A surrogate marker of 'viral load' with PCR is the cycle threshold value (Ct). A low Ct value indicates a high viral RNA amount, and vice versa. As noted above, **detection of viral RNA does not necessarily mean the presence of infectious or viable virus** . In a local study from a multicenter cohort of 73 COVID-19 patients , when the Ct value was 30 or higher (ie when viral load is low), no viable virus (based on being able to*

culture the virus) has been found. "

The RKI also declares on its homepage as of August 11, 2020

(https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Vorl_Testung_nCoV.html#doc13490982bodyText4) “ *First results from the diagnostics at the RKI show that the*

Loss of cultivability in cell culture with a real-time PCR (Note: is the RT-

qPCR) determined RNA amount of <250 copies / 5 µL RNA. This RNA

The concentration in the test system used corresponded to a Ct value > 30. "

A recent study from South Korea (<https://www.nejm.org/doi/full/10.1056/NEJMc2027040>) sets the limit for virus cultivability at a CT value of 28.4.

And in a current study from Frankfurt ([https://www.mdpi.com/2077-](https://www.mdpi.com/2077-0383/10/2/328)

[0383/10/2/328](https://www.mdpi.com/2077-0383/10/2/328)) it was shown that of 64 RT-qPCR positive patient samples (one gene tested) virus cultivation in cell culture succeeded only out of 33 (= 52%). These infectious samples

have already been positive up to a mean CT value of 26 (Supplementary Figure 1)

whereas no virus cultivation was successful from the samples with a higher CT.

In the round-robin test facility eV (http://www.finddx.org/covid-19/pipeline/?section=molecular-assays#diag_tab.), see also the next point, shows the enormous range of CT

Values even for highly standardized samples between the various laboratories and

also with regard to the different target genes. For example, the CT fluctuates here for the same defined diluted sample of SARS-CoV-2 (sample number 340061) for the WHO

recommended genes between 15-40 (E-gene), 20-40.7 (N-gene) and 19.5-42.8 (RdRp-gene).

This impressively shows an extreme lack of test standardization within the

participating (and certified) laboratories.

Against this background, it is strange if the RT-qPCR is still recognized by the RKI as

"Gold Standard" is viewed without the exact validations and external

Define certification conditions (and without this from the authorities

obviously be fully monitored).

Rating:

In general, an RT-qPCR cannot detect intact, interrogative (infectious) viruses

prove, not even the complete intact virus genome, but exclusively

Nucleic acid of the searched segment. It is generally possible with well-adjusted and

correctly performed PCR tests **by validation with a parallel performed**

Virus cultivation in cell culture to define a limit value (CT) from which a positive PCR

Signal no longer correlated with viruses that could be heard. This is under surveillance

Well-practiced routine of blood products for years.

This stringent validation then allows - as long as the test system is NOT changed -

as a surrogate marker an estimate of the viral load and thus the possible infectivity of the

tested sample, but never definitive evidence. Once a component

on the PCR test system (be it chemicals, plastic goods, enzymes, protocol processes or

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Machines) is changed in one of the steps used, the system must be recalibrated again.

From all information published so far (see above) it can be assumed that

that every CT value above 35 is no longer associated with the cultivation of infectious viruses

and thus the absolute limit value for the decision is "positive", regardless of the

test system used. The CT range 25-35 may still be depending on the test

valid to be assessed as "positive in the sense of an infectiousness" if, as described, by adequate validation in the performing laboratory was compared with virus cultivation.

CT ≤ 25

: positive

CT 26-35

: only positive when compared with virus cultivation

CT > 35

: negative

The strict evaluation of the CT value plays a role above all when the target number is one, but generally applies to each individual target.

Taken by itself, without information about the comparison with the specific number of Virus genomes (viral load) and the correlation with a cultivability corresponding Virus quantities, however, the CT value is used as an assessment criterion for a positive PCR Evidence worthless.

1.3.3. Adequate controls

In order to be able to correctly assess the **sensitivity** and **specificity** of an RT-qPCR, Adequate samples are taken along with each reaction run. This starts with the Test site with "blank smears" to ensure contamination at the sample collection point Rule out goes on via extraction controls to ensure correct isolation to ensure reproducible RNA with all subsequent processing steps, ie one artificially produced defined RNA, which is used in all working steps of the sample preparation up to the PCR is carried out and processed and then with the help of suitable primers the PCR is also carried out. It can hereby be excluded that in the context of the Substances that inhibit sample processing or errors in the amplification of RNA prevent.

Furthermore, in each correct test series, a number of external (i.e. parallel such as Patient samples) as well as a positive control, which ideally consists of an inactivated defined SARS-CoV-2 virus strain. This would be one The RKI's very own task (with the help of other, suitable public institutions such as the Bernhard Nocht Institute or the Friedrich-Löffler Institute), in the ones available there Laboratory facilities (security level 4) a sufficient number of SARS-CoV-2 To isolate viruses from patient samples, define strains from them as controls cultivate, inactivate them and in defined virus numbers over the local To submit to supervisory authorities as controls to the testing laboratories. After this important service, however, still after more than a year of the "pandemic" is not offered, the positive control usually consists of a synthetic RNA, which only encodes the target genes of the test system. The lower detection limit of the PCR can be determined. This is used by some commercial Kits with 20 or fewer viral genomes per sample are indicated and thus indicate (see point 1.3.2.) Already shows an amount of virus in the smear that is 10⁵ below the infectious dose, means: has no diagnostic / prognostic value. A Find an overview of the commercial kits currently in use with their line data under http://www.finddx.org/covid-19/pipeline/?section=molecular-assays#diag_tab.

Round robin tests:

Correctly carried out controls also include participation in the test conducting laboratories in so-called " **ring tests** " (see also 1.3.1.). With these an anonymous panel of test samples is available from an external provider posed. In the case of virus detection, these contain negative samples and samples closely related viruses (inactivated) to check the specificity (these samples must not contain result in a positive signal) and positive samples with different dilutions of the virus searched for (inactivated), in order to increase the sensitivity (from what number of viruses the PCR positive, with which CT value).

In the case of SARS-CoV-2, the first round-robin test "Virus Genome Detection - SARS-CoV-2 (340) "by the association" INSTAND eV "ready in April 2020. In this round robin test 488 laboratories participated, of which 463 reported results, according to the report. The Results can be found in the published commentary (Signature M: *Commentary on the Extra Round robin group 340 virus genome detection SARS-CoV-2* ", available at: <https://corona-ausschuss.de/wp-content/uploads/2020/07/Instand-Ringversuch-Virusgenom-Proof-SARS-CoV-2.pdf>) and show two deviations from the

usual round robin test procedures, which are already here on laboratory problems with the RT-qPCR pointed out to the evidence of SARS-CoV-2: This is what it says on page 4 of the publication:

" Important message about the evaluation: Only 4 of the 7 samples that were used in this extra round-robin test have been examined for obtaining a certificate of successful

Participation takes into account". The footnote on page 10 of the comment states: " *In the Interim evaluation from April 17, 2020, all participants in the Extra INSTAND Round-robin test (340) virus genome detection of SARS-CoV-2 April 2020 the Sample properties of samples 340059, 340060 and 340064 communicated ahead of time. The Results of these 3 samples are not taken into account for the issuing of a certificate [...]* "

The reason for this exclusion of certain samples is given on page 4 of the comment explained: " *While the extra round-robin test was still running, INSTAND eV received from Germany and Urgent inquiries abroad, before the end of the extended deadline, i.e. before the 28th April 2020 to uncover the properties of the samples to be examined, with it Laboratories can improve their test method in the short term in the event of incorrect measurements .* " (Page 4 at the top of the INSTAND eV report))

This procedure is very unusual for a real round robin test and therefore does not constitute a independent external review process of the laboratories involved.

Despite the samples that had already been uncovered and the reduced scope of tests, one of them occurred Large number of laboratories to mix up samples - so it says on page 18 of the Comment: " *With sample 340064 (SARS-CoV-2 positive diluted 1: 100,000) the reduced success rate of only 93.2% mainly due to incorrect result assignments (Mix-ups) for sample 340064 and sample 340065 (negative for SARS-CoV-2 and positive for HCoV 229E). The mix-ups for samples 340064 and 340065 concern 24 laboratories with a total of 59 results per sample. See also section 2.4.2.1. [...]* "

So a large number of laboratories wrongly took the sample 340064 (slightly diluted SARS-CoV-2) with sample 340065 (negative for SARS-coV-2 and positive for the closely related Virus HCoV 229E) confused.

Aside from the appalling fact that obviously even under high standardized procedures in an interlaboratory comparison a considerable number of samples were swapped (which is related to the question of the corresponding quota

Sample swaps and thus incorrectly assigned swab samples under

Raises mass test conditions), it is noticeable that all reported mix-ups are only these affected both samples, but not the samples with the final number 61 that were also assessed (very highly diluted SARS-CoV-2) and 62 (negative). The detailed results of a second proficiency test from June / July 2020 (<https://www.instand-ev.de/System/rv-files/summary%20of%20sample%20properties%20and%20target%20values%20virology>

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[%20340%20June%20July%202020%2020200911a.pdf](#)) are still not public visible.

1.3.4. Exclusion of **contamination** of reagents and " **problems in Course of action** "

The best PCR design can still produce false positive results, though either the underlying reagents / kits are contaminated with positive samples, or, much more likely, **contamination occurs in the laboratory** process. Since the PCR is an extremely sensitive method (exponential reaction process), which few molecules can detect a DNA, the laboratory contamination is by in clinical diagnostics PCR end products a main problem (described e.g. already in 2004 in Aslanuadeh J et al., <http://www.annclinlabsci.org/content/34/4/389.full.pdf+html>: " *A typical PCR generates as many as 10⁹ copies of target sequence and if aerosolized, even the smallest aerosol will contain as many as 10⁶ amplification products [6]. If uncontrolled, within a relatively short time the buildup of aerosolized amplification products will contaminate laboratory reagents, equipment, and ventilation systems [6] .*) This extreme risk of contamination requires that in the diagnostic laboratories that work with the PCR, the utmost care is taken in the Testing prevails - very knowledgeable staff, contamination-proof environment, permanent independent control.

Already in the above mentioned proficiency test 340 in April a problem with wrong appeared positive results, which was commented as follows (page 20 below): " *In addition In some cases, the tests with the SARS-CoV-2 negative control samples indicate 340060, 340062, and 340065 indicate specificity issues that are independent of*

Swaps of samples 340064 and 340065 are. It must be clarified whether this is **wrong positive results on a specificity problem of the tests used or on a Carry-over of SARS-CoV-2 when carrying out the test or if it was mixed up with other samples** in this round robin test in the respective laboratories are . "(page 21 below in <https://www.instand-ev.de/System/rv-files/340%20DE%20SARS-CoV-2%20Genom%20April%202020%2020200502j.pdf>). Confusion in this

Round-robin test see details in point 3.3. End of paragraph.

If one also sees against this background, as for example after a BBC report in large Test laboratories in England open and extremely susceptible to contamination with untrained personnel is being worked (<https://www.youtube.com/watch?v=Uk1VK1reNtE>), it is not surprising even if in Germany (where such contributions have not yet been filmed) occasionally

Find reports of "false positives" from laboratory contamination in the media

(Eg MVZ Augsburg - link at the end of the section). Even under controlled

Laboratory conditions are contamination from the work steps of the PCR in such a case

highly sensitive method cannot be excluded with certainty. So the problem of

false positive PCR results in the SARS-CoV-2 diagnostics due to

Laboratory processes and already in the first publication of the RT-qPCR (Corman et al., DOI:

[10.2807 / 1560-7917.ES.2020.25.3.2000045](https://doi.org/10.2807/1560-7917.ES.2020.25.3.2000045)) pointed out: " *In four individual test reactions, weak initial reactivity was seen but they were negative upon retesting with the same assay "*

[.....] " *... most problemably to handling issues*"

Even if the course of action in the laboratory works optimally and extremely monitored, in order to

Greatly minimizing laboratory contamination can be an unexpected source of this

false positive results in the **contamination of the materials / chemicals used**

from the manufacturer. In this way, the smear samples used for taking samples can be

Materials may be contaminated ex works - such as in the case of the "Phantom of Heilbronn" in

which the cotton swab to remove the DNA traces at the crime scenes with the DNA

a packaging force of the manufacturer were contaminated and so for years the

forensic science

With

wrong

traces

Disabled person

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(<https://www.faz.net/aktuell/gesellschaft/kriminalitaet/dna-ermittlungspanne-das-phantom-von-heilbronn-ist-refuted-1925411.html>) .

In the case of SARS-CoV-2 diagnostics, a

Contamination problem due to PCR primers mixed with positive controls at the factory

published (Wernike et al., DOI: [10.1111 / tbed.13684](https://doi.org/10.1111/tbed.13684)) . It was noticed here that even pure

Water samples with several independent primer lots show a clearly positive SARS-

CoV-2 detection in the RT-qPCR showed: " *However, there were also primers / probe sets*

that displayed very low - level contaminations, which were detected only during thorough internal validation . "

Some also reported false-positive results in the daily press in the summer of 2020

the SARS-CoV-2 RT-qPCR testing was assigned material problems (e.g.

<https://www.br.de/nachrichten/bayern/probleme-in-augsburger-labor-haben-falsche-test-ergebnisse>, SEh5Qq4)

Rating:

Even with an ideal RT-qPCR design and good laboratory practice with adequate validation

problems can arise in the daily course of action as well as externally via ex works

contaminated samples significantly influence the quality of the results of the RT-qPCR

false positive results.

1.3.5. Commercial PCR test kits: approval for diagnostics?

Commercial PCR test systems, the "PCR kits" in the

Routine laboratories are used for diagnostics, although the majority of them are only used for "RUO"

(research

use only ") was declared.

Particularly noteworthy here is the first and therefore most concise test manufacturer, the Berlin company TIB Molbiol, whose company owner (Olfert Landt) is already on the WHO Protocol recommendations was listed alongside Christian Drosten as the author. The kits, which are based on the WHO recommendations, Roche will use their

Large machines "Cobas" are used and are therefore likely to use the majority of the Routine diagnostics make up the kits used in Germany.

Exact numbers cannot be determined, but TIB Molbiol will have them in 2020 own information already delivered over 60 million tests worldwide (<https://www.tib-molbiol.de/de/covid-19>), although this is still listed as " *Not tested for use in diagnostic procedures* " (e.g. header in https://www.roche-as.es/lm_pdf/MDx_53-0777_96_Wuhan-R-gene_V200204_09155376001%20%282%29.pdf) are declared. The corresponding Package insert with the protocol information and kit descriptions from TIB Molbiol astonishingly, according to meta data from the originally available PDFs (can be made available electronically) already on **01.15.2020** (!!!) complete with ROCHE SAP numbers created are still available unchanged (albeit with Metadata analysis 02/06/2020) parallel to other test kits, which are now a Have approval for in vitro diagnostics.

**1.4. Relationship between positive nucleic acid detection in the RT-qPCR and infectivity
Only those who are actually infected can pass the virus on and run the risk of developing it
Disease and are thus used to determine the course of an infection rate and**

To use disease wave

“ PCR detection is the standard test for diagnosing viral infections such as SARS-CoV-2. The test identifies individual pathogen genes, but no intact pathogens after . ” And: *“ There is a possibility that the test will continue beyond the duration of the infection*

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*is positive because there are still “virus debris” in the nose or throat. A sure one
Evidence of infectivity is only possible with complex tests, those in the laboratory
it is investigated whether the material from the smears can kill living cells . ”*

This

wrote

the

German

Medical journal

at the

02/01/2021

(<https://www.aerzteblatt.de/nachrichten/120745>) .

*“ The PCR test detects SARS-CoV-2 gene segments; he says nothing about it
whether it is infectious viruses or virus residues after they have gone through
Infection. For this a pathogen cultivation would be necessary . ”* Was in one
Publication of the head of the Frankfurt health department from August 2020

read

(https://www.laekh.de/fileadmin/user_upload/Heftarchiv/Einzelartikel/2020/10_2020/Die_Covid-19-Pandemic_in_Frankfurt_am_Main.pdf).

In a CDC publication dated July 13, 2020 under the heading *“CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel For Emergency Use Only Instructions for Use “*, (<https://www.fda.gov/media/134922/download>) can be found on p. 38 under the heading "Limitations" (still to be found on p. 37):

***" Detection of viral RNA may not indicate the presence of infectious virus or that
2019-nCoV is the causative agent for clinical symptoms. "***

The translation reads: *" Detection of viral RNA may not indicate that*

*The presence of an infectious virus suggests or suggests that 2019-nCoV is the causative
Is the causative agent for clinical symptoms. "*

That a pure mRNA detection of SARS-CoV-2 does not necessarily mean a disease must correlate and not as the sole criterion for assessing the disease

may be used, but only an aid to confirm a clinical

Diagnosis is also clearly stated in the WHO information “ *Notice for IVD Users 2020/05, Nucleic acid testing (NAT) technologies that use polymerase chain reaction (PCR) for detection of SARS-CoV-2* ” from January 13th, 2021 (published on January 20th, 2021 under <https://www.who.int/news/item/20-01-2021-who-information-notice-for-ivd-users-2020-05>)

described: *“If the test results **do not agree with the clinical picture** , should a new sample be taken and with the same or a different NAT-Technology to be tested again. ” - in the original:“ Where test results do not correspond with the clinical presentation, a new specimen should be taken and retested using the same or different NAT technology. ”*

Furthermore: “ *Most **PCR assays are indicated as an aid to diagnosis** , therefore Health care providers need to combine each outcome with the timing of the Specimen collection, specimen type, assay specifics, **clinical observations, the Patient history** , confirmed status of all contacts and epidemiological Consider information .* ” In the original:“ *Most PCR assays are indicated as an aid for diagnosis, therefore, health care providers must consider any result in combination with timing of sampling, specimen type, assay specifics, clinical observations, patient history, confirmed status of any contacts, and epidemiological information ”*

Also

in

one

current

publication

in

Lancet

([https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00425-6/fulltext#%20](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00425-6/fulltext#%20))

the authors refer to the RT-qPCR test as follows: “*In our opinion, this is the current one PCR test is therefore not the suitable gold standard for the assessment of a SARS-CoV-2 Public health tests* ” Originally:“ *In our view, current PCR testing is therefore not the appropriate gold standard for evaluating a SARS-CoV-2 public health test ”*, because, in their opinion, the PCR still has a positive effect even if the tested are no longer positive because the RNA continues to be more successful for weeks and months Fighting by the immune system can continue to persist in the body without the Person is still contagious. ” *As soon as the replication of SARS-CoV-2 through the*

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Once the immune system has been brought under control, the PCR results in the Respiratory secretions detectable RNA concentrations to very low levels at which they are much less likely to infect others. The remaining RNA copies can take weeks, and occasionally months, to disappear are, during this time the PCR remains positive ” in the original:“ *Once SARS-CoV-2 replication has been controlled by the immune system, RNA levels detectable by PCR on respiratory Secretions fall to very low levels when individuals are much less likely to infect others. The remaining RNA copies can take weeks, or occasionally months, to clear, during which time PCR remains positive ”*

1.5. Conclusion: Significance of the RT-qPCR tests for recognizing an infection with the Coronavirus SARS-CoV-2

1. Against the background of the problems outlined in point 1.3, the RT-qPCR is not a suitable reliable (and approved) diagnostic agent for the detection of infectious (replicable) SARS-CoV-2 viruses.

2. Furthermore, the pure RT-qPCR test result is only a laboratory value, which in view of the under point 1.4. The aspect presented does not make any statement about the presence infectious viruses allowed and only in conjunction with a clinical Symptom diagnosis (collected by health care providers, in Germany Medical professionals) may be used at all.

Summary: For testing asymptomatic people using a nasal

Throat swabs of the kind that are uncritical and mostly non-medical Personnel WITHOUT (here decisive: contrary to the WHO requirement!) Anamnesis and Symptoms are assessed in the test subjects, the RT-qPCR used is not suitable, detect an infection with SARS-CoV-2.

2. The antigen detection by means of a rapid test

2.1. Explanation of terms / basics of the rapid test

The "rapid tests" currently used to diagnose SARS-CoV-2 are based on the Principle of an antigen test based on the " **lateral flow** " test procedure. This becomes a Protein component of the virus detected.

An **antigen** is a three-dimensional structure of proteins and others organic materials recognized and bound by antibodies (immunoglobulins) can be.

In the case of **virus antigens** , these are usually individual protein components (Proteins) from the virus structure. These can either be complete structural proteins like that "Spike" protein located on the surface (S-protein, these are the "stalked knobs" in the virus drawings) or the envelope protein (E-protein) or that protein from which the nuclear envelope is built (nucleocapsid = N-protein). Also fragments these complete structural proteins are often sufficient to be bound by antibodies become. These are the so-called **epitopes**, which are also found on the intact structural protein represent the actual antibody binding site. Each structural protein usually has one Variety of epitopes, so that different antibodies at the same time to different Can bind epitopes of the same protein.

In SARS-CoV-2, the most important antigens (the above, S, E and N proteins) those that trigger an immune response in the body when infected with the virus. As a result, the body forms antibodies that specifically recognize these antigens, then bind to it (**antigen-antibody reaction**) to neutralize and protect the viruses Making immune cells destructible.

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This antigen-antibody reaction can be used in the laboratory to work with synthetically to search for the antigens in any sample using the antibodies produced.

The basic principle of the so-called **antigen tests** in the laboratory (these aim to detect the antigens by antibodies, unlike the RTPCR, which nucleic acids detects) consists in producing two suitable antibodies in vitro, which two recognize different epitopes of the antigen sought, a so-called " **Antibody Pair** ". Both antibodies must be selected in such a way that they only use the each desired epitope on the antigen sought, but not other structures recognize and bind similar antigens. So you have to be highly specific in order to to be used in diagnostics. This **high specificity of** the diagnostic antibodies is used in test development through comparisons with many very similar epitopes ensured. All antibodies that bind unwanted epitopes are discarded, until only one ideal pair of antibodies remains, which meets the requirements: very high Specificity, high binding properties (sensitivity) and no mutual interference having.

The antigen test is then set up on this pair of antibodies, in which the sought Antigen is bound by both antibodies at the same time and between these as the The patty is inside the sandwich roll (hence the " **sandwich test** ").

For the lateral flow **antigen rapid tests** , which are currently in the broadband testing of the Population are used for the detection of SARS-CoV-2 antigens, this is now Sandwich test system used.

The first of the two specific antibodies is applied to a carrier material bound so that its antigen binding site points freely upwards. This is the later region in Quick test at which a color change results in the signal "positive". The second antibody will coupled with a detection system, which is later responsible for the color reaction, and is located directly as a depot next to the point in the rapid test where the sample is dripped on.

Test procedure: If the antigen **you are looking for** is now in the swab **sample** , here the one **you are looking for**

Protein from SARS-CoV-2, it combines after being dripped into the test field
Detection cassette with the first specific antibody from the depot. over
Capillary forces migrate the mixture of antigen with bound first antibody
as well as excess unbound antibodies from the depot in the direction of the test field
to. The second specific antibody fixed there then binds the antigen with the
first antibody already bound to it. The solution migrates beyond the test field
via another field in which the excess antibodies are intercepted (control field).
The detection system of the test starts wherever the first antibodies are bound
are to become visible with a **chemical color reaction** . This caused this in the control panel
the superfluous excess and here now bound first antibodies, which the
Detection system "brought along" and thus indicate that the test is in principle
worked properly.

There is only a color change in the test field if there is actually an antigen in the Sample was and was bound via the second antibody fixed there. Since that
Antigen with the first antibody and the detection system on the test field
has arrived, the chemical color reaction also begins here, which leads to the
Color change (usually purple stripe) leads to the test region.

Whenever the desired antigen was consequently present in the swab sample, can
this binds the first antibody and together with the detection system up to the fixed second
Transport antibodies, which then this antigen-antibody detection system complex
intercepts and thus causes the positive signal at this point.

The color change on the test field (signal "positive"), the visible stripes in the quick test
causes is a **chemical reaction** and therefore depends on the reaction conditions such as

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pH value or chemicals that come with the sample can be influenced and a clear one
Weak point in the reliability of the test.

This explains the many videos that are circulating on the Internet and the SARS-CoV-2
using the rapid antigen tests in apple juice, red wine, beer, etc.

2.2. Basic information on the diagnostic significance of the rapid antigen test

**As with RT-PCR, rapid antigen tests cannot, in principle, prove whether this is
The virus antigen found belongs to or is an intact, infectious virus
Remnants (fragments) of viruses are killed by the immune system
were.**

Regardless of this general restriction of the informative value with regard to a
Rapid tests are only indicative of infectivity, not reliable diagnostic tests
Expressiveness.

The rapid test that was best known before the Corona era was the rapid pregnancy test, the
works on the same principle as the antibody-antigen test. However, acts here
the pregnancy hormone (HCG) as an antigen. Is this in sufficient quantity in the
if tested urine is present, the test shows "positive" - in this case probably pregnant -
at. However, the rapid test alone is never used as well-founded proof of pregnancy
sufficient, the doctor will diagnose HCG in the blood and an ultrasound
be applied.

The rapid antigen tests for the detection of SARS-CoV-2 components can only
give an indication of possible colonization or infectivity and are subject to it
similar limitations as the RT-qPCR.

2.3. Factors influencing the reliability of the rapid antigen tests

2.3.1. Pre-test probability

The RKI explains in an infographic under the heading "Corona rapid test results
understand"

(https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Infografik_Antigentest_PDF.pdf?__blob=publicationFile) vividly how the probability of a test result

true, depends on the so-called **pre -test probability** , ie on the real one

Number of genuinely infected people in the tested population. This aspect of the Pre-test probability applies to both the rapid antigen tests and to the RT-qPCR tests.

The calculation example presented by the RKI for the interpretation of the rapid antigen tests sets a realistic scenario based on a sensitivity (sensitivity) of the

Antigen tests of 80% and a specificity (reliability) of 98% preceded it, here too

(https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Vorl_Testung_nCoV.html)

It is expressly mentioned: “ *The considerable differences in performance must be taken into account here*

the

different

commercially

available

Testing

(Reference

on:

<https://www.medrxiv.org/content/10.1101/2020.10.01.20203836v1>. ”

Assuming 5 people out of 10,000 people tested are really infected with SARS-CoV-2,

Nevertheless, there are **200 false positive tests** and 4 true positive tests. That means,

that 1 genuinely infected person per 10,000 would be overlooked, but 200 would be a false positive

Result and therefore have to be in quarantine / isolation until the check with

an RT-qPCR then gives the “all-clear”. This would be in the case of a school test with, for example

1000 students mean that 20 are told a false "You are Corona-Positive",

and the school would first be closed as an "outbreak location" until the follow-up testing

gives the all-clear by means of RT-qPCR. Such cases have already been reported in the press.

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- In Altdorf near Nuremberg, 29 out of 180 high school students were positive in the rapid antigen test tested, when checked, 28 of them turned out to be negative (Mercury:

<https://www.merkur.de/bayern/nuernberg/nuernberg-corona-bayern-test-fiasko-schnelltests-defective-positive-school-alt-dorf-gymnasium-zr-90253265.html>)

- In Potsdam, 12 of 36 teachers tested positive with a rapid antigen test and were in

Sent to quarantine. Upon review, all test results were found to be incorrect

positive (<https://www.news4teachers.de/2021/03/sorgen-schnelltests-fuer-chaos-an-schulen-false-alarm-paralyzes-elementary-school/>)

- Medscape even headlines: “200 false positives, 8 discovered, 2 overlooked - why children's and Adolescent doctors are skeptical of mass rapid tests

(<https://deutsch.medscape.com/artikelansicht/4909842>)

And even if the rate of genuinely infected in the tested group of people is very high

would be, as in the second calculation example by the RKI (with 1000 out of 10000 people tested),

the success rate of the rapid tests would be bad and 180 people would do one here

get a false positive answer and also 200 a false negative test. Here works

The main result is the poor sensitivity of the test.

In the " *Notes on the evaluation of the results from AG tests* " (Note: antigen

Rapid tests) on the part of the RKI **the problem of false positives**

Antigen tests thematize: “ *A positive test result by means of an AG test solves the suspicion for a transmission-relevant infection with the SARS-CoV-2 and needs to*

Avoidance of false-positive results from post-testing using PCR. Considering the

The potentially significant consequences of incorrect results are not confined to the

Sensitivity of antigen testing makes high demands, but also on specificity. That would be

with a low prevalence / pre-test probability and low test specificity with a

high number of false-positive results and a corresponding additional

Burden of the ÖGD through the imposition and, if necessary, withdrawal of measures

calculate . ”

" https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Vorl_Testung_nCoV.html

2.3.2. Sensitivity (**Sensitivity**)

Due to the fact that in the antigen test there was no such strong (exponential) amplification of the

Output signal takes place as in the RT-qPCR, but only a limited one
Signal amplification through the chemical color reaction, **this type of test is significantly less more sensitive than the RNA detection using RT-qPCR used for comparison .**

This "underperformance" of the rapid antigen tests is the subject of a Lancet article ([https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00425-6/fulltext#%20](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00425-6/fulltext#%20)), here, however, the negative test result in the rapid antigen test (here LTF, lateral flow called test) put into perspective: "*[...] in all six observed cases **the viral loads were very low** ($Ct \geq 29$, which is about <1000 RNA copies per mL in the laboratory used reflects) - **if the LFT should be negative** . "* In the original: "*[...] in all six observed cases, viral loads were very low ($Ct \geq 29$ reflecting around <1000 RNA copies per mL in the laboratory used) —when LFT should be negative . "*

A brand new study from Norway (<https://pubmed.ncbi.nlm.nih.gov/33736946/>) approved this finding that with asymptomatic the rapid tests an unsatisfactory high Show inaccuracy and that only halfway exactly that in symptomatic people actually infected people are discovered. The authors conclude: "*Our results show that the test correctly identifies most infectious individuals. Still that is Sensitivity significantly lower than with PCR* ", in the original: "*Our results indicate that the test correctly identified most infectious individuals. Nevertheless, the sensitivity is considerably lower than for PCR* "

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This **supposed lack of sensitivity** is the most common criticism when about that Unreliability of rapid antigen tests is reported. So writes the pharmaceutical Newspaper (<https://www.pharmazeutische-zeitung.de/in-der-praxis-deutlich-unzuverlaessiger-als-auf-dem-paper-123017/>): "*Antigen rapid tests could mostly" be highly infectious Recognize people with high viral loads* », explains Keppler. "*However, it's not that an infection due to the negative result of a rapid test can be reliably excluded could be .*" Here, however, the rapid antigen test with the RT-qPCR compared and criticized that only a part of the RT-qPCR positive swab samples also in the Rapid antigen test become positive.

In the Epidemiological Bulletin 3/2021 of the RKI, for example, a study with rapid tests in one

Stuttgart
clinic
reported
(From
page
11
in:

https://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2021/Ausgabe/03_21.pdf;jsessionid=15E8B09E615AECED77C34439BB8052AF.internet051?__blob=publicationFile). Here shows

Table 1 shows that of 18 RT-qPCR tested positive for SARS-CoV-2 RNA asymptomatic persons only 7 also gave a positive signal in the rapid antigen test and of symptomatic persons 36 out of 42. In the discussion it says accordingly: "*Due to the very limited sensitivity of the antigen test at asymptomatic persons, the individual test in this collective can be infected with SARS-CoV-2 cannot be adequately excluded. Highly contagious people with low Ct Values (ie high viral load) are recognized with sufficient certainty .*" Show here the data, "*From a Ct value of 22 or less, the detection rate of the antigen test was at 100% .* "

This example shows very clearly that a reliable antigen test with correct Implementation for symptomatic persons with a rapid response in the RT-qPCR (low CT value) correlated very well in asymptomatic and only with high CT RT-qPCR positive value, but not individuals. **This speaks for the real expressiveness the rapid antigen tests for the detection of a high viral load symptomatic people .** For testing asymptomatic people, the test is

however, according to these data unsuitable, both to possibly infected people to identify safely, as well as to safely identify healthy people as negative. Such a finding was also made in the current Frankfurt study (<https://www.mdpi.com/2077-0383/10/2/328>), three rapid antigen tests were performed here (there AG-RDT, Antigen-Rapid Diagnostic Test) with virus cultivation from the same samples calibrated in cell culture and correlated to RT-qPCR. For this purpose, the authors write in Abstract: " *In contrast, three Ag-RDTs demonstrated a more significant correlation with cell culture infectivity (61.8-82.4%).* " Which means that from those samples which are in the Antigen test were positive, with a significantly higher hit rate also in virus cultivation A positive result was seen than with the clearly more sensitive RT-qPCR "positives". A recently published study by the CDC also points to the high degree of agreement of the Antigen tests with virus that is actually capable of replication in a sample in symptomatic cases Patient (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7821766/>). Here became a commercial rapid antigen test with virus culture in cell culture and RT-qPCR matched. It shows a high hit rate (positive result) of the antigen test only if the samples also contained **virus capable of replication** . Here, 85 of the a total of 147 samples (= 58%) which were tested in the antigen rapid test and RT-PCR (here with a CT of approx. 22) were positive, viruses are grown, but only from 11 of the 124 Samples (= 9%), which are RT-qPCR positive (here with a CT of 33-34), but antigen-Quick test were negative.

The following can be generally stated from these published data:

- Samples from which viruses can be grown in cell culture, i.e. which have a high (infectious) viral load are detected with good accuracy by the

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Rapid antigen tests and identified by RT-PCR with low CT (below 25), but originate in the vast majority of symptomatic persons.

- Samples from which viruses cannot be grown in cell culture are evaluated and correctly applied antigen rapid tests mostly negative (apart from of the false positives - see 2.3.3) and show high CT values in the RT-qPCR (mostly over 33). Most of these samples come from asymptomatic ones tested people and prove that these random "positives" without clinical Symptoms do not have an infectious viral load.

2.3.3. Reliability (**specificity**) - exclusion of false positive results

Many of the rapid antigen tests used so far have no regular conformity have gone through an assessment process for CE marking and have so far only received from the Bfarm a **special approval according to § 11 Medical Devices Act** get granted

(https://www.bfarm.de/DE/Medizinprodukte/Antigentests/_node.html). Be in width these tests by untrained, non-medical personnel or even as a "Self-tests" carried out.

With regard to the problem of performing rapid antigen tests, Professor Dr. Oliver Keppler, head of virology at the Max Pettenkofer Institute of the Munich Ludwig Maximilians-Universität, in the article in the Pharmazeutische Zeitung from January 13th, 2021 (DOI: [10.1007 / s00430-020-00698-8](https://doi.org/10.1007/s00430-020-00698-8)): " [...] *these tests must also be absolutely correct be performed. "That should be in the hands of trained specialists," he says. "Now there is the idea of recruiting large numbers of job seekers to take such tests in Carry out retirement and nursing homes **When untrained personnel are used comes, I worry that the reliability of the test results will continue will suffer*** "

A recent Cochran review article (<https://www.cochrane.de/de/news/aktualisiert-cochrane-review-evaluates-reliably-of-rapid-tests-for-proof-of-covid>) also comes to the conclusion that the rapid antigen tests at symptomatic people are significantly more reliable than those tested without symptoms. But even with symptomatic individuals, reliability is the best in this one The study assessed rapid tests as clearly limited, so the authors made the following

Describe scenarios:

1. "In a population of **1,000 people with symptoms** , of whom **50 people actually have COVID-19** , one can expect with these rapid tests that about **40 people can be correctly identified as COVID-19 infected** and between 6 and 12 cases of COVID-19 are missed. **Between 5 and 9 of the positives Test results would turn out to be false positive if verified point out. "**

2. "In a group of **10,000 people without symptoms** , in the **50 people** really infected with SARS-CoV-2 would be between **24 and 35 people correctly identified as a virus carrier** , between 15 and 26 cases would be overlooked. You should expect the tests to be between 125 and 213 would give positive results and **that between 90 and 189 of these positive results would actually be false positives .**

For the consequences of false positive results due to insufficient test specificity, see below

2.3.1. "Pre-test probability"

2.5. Conclusion:

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The rapid antigen tests used for the mass test can **not provide any information about an infectiousness** , because hereby only protein components without Proven to be a connection with an intact, replicable virus can be.

1. In order to allow an assessment of the infectiousness of the tested persons, would have to the positive test carried out in each case (similar to the RT-qPCR) individually a cultivability of viruses from the test sample can be compared, which is below The extremely variable and non-verifiable test conditions are impossible.

2. The low specificity of the tests results in a **high rate of false positives Results** , which are unnecessary personal (quarantine) and social (e.g. Schools closed, "outbreak reports") have consequences until they settle turn out to be a false positive.

For further details, please refer to the written submissions of those involved referenced.

B: Reasons for the decision

I. Admissibility of the suggestion to the family court

The suggestion to the family court to examine whether the child is at risk is permissible.

In particular, legal recourse to the ordinary courts is open and the Family courts have material jurisdiction.

According to § 13 GVG, family matters, among other things, belong before the ordinary courts.

The factual responsibility results exclusively from § 23a paragraph 1 no. 1 GVG.

According to this, the local courts are responsible for family matters. § 23b GVG only concerns the Legally regulated business distribution of family matters within the local court.

According to § 111 No. 2 FamFG, family matters are also child matters. To the

According to § 151 No. 1 FamFG, parental custody belongs among other things. To parental Concern also belongs to the regulation of § 1666 BGB, according to which the family court the Has to take the necessary measures if the physical, mental or emotional

The child's well-being or property is at risk and the parents are unwilling or unable to

Are able to avert the danger. According to Section 1666 (4)

BGB in matters of personal care also measures with effect against one

Meet third parties.

Something else for the legal process does not result from § 40 VwGO. The legal process to

the administrative courts are not open to child welfare proceedings. Because

Proceedings due to endangerment of the child's welfare are subject to another court by federal law

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namely the family court, expressly assigned, § 40 paragraph 1 sentence 1 VwGO in Connection with § 1666 BGB.

This is also based on constitutional necessities.

Child protection in German law is structured on a number of tracks. For proceedings before the general civil or administrative courts are genuine applications in the legal sense necessary. The courts mentioned can only act if such an application has been submitted become.

The procedures according to § 1666 BGB, on the other hand, do not belong to the application procedures as defined

of § 23 FamFG, but to those according to § 24 FamFG, which are initiated ex officio can be; at the suggestion of any person or even without such, if

the court considers intervention necessary for reasons of the best interests of the child, Section 1697a BGB.

A risk to the child is to be affirmed in the case of a present one, to such an extent existing danger to the mental, physical or emotional well-being of the child that if further developed without intervention, considerable damage with quite a bit Security allows foreseen (Palandt-Götz, § 1666 marginal number 8).

One such hazard is from wearing a mouth and nose covering after current state of science at least obvious, so that the court a

Proceedings had to be initiated to examine this question.

According to the principle of equal treatment from Article 3 of the Basic Law and the Article 6

It would be the guardianship of the state community for the family enshrined in the Basic Law Constitutionally unacceptable when some children might hope for

an application is made to a court that appears suitable, but not others.

Even children whose parents would be fundamentally ready and able, depending on the situation

Filing appropriate applications can be left behind if their parents are advised to do so

Refrain from fear of disadvantages for their children, or at least delay them. § 1666 BGB applies for all children. In the procedure itself, the official investigation principle, § 26 FamFG applies.

According to the prevailing view, parents are therefore not obliged to give the to pursue general civil law channels (Palandt-Götz, § 1666 Rn. 41). You are too not forced to first violate the regulation on which the order is based

To take administrative legal channels and, if necessary, to strive for a standards control procedure.

Incidentally, that follows from the fact that the administrative procedure is a different one

Legal protection goal is pursued than with the order sought here against the School management and the child's teachers.

Finally, there are also the admissibility requirements for issuing an interim measure Order according to §§ 49 ff FamFG.

In particular, an interim order is permissible because it is asserted here that this in accordance with the regulations governing the legal relationship (§ 1666 BGB) is justified and with regard to the school lessons taking place with the obligation, wearing a face mask, an urgent need for immediate action consists.

II. Justification of the suggestion to the family court

1. General

The suggestion to the family court to avoid endangering the welfare of the child Establishing a regulation apparent to the tenor is justified in accordance with Section 1666 of the German Civil Code (BGB).

A risk to the child is to be affirmed in the case of a present one, to such an extent existing danger to the mental, physical or emotional well-being of the child that if further developed without intervention, considerable damage with quite a bit Security allows foreseen (Palandt-Götz, § 1666 marginal number 8).

Such a hazard exists here. Because the children are in particular through the Obligation to wear face masks during school hours and to keep clearances between themselves and to other people to adhere to in their mental, physical and spiritual well-being

not only endangered, but also currently damaged. This will be at the same time numerous rights of children and their parents under law, constitution and violated international conventions. This is especially true for the right to freedom Development of personality and physical integrity from Article 2 of the Basic Law as well as for the right under Article 6 of the Basic Law to education and care by parents (also with regard to preventive health measures and to be borne by children "Objects"). But this also applies to other rights of children, as described in A IV. Of the Mother of the children to be cited.

The children are damaged physically, mentally and educationally and in their rights hurts without this being of benefit to the children themselves or to third parties.

The state legal provisions, as detailed in A II., Can be relied on by the School administrators, teachers and others are not appointed. Because these regulations are unconstitutional and thus void.

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The obligation in Article 100 paragraph 1 of the Basic Law, a possibly unconstitutional To submit the law to the Federal Constitutional Court or a state constitutional court, expressly applies only to formal federal and state laws, but not to substantive laws such as ordinances or the general decree in question.

According to settled case law of the

Federal Constitutional Court (fundamentally BVerfGE 1, 184 ((195 ff)) each court itself decide, also AG Weimar, judgment of January 11, 2021 - 6 OWi - 523 Js 202518/20 -, juris.

Like the family court on child welfare endangerment, formal justification Federal or state laws are consulted on the submission to the federal or a state constitutional court can react is not relevant here and therefore does not require any further explanations.

The national regulations, as detailed in A II. (This also applies to them updating content with the same or similar content) are unconstitutional because they are against violate the principle of proportionality rooted in the rule of law, Article 20, 28 Basic Law.

According to this principle, also known as the prohibition of excess, the must to achieve Suitable, necessary and intended measures for a legitimate purpose relatively in the narrower sense - that is to say: when weighing up the advantages achieved with them and cons - be.

Measures that are not evidence-based contrary to Section 1 (2) IfSG are already unsuitable, to achieve the fundamentally legitimate purpose pursued by them, an overload of the Health system or the infection process with the virus SARS-CoV-2 lower. In any case, they are disproportionate in the narrower sense, because the The considerable disadvantages / collateral damage caused by this are of no discernible benefit for the children themselves or to third parties.

The inappropriateness and disproportionate nature of the measures prescribed will justified below. Nevertheless, it should be noted that the parties involved are not the The unconstitutionality of the interference in their rights, but vice versa the Free State of Thuringia, which with its state regulations in the rights of Intervening with the necessary scientific evidence would have to prove that the measures prescribed by him are suitable for the intended purposes reach, and that they if necessary. are proportionate. So far this is not even close happen.

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2. The lack of utility in wearing a mask and adhering to Distance regulations for the children themselves and third parties

The reviewer Prof. Dr. med. Ines Kappstein has in her completely present

Expert opinion, see A VIII., The entire international scientific data on masks evaluated.

In order to convince the court, she summarizes that an effectiveness of Masks for healthy people in public not supported by scientific evidence is occupied. Likewise, 'third-party protection' and 'unnoticed transmission', with which the RKI justified its 'reassessment' was not supported by scientific evidence.

Plausibility, mathematical estimates and subjective assessments in Opinion contributions can

population-based
clinical-epidemiological

Do not replace examinations. Experimental studies on the filter performance of Masks and mathematical estimations are not suitable for an effectiveness in the real life evidence. The international health authorities are speaking for wearing masks in public spaces, but also say that there are no masks for this. There is evidence from scientific research. Rather, everyone is speaking presently available scientific evidence that masks have no effect on the. Have an infection. Consistently all publications that prove the effectiveness cited by masks in public space do not allow this conclusion.

This also applies to the so-called Jena study, as the expert explains in detail in the report.

Because in the Jena study - like the vast majority of other studies one on purely mathematical estimates or estimates based on theoretical assumptions Modeling study without real contact follow-up with authors from the field of Macroeconomics without epidemiological knowledge - remains, as from the expert explained in detail, ignoring the crucial epidemiological circumstance that the Infection values already before the introduction of the mask requirement in Jena on April 6, 2020 (around three

Weeks later in the whole of Germany) fell significantly and it already at the end of March In 2020 there was no longer any relevant infection occurrence in Jena.

As the reviewer further explains, every mask must be effective in principle can be worn properly. Masks can become a contamination risk, when they are touched. On the one hand, however, they are not being corrected by the population worn and on the other hand very often touched with the hands. It's the same with politicians to watch that can be seen on television. The population was not taught Using masks properly, there was no explanation of how to move hands should wash or how effective hand disinfection is carried out. It was further does not explain why hand hygiene is important and that one must take care of oneself

Do not touch your eyes, nose or mouth with your hands. The population was with the Masks left alone.

The risk of infection is not only not reduced by wearing the masks, but increased by the incorrect handling of the mask. The reviewer puts this in their expert opinion as well as the fact that and for what reasons it is "unrealistic" to allow the population to use masks appropriately to reach.

The transmission of SARS-CoV-2 through 'aerosols', i.e. through the air, is not medical plausible and scientifically unproven. It is a hypothesis that mainly goes back to aerosol physicists who, according to the reviewer, understandably from are unable to assess medical relationships based on their specialist area. The 'aerosol' Theory is extremely detrimental to human coexistence and leads to that people can no longer feel safe in any interior space, and some fear even outside of buildings from being infected by 'aerosols'. Together with the 'Unnoticed' transmission leads the 'aerosol' theory to a Risk of infection can be seen.

The changed policy statements on masks, first cloth masks in 2020, then since

At the beginning of 2021, either surgical masks or FFP2 masks, lack any clear line. Even if surgical masks and FFP masks are both medical masks, they have different functions and are therefore not interchangeable. Either politics who made these decisions didn't even understand what type of mask was used for is suitable in principle, or it does not matter to her, only the symbolic Value of the mask. The mask decisions of politics are from the technical point of view of the To describe the expert as implausible in a way that is incomprehensible and expressed gently. The reviewer further points out that there are no scientific studies to keep your distance outside of medical patient care. In summary, in their opinion, the court can only convince the following rules are established:

1.
Maintain a distance of around 1.5 m (1 - 2 m) for face-to-face contact, if Either person who has symptoms of a cold can be considered a useful measure are designated. In the scientific sense, however, it is not secured, but it is merely indicative or can be described as plausible that it is an effective one The measure is to avoid contact with the pathogen through droplets of respiratory secretions to protect if the contact person shows signs of a cold. An all-round distance however, it does not make sense to protect yourself if the contact person has a cold.

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2.
An all-round distance or just a vis-à-vis distance of about 1.5 m (1 - 2 m) to be observed if none of the people present shows signs of a cold unsupported by scientific data. But this makes the coexistence of the People and especially the carefree contact between children is very strong impaired without any benefit in terms of infection protection being discernible.

3.
Close contacts, i.e. less than 1.5 m (1 - 2 m), between students or between teachers and students or among colleagues at work etc. even then do not provide any Risk if either contact has symptoms of a cold because of the duration Such contacts in school or with adults somewhere in public a lot is too short for droplet transfer to occur. Show that too Investigations from households, where despite the close coexistence with numerous Skin and mucous membrane contact only a few members of the household become ill, if one has a respiratory infection.

The reviewer convincingly highlights the problem of mathematical modeling. Mathematical modeling (also called mathematical estimating) is from the Weather forecast and climate research are well known, but have also been for many years used to track the course of epidemics and the influence of various Predict preventive actions. They are especially used when only there is little meaningful data from direct investigations. For a very large part of all studies on SARS-CoV-2 (e.g. effectiveness of masks) are mathematical modeling, which has only a very limited informative value because of its Results do not reflect 'real' life, but are based on assumptions. Of The results are dependent on these 'adjusting screws', which therefore provide a simplified picture of the Reflect reality. Such studies can therefore only be 'if-then-Deliver results'. On one side of the spectrum there are purely theoretical ones Modelings and on the other those in which with so much clinical-epidemiological Data as it exists is being worked on. But always has the result, like that Expert details, only a very limited informative value, and the quality of the scientific evidence is moderate at best. The results of such studies in the Connection with SARS-CoV-2 will be in their meaning for reality, however often far overestimated and with a positive result as proof of the effectiveness of Measures taken. This has been observed repeatedly in the course of the pandemic , as the reviewer expressly points out, even in the case of scientific

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The expert also points out this problem when asked which transmission rates expected from symptomatic, presymptomatic, and asymptomatic people are. According to her explanations, presymptomatic transmissions are possible, but not inevitably. In any case, according to her, they are evaluating real contact scenarios significantly lower than with mathematical modeling.

From a systematic review with meta-analysis published in December 2020 on Corona transmissions in households are higher, but still not excessive transmission rate in symptomatic index cases of 18% an extremely low transmission in asymptomatic cases of only 0.7%. The

Possibility that asymptomatic, formerly known as healthy, transmit the virus, is therefore meaningless.

In response to questions 1, 3 and 4, the expert concludes:

There is no evidence that face masks of different types reduce the risk of infection through SARS-CoV-2 at all or even significantly. This statement is true towards people of all age groups, including children and adolescents as well asymptomatic, presymptomatic and symptomatic persons.

On the contrary, there is more of a possibility that by wearing masks frequent hand-face contact increases the risk of even coming into contact with the pathogen to come into contact with other people.

For the normal population there is neither a public nor a private one

Risk of infection from wearing face masks (or other measures) could be lowered.

There is no evidence that distance compliance is the

Can reduce the risk of infection. This applies to people of all ages, including children and young people.

These results are supported by the extensive findings of the expert Prof. Dr.

Kuhbandner confirmed. Even after that, there is still no high-quality scientific one

Evidence that wearing face masks increases the risk of infection

can be significantly reduced. The recommendations of the RKI and the S3 guideline of

Professional societies are based on the findings of the expert

Observational studies, laboratory studies on the filter effect and modeling studies,

which only provide low and very low evidence, because from such studies due to the

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The underlying methodology does not provide any really valid conclusions about the effect of masks in the Everyday life and schools can be drawn. In addition, the results of each Studies that are heterogeneous and more recent observational studies also provide contradicting results Findings.

The existing randomized controlled studies on the effect of the

When wearing masks, the appraiser found that masks are not effective

reveal. Rather, it is the only extensive randomized controlled so far

Study on the wearing of cotton masks suggests that cotton masks are the

Can even increase the risk of infection. The handling of the

Mask, which, if handled poorly, have a negative effect on the risk of infection

can. Especially for school pupils, especially younger ones

However, handling problems are inevitable. The reviewer Prof. Dr. med.

Kappstein had pointed out that the handling problem leads to the

Wearing masks not only from the point of view of infection prevention nothing helps, but even harms.

In addition, the achievable extent of the reduction in the risk of infection through the wearing of masks in schools is very low, because in schools without masks

infections occur very rarely. Accordingly, the absolute risk reduction is like this little that a pandemic cannot be combated in a relevant way with it. The currently allegedly increasing number of infections in children go according to the statements of the appraiser is very likely to actually rely on the fact that the The number of tests in the children has increased sharply in the previous weeks. There the risk of infection in schools is in itself very small, even with one possible Increase in the infection rate with the new virus variant B.1.1.7 in the studies assumed order of magnitude not to be expected in schools the Virus spread significantly increased. This little benefit comes with numerous possible side effects related to that physical, psychological and social well-being of children opposed to, among those numerous children would have to suffer to prevent a single infection. The appraiser sets this on the basis of, among other things, the information published in the monthly journal Paediatrics published side effect register in detail.

3. The inappropriateness of PCR tests and rapid tests to measure the Infection process

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The reviewer Prof. Dr. med. In her report, Kappstein points out that only genetic material can be detected with the PCR test used, but not whether the RNA from infectious and thus replicable (= reproducible) virus originates. The reviewer Prof. Dr. rer. biol. hum. Chamberlain affirmed in her molecular biology expert opinion that a PCR test - even if he is carried out correctly - no statement whatsoever can be made as to whether a person is with a active pathogen is infected or not. Because the test cannot differentiate between "dead" matter *, e.g. one completely harmless genome fragment as a remnant of the struggle of the body's own Immune system against a cold or flu (find such genome fragments many months after the immune system has "dealt with" the problem) and "Living" matter, ie a "fresh", reproductive virus. For example, PCR is also used in forensics to extract hair residues or to reproduce residual DNA present in other trace materials by means of PCR in such a way that the genetic origin of the perpetrator (s) can be identified ("genetic fingerprint"). Even if that means when performing the PCR including all preparatory steps (PCR design and establishment, sampling, preparation and PCR execution) everything Is done "correctly" and the test is positive, ie: a genome sequence recognizes which possibly also exists in one or even the specific "Corona" virus (SARS-CoV-2), Under no circumstances does this mean that the person who tested positive is with a replicating SARS-CoV-2 and consequently infectious for other people = is dangerous. Rather, more, and specific diagnostic methods such as the isolation of viruses that are capable of replicating can be used. Regardless of the fundamental impossibility of using the PCR test to detect an infection with the Determining the SARS-CoV-2 virus also depends on the results of a PCR test according to the statements of the expert Prof. Dr. Chamberlain of a number of Parameters that, on the one hand, cause considerable uncertainties and, on the other hand, are targeted Can be manipulated so that many or few (seemingly) positive results be achieved. Two striking sources of error should be singled out.

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On the one hand, this includes the number of target genes to be tested. This was according to the specifications

the WHO successively reduced from the original three to one.

The appraiser calculates that through the use only one has to be tested

Target gene in a mixed population of 100,000 tests with none actually

infected person on the basis of a mean one determined in an instant interlaboratory comparison

Error rate results in a result of 2,690 false positives tested. When using

3 target genes, there would be only 10 false positives.

Would the 100,000 tests carried out be representative of 100,000 citizens

City / district must be carried out within 7 days, that is the result of this alone

this reduction of the target genes used with regard to the "daily incidence"

Difference between 10 false positives and 2690 false positives and dependent on it

the severity of the restrictions imposed on the citizens' freedom.

Would consistently the correct "target number" of three or even better (such as in

Thailand) up to 6 genes had been used for the PCR analysis, the rate of

positive tests and thus the "7-day incidence" almost completely reduced to zero.

On the other hand, one of the sources of error is the so-called ct value, i.e. the number of amplification / Doubling steps up to which the test is still rated as "positive".

The reviewer points out that, according to unanimous scientific opinion, all

"Positive" results, which are only recognized from a cycle of 35, do not have any

have a scientific (ie: no evidence-based) basis. In the range of ct value 26-35

the test can only be rated as positive if compared with virus cultivation. The one with

With the help of the WHO, RT-qPCR test for the detection of SARS-CoV-2, propagated worldwide

on the other hand (and following it all other tests based on it as a blueprint)

set to 45 cycles without defining a CT value for "positive".

In the report, the reviewer lists other sources of error in the handling of the test.

In addition, when using the RT-q-PCR test, the WHO information

Notice for IVD Users 2020/05 must be observed (No. 12 of the legal information of the court).

Thereafter, if the test result does not match the clinical findings of an examinee

matches, a new sample is taken and a further examination is carried out

as well as differential diagnostics are operated; only then can a

positive test are counted. <https://www.who.int/news/item/20-01-2021-who-information-notice-for-ivd-users-2020-05>

This requirement is as little observed in Thuringia and nationwide as

Multiple counts in the case of multiple tests by the same person are excluded (No.

13 of the legal notices of the court).

The rapid antigen tests used for the mass test can also be carried out according to the explanations

do not make any statement about an infectiousness in the report, since this only means protein

Components unrelated to an intact, replicable virus

can be proven.

In order to allow an assessment of the infectiousness of the people tested, the

positive test carried out in each case (similar to the RT-qPCR) individually with a

Cultivability of viruses from the test sample can be compared to what is under the extreme

variable and non-verifiable test conditions is impossible.

Finally, the reviewer points out that the low specificity of the tests is a high one

Rate of false positive results depends on which unnecessary personnel (quarantine) and

social (eg schools closed, "outbreak reports") consequences

until they turn out to be a false positive. The failure effect, so a high number of

False positives are particularly strong in tests on those without symptoms.

It should be noted that the PCR test used, as well as the rapid antigen tests,

as verified by an expert, in principle not to determine an infection with the

Virus SARS-CoV-2 are suitable. There are also those described and others in the

Expert opinion listed sources of error with serious effects, so that an adequate

Determination of the infection with SARS-CoV-2 in Thuringia (and nationwide) not

is present to some extent.

In any case, the term “incidence” is misused by state legislators. Because "Incidence" actually means the occurrence of new cases in a (again and again tested and if necessary, medically examined) defined group of people in a defined Period, see No. 11 of the court's legal notice. In fact it will be undefined groups of people tested in undefined periods of time, so that it turns out to be what is reported as “incidence” is simply a matter of simple reporting rates.

In any case, the infection fatality rate is according to a meta-study of the Medical scientist and statistician John Ioannidis, one of the most cited Scientists worldwide published in a WHO bulletin in October 2020 was, 0.23% and is thus no higher than in moderate influenza epidemics.

https://www.who.int/bulletin/online_first/BLT.20.265892.pdf

Ioannidis also found in a study published in January 2021 that lockdowns have no significant benefit.

https://www.who.int/bulletin/online_first/BLT.20.265892.pdf

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4. The violation of the right to informational self-determination by Rapid tests in schools

The right to informational self-determination as part of the general The right of personality in Article 2 (1) of the Basic Law is the right of the individual basically himself about the disclosure and use of his personal data to determine. This personal data also includes a test result. A this is also a personal health "date" in the sense of data protection Basic Regulation (GDPR), which is basically nobody's business.

This encroachment on fundamental rights is also unconstitutional. Because with the specific processes of the

Testing in schools it seems inevitable that numerous more People (classmates, teachers, other parents) knowledge of a, for example, "positive" Test result would be obtained.

This also applies accordingly if there are similar test barriers when accessing shopping or for cultural events.

In addition, there is already a test obligation for schoolchildren under state law not from the Infection Protection Act - regardless of the fact that this is itself sees considerable constitutional concerns exposed - is covered.

According to § 28 IfSG, the competent authorities can, in the manner specified there, the take necessary protective measures if "sick people, suspects, Suspected contagion or eliminators "can be determined. According to § 29 IfSG are subject to observation and then also have required

To tolerate investigations.

The Bavarian Administrative Court ruled it in its decision of March 2nd, 2021, Az.: 20 NE 21,353, rejected, employees in nursing homes as sick from the start, suspect or excretory. That should also apply to schoolchildren. But classification as suspected of being contagious is also out of the question.

According to the case law of the Federal Administrative Court, the According to § 2 No. 7 IfSG, who has a sufficient probability of contact with a infected person had; a mere distant probability is not enough. Is required, that the assumption that the person affected has ingested pathogens is more likely is as the opposite. Only that is decisive for a suspicion of infection Probability of a previous infection process, see judgment of March 22, 2012 - 3 C 16/11 - juris marginal number 31 ff.

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The BayVGH, op. Cit., Rejected this for employees in the care professions. For students

nothing else applies.

5. The right of children to education and schooling

The schoolchildren are not only subject to compulsory schooling regulated by state law, but also have a legal right to education and schooling.

This is also derived from Articles 28 and 29 of the UN Convention on the Rights of the Child, which is contained in

Germany is applicable law.

After that, all contracting states not only have to attend primary school for everyone

Make it compulsory and free of charge, but also development

various forms of secondary schools of general and vocational education

Promote art, make it available and accessible (!) To all children and make it suitable

Measures such as the introduction of free of charge and the provision of financial

Meet support when in need. The educational goals from Article 29 UN

Children's rights conventions are to be observed.

6. Result

The compulsion imposed on school children to wear masks and to keep a distance between themselves and

Keeping to third persons harms the children physically, mentally, educationally and in

their psychosocial development without any more than a marginal benefit

for the children themselves or for third parties.

Schools do not play a major role in the "pandemic" event.

The PCR tests and rapid tests used are in themselves in principle and already in the

Approach not suitable to determine an "infection" with the SARS-CoV-2 virus.

According to the statements in the expert reports, this results from our own

Calculations by the Robert Koch Institute. According to RKI calculations, such as expert Prof. Dr.

Kuhbandner executes, is independent of mass tests with rapid tests

Symptoms actually increase the likelihood of getting a positive result

of being infected, with an incidence of 50 (test specificity 80%, test sensitivity 98%) only two

Percent. That would mean: For two genuinely positive rapid test results, there would be 98 false-

positive quick test results, all of which can then be retested with a PCR test

would have to.

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A (regular) compulsion to mass test on asymptomatic subjects without cause, that is

Healthy people, for which there is no medical indication, cannot be imposed because

it is disproportionate to the effect that can be achieved with it. At the same time, the

Regular compulsion to test the children under psychological pressure, because so their school ability

is constantly put to the test.

Based on surveys in Austria, where no masks were worn in primary schools

but rapid tests are carried out across the board three times a week

according to the explanations of the expert Prof. Dr. Cow bandner:

100,000 primary school students would have to deal with all side effects of the

Put up with wearing a mask to only get one infection per week

prevent.

To describe this result as disproportionate would be completely inadequate

Description. Rather, it shows that the one regulating this area

Provincial legislators have come to a distance from the facts, the seemingly historical

Has reached proportions.

By ordering such measures, the well-being of the children is endangered, as shown,

Section 1666 BGB. The teachers are therefore not allowed to order them. On the appropriate

You can refer to state regulations and the cited general decree

not called here, as this already because of their unsuitability to achieve the desired goals

achieve, but in any case because of their disproportionate to the

Violate the principle of proportionality and are therefore unconstitutional and null and void.

In addition, the children have a legal right to accessible school lessons.

According to the current state of the investigation, it appears very likely that this

The result in the main proceedings is confirmed. Further remarks remain one

Decision reserved there.

In the context of an assessment of the consequences, when an interim order is issued, the Weighing up the disadvantages that arise when the parents of the children are striving for Initially, there was no regulation by the family court in the preliminary injunction procedure is taken, but then later in the main proceedings, and the effects that arise if the family court decides the regulation aimed at by the parents of the children already meets in the preliminary injunction proceedings, but later in the main proceedings not confirmed.

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The disadvantages for the children if the intended regulation by the family court is delayed, predominate considerably.

In any case, the parents are not able to avert the danger, § 1666 BGB. With a view There is also an urgent need for the imminent end of the Easter break immediately to take action.

After all that, the decision evident from the tenor was necessary. As the classmates of the children named in the operative part are affected in the same way, the court has made his decision for this with.

The decision on costs is based on § 81 FamFG