

1

Weimar Local Court, Order of 08.04.2021, Ref.: 9 F 148/21

the Weimar Local Court has decided by ...

by way of interim injunction:

I. The head teachers and teachers of the schools of the children A, born on ..., and B, born on ..., namely the Staatliche Regelschule X, Weimar, and the primary school Y, Weimar, as well as the superiors of the school the following for these and all other children and pupils taught at these schools children and pupils taught at these schools as follows

prescribe:

1. to wear face masks of any kind during lessons and on the school premises, especially mouth-nose coverings, so-called qualified masks (OP mask or FFP2 mask) or others,
2. to maintain minimum distances from each other or from other persons, that go beyond what was known before 2020,
3. participate in rapid tests to detect the SARS-CoV-2 virus.

II. the management and teachers of the schools of the children A, born on ..., and B, born on ..., namely the Staatliche Regelschule X, Weimar, and the primary school Y, Weimar, as well as the superiors of the school are commanded to ensure the presence of these and all other children and pupils and all other children and pupils taught at these schools. be maintained at the school.

III. court costs shall not be charged. The children involved The children involved shall not bear any costs. The parties shall bear their own extrajudicial costs. parties themselves.

IV. The immediate effectiveness of the decision is ordered.²

Reasons

Outline:

A: Facts

I. Introduction

II. the provisions of the Free State of Thuringia on the compulsory masking of children in schools Thuringia on the compulsory wearing of masks

III The concrete situation of the children involved in their schools

IV. Legal comments by the mother of the children involved on the rights to which her rights to which her children are entitled, also from international conventions

V. Legal advice of the court to the parties involved and decision to take evidence in the parallel proceedings on the merits

VI. statement of the legal adviser

VII. comments by the other parties involved

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

IX. Expert opinion Prof. Dr. Christof Kuhbandner

X. Expert opinion Prof. Dr. rer. biol. hum. Ulrike Kämmerer

B: Reasons for the decision

I. Admissibility of the petition to the Family Court

II. the merits of the application to the family court

1. general points

2. the lack of benefit to the children themselves and third parties of wearing masks and distance regulations for the children themselves and third parties

3. the inappropriateness of PCR tests and rapid tests for measuring the incidence of infection incidence

4. the violation of the right to informational self-determination through rapid tests in schools

5. the right of children to education and schooling

6. result

A: Facts³

I. Introduction

For the children named in the operative part, their mother, who has joint custody with the father of the children, filed a petition of

who has joint custody with the father of the children, filed a "Child Protection Proceeding" with the Local Court - Family Court - Weimar on 13.03.2021.

Family Court - Weimar "Child protection proceedings pursuant to § 1666.1 and 4 of the Civil Code". suggested.

The children attend the state regular school X and the state primary school Y in Weimar.

primary school Y, the older son, aged 14, attends the eighth grade, the younger son, aged 8, attends the third grade.

aged 8, attends the third grade.

Her mother claims that the compulsory wearing of a face mask by her children at their face masks and to keep a minimum distance from each other and from other persons.

and to keep a minimum distance from each other and from other people.

The children would be physically, psychologically and pedagogically harmed without any benefit for the children or third parties.

benefit for the children or third parties. At the same time, this would violate numerous rights of the children and their parents under the law, the constitution and international and international conventions.

Pursuant to § 1666 paragraph 4 of the German Civil Code, the school administrators and teachers should be

be expressly ordered by the court to rescind the relevant orders.

Insofar as these orders were based on Land regulations such as statutory instruments, the school headmasters and others could not invoke them, as they were unconstitutional. unconstitutional.

The obligation in Article 100(1) of the Basic Law to refer a possibly unconstitutional law to the Federal

unconstitutional law to the Federal Constitutional Court or a Land constitutional court,

expressly applies only to formal laws of the Federation and of the Länder, but not to

substantive laws such as ordinances. According to the established case-law of the

the Federal Constitutional Court (fundamentally, the Federal Constitutional Court

BVerfGE 1, 184 ((195 et seq.)), each court has to decide for itself, as already AG Weimar,

Judgment of 11 January 2021 - 6 OWi - 523 Js 202518/20 -, juris.

Insofar as a decision on the merits of the case is not possible in the short term, the court may issue a temporary injunction pursuant to §§ 49 et seq. of the Family Proceedings Act (FamFG).

In addition, the court may take measures to ensure that the legal situation is observed in the future by the competent state authorities.

legal situation by the competent state authorities.

For this purpose, the court should, in a separate part of the proceedings pursuant to Article 100.1 of the Basic Law, refer the matter to the Federal Constitutional Court.

Basic Law, the court should submit the case to the Federal Constitutional Court with the proviso that the 4

nullity of the Infection Protection Act, which would otherwise be used in the future as an which, as a basis for authorisation, could otherwise cause new hazards for children. The Federal Constitutional Court be asked to deal with this separate part of the proceedings in the the constitutional complaint of the judge at the Regional Court Dr. Pieter Schleiter of 31.12.2020, Ref.: 1 BvR 21/21, with reference to the detailed reasons given there. to be joined.

The court thereupon dismissed the present temporary injunction proceedings 9 F 148/21 and the parallel main proceedings 9 F 148/21.

and the parallel proceedings on the merits 9 F 147/21, and granted the children, in accordance with § 158 of the Family Proceedings Act (FamFG) and appointed the lawyer named in the heading as guardian ad litem.

II. The provisions of the Free State of Thuringia that apply to the children in schools on the obligation to wear a mask

The provisions of the general decree of 31.03.2021 on the Enforcement of the Thuringian Ordinance on Infection Protection Rules for the Containment of the spread of the coronavirus SARS-CoV-2 in day-care centres, further youth welfare schools and for sports (ThürSARS-CoV-2-KiJuSSp-VO), insofar as they require in no. 7 the wearing of a mouth-nose covering and a qualified face mask, as well as against the legal ordinances cited by the general decree.

The provisions in question have the following overall wording:

1.

General decree of 31.03.2021 on the enforcement of the Thuringian ordinance on the Infection Protection Rules for Containing the Spread of the Coronavirus SARS-CoV2 in Day Care Facilities for Children, Other Youth Welfare, Schools and for Sports

(ThürSARS-CoV-2-KiJuSSp-VO)

General decree

Pursuant to § 2 Para. 2 in conjunction with § 15 Sentence 1 and § 37 Sentence 1 of the Thuringian Ordinance

on infection control regulations to contain the spread of the coronavirus

SARSCoV-2 in day-care facilities for children, other youth welfare services, schools and for

(ThürSARS-CoV-2-KiJuSSp-VO) of 13 February 2021 and pursuant to § 35 sentence 2

Thuringian Administrative Procedure Act of 1 December 2014 (GVBl. p. 685) the

Thuringian Ministry of Education, Youth and Sports (TMBJS) in consultation with the
Thuringian Ministry of Labour, Social Affairs, Health, Women and Family (TMASGFF) 5
for the Free State of Thuringia
the following general decree:

...

No. 7.

Pursuant to section 38 (5) of the ThürSARS-CoV-2-KiJuSSp-VO, pupils from the age of six and
and teachers at state schools are required to wear a qualified face mask within the school building.
school building to wear a qualified face mask in accordance with § 5 Para. 3 3rd ThürSARS-CoV2-

SonderEindmaßnVO to wear. For pupils in grades 1 to 6, the use of a mouth-nose
a face mask according to § 6 Abs. 3 to 5 2. ThürSARS-CoV-2- IfS-GrundVO is sufficient.

The obligation to wear a qualified face mask applies to pupils from grade 7 onwards and to teachers.
grade 7 and for teachers at all state schools in every grade level, also during lessons.
during lessons.

The mask obligation for pupils does not apply to physical education classes. At
a break from wearing the face mask or mouth/nose covering must be ensured at regular
mask or mouth/nose covering, which shall take place outdoors or during the ventilation break.

during a break for ventilation. The obligation does not apply when taking meals, whereby a
1.50 m must be ensured. The school management decides on further exceptions to the

The school management shall decide on further exceptions to the obligation in individual cases at its
own discretion.

2.

Thuringian Ordinance on the Updating of the Measures Required for the
containment of the spread of the SARS-CoV-2 coronavirus in day-care
day-care facilities for children, other youth welfare services, schools and for sports activities
From 13 February 2021

On the basis of section 32 sentence 1 of the Infection Protection Act (IfSG) of 20 July 2000 (BGBl. I p.
1045), last amended by Article 4a of the Act of 21 December 2020 (BGBl. I p.

3136), in conjunction with Section 7 (2) of the Thuringian Ordinance on the Regulation of
Responsibilities and for the Transfer of Authorisations under the Infection Protection Act
(ThürlfSGZustVO) of 2 March 2016 (GVBl. p. 155), last amended by Article 3 of the

Ordinance of 21 September 2020 (GVBl. p. 501), the Ministry of Education,
Youth and Sport in agreement with the Ministry of Labour, Social Affairs, Health,
Women and Family Affairs

and on the basis of section 32 sentence 1 in conjunction with sections 28, 28a, 29, 30 subsection 1
sentence 2 and section

31 IfSG in conjunction with section 7 subsection 1 ThürIfSGZustVO, the Ministry of Labour,
Social Affairs, Health, Women and Family:

....

§ 376

Modified presence for pupils during the "Yellow II" phase

The Ministry may, on a state-wide basis or for specific regions, introduce measures for increased
protection against infection in accordance with sections 38 to 40. These measures shall alter the
school operation statewide or regionally for all pupils and restrict the entitlement to
support under section 10(2) of the ThürSchulG. The organisational implementation on site is the
responsibility of

The organisational implementation on site is the responsibility of the school headmasters within the
framework of their professional responsibility.

§ 38

Organisation of classroom teaching during the "Yellow II" phase

...

(5) Pursuant to section 2 sub-section 2, the Ministry may waive the obligation to use a mouth-nose
covering in accordance with the provisions of section 6 sub-sections 3 to 5 2nd ThürSARS-CoV-2-

IfSGGrundVO or a qualified face mask in the sense of § 5 para. 3 3.

ThürSARS-CoV-2-SonderEindmaßnVO for pupils in grade 7 and above and for all teachers.

teachers; § 5 Para. 2 Sentence 2 3rd ThürSARS-CoV-2-.

SonderEindmaßnVO shall apply accordingly. At regular intervals, a break from the
use of the mouth-nose covering or the qualified face mask must be

face mask must be ensured. Exceptions to the obligation according to sentence 1

shall be decided by the school management at its due discretion.

3.

Third Thuringian Ordinance on Extraordinary Special Measures for the
containment of a sudden spread of the coronavirus SARS-CoV-2 (Dritte

Thuringian SARS-CoV-2 Special Containment Measures Ordinance -3rd Thuringian SARS-CoV-2 Special Containment Measures Ordinance-) of 12.03.2021

Section One

Priority of Application

§ Section 1 Priority of Application

(1) Supplementary to the provisions of the Second Thuringian SARS-CoV-2-Infection Protection Basic Ordinance (2nd Thuringian SARS-CoV-2-IfS Basic Ordinance) of 7 July 2020 (GVBl. p. 349) as amended from time to time and the provisions of the Thuringian Ordinance on Infection Protection Rules for Containing the Spread of the SARS-CoV-2 coronavirus in day-care facilities for children, other youth welfare services, schools and for sports activities (ThürSARSCoV-2-KiJuSSp-VO) of 13 February 2021, as amended. the provisions of this Ordinance shall apply in each case.

(2) In the event of deviations, the provisions of this Ordinance shall take precedence; to this extent, the provisions of the the provisions of the Second Thuringian SARS-CoV-2 Basic Infection Protection Ordinance 7 as well as the Thuringian Ordinance on the Infection Protection Rules for the Containment of the spread of the SARS-CoV-2 coronavirus in day-care facilities for children, the further youth welfare, schools and for sports activities.

(3) Further orders and measures according to § 13 2. ThürSARS-CoV-2-IfSGrundVO shall remain unaffected. For more far-reaching orders according to sentence 1, in the of §§ 6a and 6b, the prior consent of the supreme health authority shall be obtained. shall be obtained.

....

§ 5 Extended obligation to use a mouth-nose covering, face mask

(1) In addition to Section 6 (1) and (2) 2nd ThürSARS-CoV-2-IfS-GrundVO, the following obligation shall apply

to use a face mask also applies to

1. in all enclosed rooms that are accessible to the public or where there is visitor and customer traffic (public traffic),

2. in all places defined and marked in accordance with sentence 2 which are frequented by the public in

and in the public open air, where people are either in close proximity or not only either in a confined space or not only temporarily,

3. in front of retail shops and in car parks,
4. at gatherings in accordance with section 8 (1) sentence 1 no. 1 2nd ThürSARS-CoV-2-IfS-GrundVO,
5. at events and gatherings for religious and ideological purposes according to section 8 para. 1 sentence 1 no. 2 2nd ThürSARS-CoV-2-IfS-GrundVO and
6. at events of political parties according to section 8 para. 1 sentence 1 no. 3 2. ThürSARSCoV-2-IfS-GrundVO.

The competent authorities pursuant to section 2 para. 3 ThürIfSGZustVO shall determine the locations pursuant to sentence 1 no.

2 and mark them. Regulations on the use of a mouth-nose covering shall remain applicable to the facilities and services pursuant to section 1 sub-section 1 sentence 1 nos. 1 to 4.

ThürSARSCoV-2-KiJuSSp-VO are reserved for the separate orders of the ministry responsible for education.

Ministry responsible for education.

(2) Persons over the age of 15 shall use a qualified face mask instead of the mouth-nose covering:

1. at events and gatherings for religious and ideological purposes according to § 8 para. 1 sentence 1 no. 2 2nd ThürSARS-CoV-2-IfS-GrundVO,
2. as passengers as well as control and service personnel in closed vehicles of the public transport in accordance with section 6 subsection 1 2. ThürSARS-CoV-2-IfS-GrundVO,
3. as customers in shops and service enterprises open to the public or in the use of services and offers

Use of services and offers open to the public,

4. during theoretical instruction in closed rooms of driving and flying schools, theoretical
8. during theoretical instruction in closed rooms of driving and flying schools, the theoretical driver's and pilot's licence examination and the practical training and practical pilot's 8 training and practical driving and flying licence examinations in enclosed driving and flying aircraft of the driving and flying schools,
5. at meetings of municipal bodies, Page 5 of 19 6. as doctors or therapists,
6. as doctors or therapists, including their staff, and as patients in doctors' surgeries, psychotherapists' surgeries, physiotherapists' surgeries or other outpatient facilities providing medical and therapeutic care.

outpatient facilities, with the exception of treatment rooms, if the nature of the service does not of the service does not permit this.

Sentence 1 shall apply accordingly to children from the age of six to the age of 15.

with the proviso that the use of a mouth-nose covering in accordance with the specifications of § 6 Para. 4 2nd ThürSARS-CoV-2-IfS-GrundVO is sufficient. Furthermore In addition, every person is required, especially in enclosed spaces in situations, in situations where close or prolonged contact with other persons is unavoidable. qualified face mask.

"(3) For the purposes of this regulation, qualified face masks are:

1. medical face masks; or
2. protective masks without an exhalation valve with a technically higher standard of protection, in particular FFP2.

Approved qualified face masks in accordance with sentence 1 are published on the website of the Ministry responsible for

Ministry responsible for health.

(4) In all other respects, the obligations to provide and use medical face masks or respirators at work in accordance with section 4 of the SARSCoV-2 Occupational Health and Safety Ordinance of 21 January 2021 (BANz AT 22.01.2021 V1), as amended. version in force at the time shall remain unaffected.

4.

Second Thuringian Ordinance on Basic Infection Protection Rules for the

Thuringia Regulation on Basic Infection Protection Rules for Containing the Spread of the SARS-CoV-2 Coronavirus (Second Thuringia SARSCoV-2 Basic Infection Protection Regulation -2. ThürSARS-CoV-2-IfS-GrundVO-) of

12.03.2021

...

§ 6 Use of a mouth-nose covering

(1) In closed vehicles of public passenger transport, in particular in trams and buses, taxis, coaches and other means of transport open to the public.

(1) In closed vehicles used for public transport, in particular railways, trams, buses, taxis, coaches and other means of transport open to the public, passengers are required to wear nasal masking.

(2) In shops open to the public, customers shall be obliged to use nasal masking. 9

(3) By way of derogation from subsections (1) and (2), the obligation to use a mouth-nose covering shall not apply to

nose and mouth covering does not apply to:

1. children up to the age of 6 years,

2. persons who are unable to use a mouth-nose covering because of a handicap or for health or other reasons is not possible or unreasonable for them; this must be

This must be substantiated in a suitable manner,

3. groups of persons as defined in section 1 subsection 2 in coaches and other means of transport in accordance with paragraph 1, provided they use the means of transport exclusively for themselves and there are no

and there is no public traffic.

(4) Mouth and nose coverings may be self-sewn or self-made fabric masks, scarves

cloth masks, scarves, shawls, bonnets and head masks as well as other coverings for the mouth and nose.

mouth and nose may be used. The mouth and nose coverings should fit snugly and be well fit snugly.

(5) The prohibition of the use of anti-constitutional symbols and other

symbols, in particular in accordance with §§ 86a and 130 of the Criminal Code and the according to the provisions of the law on associations, shall remain unaffected.

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

The older son, the party to 1), is of compulsory school age in Thuringia and, at the age of

14 years of age, he attends the 8th grade of the State Regular School X in Weimar. He therefore falls within the

scope of application of the general ruling.

The guardian ad litem submits that the party to 1) must wear a mask in the school building and in the classroom up to his place.

wear a mask in the school building and in the classroom until he reaches his seat, after which he may usually

remove the mask. A mask must also be worn in the school playground if the distance of 1.50 m cannot be maintained.

1.50 m distance could not be kept. The pupils are constantly asked to wear a qualified

to wear a qualified mask all day, even in class, although they are not yet 15 years old.

years of age.

In the week from 08.03.2021 to 12.03.2021, a qualified mask had to be worn even during physical education.

qualified mask had to be worn. According to the headmaster, the child had to

to wear the mask all day.

Since the mask was compulsory, the first party no longer liked to go to school. He

headaches and often feels nauseous when he wears the mask. Minor infections, such as cough, increase when he wears the mask. These infections also longer than usual. The party to 1) felt very nauseous two to three times a week when he nauseous two or three times a week when he wears the mask. He usually had headaches after school and at the end 10 of the school day, but then so bad that he almost has to throw up because of the pain. pain.

The party to 1) had submitted a mask certificate on 22.03.2021. As a result, he was discriminated and insulted by his teacher. He was forced to sit in the back corner of the and was no longer addressed by name, but only as "You without a mask", but only as "You without a mask". On 23.03.2021, the headmaster had then called the parents of the called the parents of the person involved in 1). He had informed them that the certificate of the 1) had been noted, but that it did not release him from the mask requirement at school. exempt him from the mask requirement at school. According to the headmaster, it was up to the headmaster to grant exemption from the mask requirement.

the headmaster continued. According to the headmaster, a doctor could not exempt the person involved in 1)

only the headmaster could exempt him from the mask requirement. According to the headmaster

According to the headmaster, all pupils from grade 7 onwards would have to wear a so-called qualified mask. In fact

masks were often not worn during lessons, which were then the mask breaks.

mask breaks.

The party to 1) had to wear a mask in the schoolyard during the break or keep his distance.

There should be no direct contact. He did not like this because it was the only time he could time when he can talk to his classmates.

There is no risk assessment.

The teachers do not pay attention to the correct handling of the mask or to changing it when it gets wet.

when the mask becomes wet. The teachers also did not explain anything about wearing the mask.

The younger son, the party to 2), is of compulsory school age in Thuringia and attends the third grade of the

and attends the third grade of the state primary school Y in Weimar at the age of 8. He therefore falls within the

scope of application of the general order.

The guardian ad litem submits that the 2nd respondent must wear a cloth mask/hose scarf in the school

scarf in the school building and in the classroom up to his seat. On the

to lunch and in the lunch room, a mask must also be worn until the second party

2) was sitting at the table with his food. He was allowed a meal time of

15 minutes, he was not allowed to eat in peace. In the after-school care rooms

mask in the after-school care rooms, so the after-school care worker went out a lot to reduce the mask

reduce the time spent wearing masks.

At the moment, masks do not have to be worn in class.

mask breaks.

Since the obligation to wear a mask, the 2nd party no longer likes to go to school.

school. He had increased headaches, sometimes with nausea. In addition, the second

2) often had stomach pains. Severe headaches and nausea occur about once or twice a week.

twice a week. The 2nd respondent had abdominal pain about four times a month, then 11

but also with vomiting. The 2nd party had headaches and malaise in connection with the

in temporal connection with the wearing of the mask, abdominal pain mostly at night.

at night. He cries in his sleep and sleeps very restlessly. At school, the person concerned

2) did not dare to say anything when he was feeling bad.

The problems were not discussed with the school management because the parents were afraid of reprisals against their child.

of reprisals against their child and wanted to protect it.

There was no risk assessment. The teachers did not pay attention to the correct

teachers did not pay attention to the correct handling of the mask or to changing it when it became wet. The teachers

did not explain anything about wearing the mask.

In addition, the 2nd party had already been told by another teacher that he should not wear a tube scarf.

not to wear a tube scarf, but a real mask. The party to 2) was

was so disturbed that he now did not like going to school.

IV. Legal statements by the mother of the children involved on the rights to which her children are entitled

to which her children are entitled, also from international conventions

In detail, the mother of the children states that children, irrespective of their age, are fundamental rights to physical integrity (emotional, mental, psychological), free development of personality, respect for human dignity, i.e. non-violent upbringing, etc, care and upbringing by their parents, etc.

Encroachments on these fundamental rights - whether caused by private individuals or public officials

cannot be assessed differently than an objective endangerment of the "best interests of the child" in the meaning of the term.

"child's welfare" within the meaning of §§ 1666 BGB, 157 FamFG.

The school's internal order to wear a mask and to maintain a physical distance from other other persons violated the best interests of the child, as did the underlying of the Free State of Thuringia specifically violated the fundamental rights of their and other children, in particular from

- Art. 1 GG: Respect for human dignity;
- Art 2 GG: to free development of the personality and physical integrity;
- Art 6 GG: to upbringing and care by the parents (also with regard to health care measures and "objects" to be carried by children).

"objects" to be carried by children). 12

In addition, children's rights and claims for protection under international conventions are specifically violated;

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

Art 3 - The best interests of the child shall be a primary consideration in all actions;

Art. 16 - Prohibition of arbitrary or unlawful interference with the child's private life, his family, his home;

Art 16(2) - on legal protection against interference;

Art 19 - on protection against physical, mental violence;

Art. 28 para. 2, 29 para. 1 - education with respect for the human dignity of the child, and dignity of the child,

compliance with specific objectives of education;

Art 37a - prohibition of torture, degrading treatment;

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

from the Convention against Torture and Other Cruel, Inhuman or Degrading

degrading treatment or punishment of 10 December 1984 (Federal Law Gazette 1990 II p. 246):

Art. 1

(1) For the purposes of this Convention, the term "torture" shall mean any act by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person.

pain or suffering intentionally inflicted on a person ...

Art. 2

1. Each State Party shall take effective legislative, administrative, judicial or other administrative, judicial or other measures to prevent acts of torture in any under its jurisdiction.

(2) Exceptional circumstances of whatever nature, whether war or threat of war, domestic instability or other public emergency, shall not be invoked as a justification for torture.

(3) An instruction given by a superior or a holder of public authority shall not be shall not be invoked as a justification for torture.

Art. 4

1. Each State Party shall ensure that, in accordance with its criminal law, all acts of acts of torture are criminal offences. The same shall apply to attempted torture and acts committed by any person which constitute complicity or participation in torture.

2. Each State Party shall make these offences punishable by appropriate penalties that take into account the gravity of the offence. 13

Art. 5

1. Each State Party shall take such measures as may be necessary to establish its jurisdiction over the offences

over the offences referred to in Art. 4 in the following cases;

from the European Convention on Human Rights

Art. 8

(1) Everyone has the right to respect for his private and family life, his home and to correspondence.

(2) A public authority may interfere with the exercise of this right only to the extent that such interference is

provided by law and is necessary in a democratic society for national security or public safety, for the economic well-being of the country, to maintain economic well-being of the country, for the maintenance of law and order, for the prevention of crime, for the health or morals, or for the protection of the rights and freedoms of others; and others;

by exceeding the limits laid down in the International Covenant on Civil and Political Rights of 19 December 1966 (Federal Law Gazette 1973 II 1553):

Art 4

(1) in the event of a public emergency threatening the life of the nation which is officially proclaimed, the States Parties to the present Covenant may take measures which obligations under this Covenant to the extent strictly required by the situation, provided that situation strictly requires, provided that such measures do not conflict with their other obligations under international law and do not discriminate on the grounds of race, skin discrimination solely on the grounds of race, colour, sex, language, religion or social language, religion or social origin.

(2) By virtue of the foregoing provision, Arts. 6, 7, 8 (paras,) 11, 15, 16 and 18 shall not be set aside.

(3) Any Contracting State which exercises the right to abrogate obligations States Parties through the intermediary of the Secretary-General of the United Nations of the United Nations, of the provisions which it has abrogated and of the reasons which provisions it has abrogated and the reasons which have led it to do so. By the same means shall, by a further communication, specify the date on which such a measure ends.

For personal freedoms, see e.g. Art. 9, 12.

Art. 1714

(1) No one shall be subjected to arbitrary or unlawful interference with his private life, family, home and correspondence, or unlawful interference with his or her or unlawful interference with his honour and reputation.

(2) Everyone shall have the right to legal protection against such interference or interference.

The family court is obliged to take measures ex officio to end further unlawful infringements of these rights.

unlawful violation of these rights to be guaranteed to the child.

An encroachment on these rights of the child from the Basic Law and international conventions could not be assessed differently than an objective endangerment of the "child", irrespective of an objective endangerment of the "best interests of the child" within the meaning of §§ 1666 of the Civil Code, 157 of the Family Proceedings Act.

If, not least on the basis of Article 2, 1 and 6 of the Basic Law, the law in § 1631.2 of the Civil Code prohibited parents from

and makes this a punishable offence in §§ 223 et seq. and 171 of the Criminal Code, similar treatment cannot be lawful simply because it is carried out by or on behalf of state officials.

by or on behalf of state officials. This is not least also

by the increased threat of punishment for violations of the law by public officials.

underlined.

Accordingly, if every restriction of the special rights of the child, whether under the or international conventions requires a special justification, it is subject to this justification in every it is subject to the constitutional requirement of proportionality in each individual area. proportionality.

In this respect, what the Federal Constitutional Court and the Federal Court of Federal Court of Justice on the permissibility of a child being separated from its parents from its parents:

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

It cannot be established with sufficient certainty that the separation of the children is suitable to eliminate or mitigate the dangers assumed by the courts.

or mitigate them. It is true that separation would in principle be suitable for eliminating the dangers the courts to eliminate the dangers that exist for the children with the mother.

eliminated. However, the separation of the child from its parents regularly causes its own

parents, because the child can suffer from the separation even if its well-being is not

child may suffer from the separation even if his or her well-being was not secured with the parents. A measure 15

cannot be regarded as suitable for safeguarding the best interests of the child without further ado, if

it may in turn have negative consequences for the welfare of the child. Such negative

consequences of a separation of the child from its parents and of placement in a
are to be taken into account (cf.) and would have to be outweighed by the elimination of the
identified danger.

danger, so that the situation of the child would be improved in the overall
overall view would improve (cf. BGH XII ZB 247/11 of 26.10.2011).

(S. 244,245)

From the BGH decision of 26.10.2011 - Ref:12 ZB 247/11= ZKJ 2012, 107 et seq:

... Suitability is not only lacking if the measure cannot eliminate the danger to the
child's best interests. Rather, the measure is also unsuitable

is also unsuitable if it is accompanied by other impairments of the child's

child's welfare and these are not outweighed by the elimination of the identified danger.

outweighed

...unsuitable if it in turn has an adverse effect on other aspects of the child's welfare.

a

situation in other aspects of the child's welfare and therefore does not lead to an

improvement in the situation of the child at risk. (ZKJ P. 109)

According to these principles, an intervention is only permissible if, prior to a restriction of the child's
rights of the child, irrespective of the dangers to the child (or others) that are to be averted.

others), a concrete weighing up of the possible dangers to the child has taken place,

child, which were threatened by the orders and executive measures that had been specifically

threatened.

Measures had to be omitted if no concrete findings were available from which a legally

from which a legally significant preponderance of the dangers to be averted could be established.

Accordingly, it could not be assumed that the restriction of fundamental rights was justified.

be assumed.

There was a lack of a comprehensible determination of existing concrete dangers to higher-value
legal interests of others through children.

higher-value legal interests of others through children (see e.g. Reiss, Bhakdi: Corona

False Alarm? GOLDEGG 2020) as well as a concrete determination of the risks to the children affected
by the measures.

the measures themselves for the children concerned, as well as a concrete balancing of the two.

concrete balancing of the two.

For further details of the suggestion, please refer to the written submission of 13.03.2021.

16

V. Legal advice of the court to the parties and decision on evidence in the parallel main proceedings
parallel main proceedings

The court issued detailed legal notices on 16.03.2021 and updated them on 25.03.2021.

25.03.2021. The Free State of Thuringia and the heads of the schools attended by the children were involved in the proceedings.

attended by the children were involved in the proceedings.

The Free State of Thuringia and the school administrations involved were requested with the legal were requested, together with the legal notices, to respond to all the questions raised in the questions raised in the suggestion on this procedure and, in addition, to the questions listed below which, in the updated version of 25.03.2021, had the following form

had:

"In the statement, the scientific evidence for all factual assertions should be scientific evidence for all factual claims and substantiate them by citing accessible sources.

1.

1) What goals is the Free State of Thuringia pursuing with the measures, in particular the

What exactly are the aims of the measures taken by the Free State of Thuringia, in particular the compulsory wearing of masks by schoolchildren and the distance regulations applicable to them? 2.

2. has the benefit of these measures been proven on the basis of evidence with regard to the spread of the SARSCoV-2 virus?

3. have the possible physical effects, in particular of the mandatory masks, but also of the distance requirements for children, been assessed?

but also of the distance regulations for children, in particular with regard to the different

the different respiratory volumes of adults and children?

children? What results did the Free State of Thuringia arrive at, based on which studies and sources?

State of Thuringia arrived at? 4.

4. have the possible psychological effects, in particular of the mandatory use of masks, but also of the distance regulations for children, been examined?

but also of the distance regulations for children? Were the following

the possible consequences due to the possibility of only reduced communication,

possible dangers due to distorted perception of facial expressions and emotions, and

possible dangers for psychosocial development? What

on the basis of which studies and sources did the Free State of Thuringia arrive at?
arrived at?

5. has the proportionality of the measures been assessed with regard to the benefits (both for the schoolchildren themselves and for the children)?

(both for the schoolchildren themselves and for third parties) against the possible
and third parties and assessed in a comprehensible manner? 6.

6. how the incidence of infection with the SARS-CoV-2 virus is determined? 17

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 perform the test accredited? Which test controls

are used? How do the authorities monitor the reliability of the

of the test performance? Are independent interlaboratory comparisons conducted on a regular
basis?

8. how many gene segments and which ones have been and are being examined in the RT-q-PCR test
in

Thuringia examined? Up to which amplification/doubling steps (ct value) was and is the test
evaluated as "positive" in Thuringia? 9.

9 Is the RT-q-PCR test able to detect a virus SARS-CoV-2 that is capable of replication and
transmission?

SARS-CoV-2 virus that is capable of replication and transmission?

10. what is the sensitivity and specificity of the RT-q-PCR tests used?

used? As far as is known, these parameters have been tested in practice by a German institution only
once.

German institution using a test design recognised for a ring trial, namely by INSTAND.

by INSTAND, a society for the promotion of quality assurance in

quality assurance in medical laboratories e.V., which cooperates with the WHO, among others.

among others. In its 51-page "Commentary on the Extra

Group 340 Virus Genome Detection-SARS-CoV-2" by Prof. Dr. Heinz

Heinz Zeichhardt, Charité - University Medicine Berlin, and Dr. Martin Kammel - in

cooperation with the Charité, University Medicine Berlin, Institute for Virology, the

National Consiliary Laboratory for Coronaviruses Prof. Dr. Christian Drosten, Dr.

Victor M. Corman et al. - dated 2.5.2020, updated on 3.6.2020, regarding the

specificity of the PCR test to a false positive rate between 1.4 % and 2.2 %;

the "outliers" due to mix-ups have already been taken into account. If

this false positive rate taken into account when calculating the "incidences"?

(Note on this: There is another interlaboratory study by Instand e.V., which was started in June/July 2020, but the results are not publicly available).

publicly available).

What remains if this false positive rate of between 1.4 and 2.2 % is included?

this may be illustrated verbally and mathematically - assuming realistic

What is left of the "incidences" currently reported for Thuringia?

<https://www.instand-ev.de/ringversuche-online/ringversuche-service.html#rvp//340/->

2020/

What exactly is meant by "incidence"? As far as is known in court, this term

term means the occurrence of new cases in a (repeatedly tested)

(repeatedly tested) group of people in a defined period of time, whereas according to the

information available to the court, 18 undefined groups of people were actually

undefined groups of persons in undefined periods of time, with which

the so-called "incidences" would only be simple reporting data. If this is the case, how does this

the significance of the tests with regard to the incidence of infection?

12.

Is the WHO Information Notice for IVD Users 2020/05 observed when using the RT-q-PCR test?

Users 2020/05 observed? According to this, if the test result does not agree with the clinical

clinical findings, a new sample must be taken and a further investigation

a new sample must be taken, a further examination carried out and differential diagnostics

Only then can a positive test be counted according to these guidelines.

<https://www.who.int/news/item/20-01-2021-who-information-notice-for-ivd-users2020-05>

13. is it ensured that persons tested more than once are not counted as a new "case" each time?

new "case" each time? How is this done, if necessary?

14. how does the additional introduction of rapid tests affect the determination of the

infection incidence? Are those tested negative in the rapid tests also counted?

also be counted in the rapid tests? How is it ensured that the combination of

positive rapid test and negative RT-q-PCR test does not appear as "positive" in the

statistics or that "positive" is only counted as "positive" once for both tests (analogous to question 13)?

(analogous to question 13)? Are the results of the rapid test also taken into account

Are those who tested negative in the rapid test also included in the calculation of a realistic infection rate?

(15) Does the other party assume that asymptomatic positives are infectious, i.e. that they carry the virus?

can be infectious, i.e. pass on the SARS-CoV-2 virus? If the answer is yes

If the answer is yes, please quantify this and provide scientific evidence to support this.

scientific evidence. Is the study from Wuhan, China, published on 20.11.2020, also taken into account?

with about 10 million participants? The researchers of this study came to the

that the detection rate of asymptomatic positive cases in Wuhan was

was very low, at 0.303/10,000, after the previous lockdown, and there was

no evidence that the asymptomatic positive cases identified were infectious at all.

were infectious at all. <https://www.nature.com/articles/s41467-020-19802-w>

16) If the other party assumes that pre-symptomatic positives are infectious, i.e. that they have

can be infectious, i.e. pass on the SARS-CoV-2 virus? If the answer is yes

please quantify this.

(17) What is the infectivity of symptomatic positives?

18. are other viruses, such as influenza, currently being screened for and tested for?

and also tested for them? "19

By order also dated 25.03.2021 in the parallel main proceedings 9 F 147/21

a taking of evidence was ordered. Regarding the evidentiary questions, the order has the following

Content:

"Evidence shall be taken on the questions listed below under I. by means of

Obtaining written expert opinions.

The expert opinion is to expressly take into account the questions set out in the updated legal

the court of 25.03.2021 shall be expressly included in the expert opinion.

I. Evidence is to be taken on the following questions:

1. can the wearing of different types of face masks reduce the risk of infection with the coronavirus?

reduce (significantly) the risk of infection with the SARS-CoV-2 coronavirus?

A distinction should be made between children in particular and adults in general.
adults in general and between asymptomatic, pre-symptomatic and symptomatic
pre-symptomatic and symptomatic people.

2. what physical, psychological and educational harm can be caused by

2. what physical, psychological and pedagogical damage can be caused by wearing masks, especially
in children? 3.

3. is there a risk of infection at all that can be avoided by wearing face masks?

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

4. can the risk of infection, especially in children, be reduced by observing distance regulations?
especially in children? 5.

5. do children possibly even offer a "protective function" against the spread of the coronavirus SARS?
with the SARS-CoV-2 coronavirus in the sense that they tend to slow down the spread of the
spread of the virus and protect against severe covid-19 diseases?

protect against severe covid-19 disease?

6 What is the methodological level and, if applicable, what are the methodological deficiencies of
existing

existing studies on the incidence of infection in schools and on the

and on the effectiveness of measures such as wearing masks and keeping
schools? 7.

7) What is the significance of the results of studies on the detectability of an infection with the
coronavirus

SARS-CoV-2 infection can be detected using the RT-q-PCR test and the rapid tests currently in use?
rapid tests currently in use? "20

Prof. Dr. med. Ines Kappstein and Prof. Dr. Christof Kappstein were appointed as experts for
questions I.1 - 6.

Prof. Dr. Christof Kuhbandner were appointed as experts. Ms. Prof. Dr. rer. b. and Prof. Dr. Christof
Kuhbandner were appointed as experts for question I.7.

Prof. Dr. rer. biol. hum. Ulrike Kämmerer was appointed.

Prof. Dr. med. Ines Kappstein, hygienist, is a medical specialist for microbiology, virology and
Infectious Disease Epidemiology and a specialist in Hygiene and Environmental Medicine. Her
habilitation

in the field of hospital hygiene. From 1998 to 2006 she worked at the Klinikum rechts der
of the TU Munich. From 2006 to 2016, she was head physician of the Department of

Department of Hospital Hygiene at the Kliniken Südostbayern AG in the districts of Traunstein and Berchtesgadener Land districts. Since 2017, she has been in charge of several acute, specialist and rehabilitation clinics in her

in an independent capacity.

Prof. Dr. Christof Kuhbandner is Professor of Psychology, Chair of the Chair of Educational Psychology at the University of Regensburg and an expert in the field of scientific scientific methods and diagnostics.

Prof. Dr. rer. biol. hum. Ulrike Kämmerer represents at the University Hospital Würzburg, gynaecological clinic, specialising in human biology, immunology and cell biology.

VI. statement of the guardian ad litem

The lawyer appointed as guardian ad litem submitted in her written statement of 06.04.2021 in detail on almost 170 pages on all factual and legal questions.

legal questions. Reference is made to this for further details.

VII. Statement of the Other Parties

A statement of the Free State of Thuringia and of the children's schools has been submitted within the

the time limit set in the present proceedings for a temporary injunction.

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

Prof. Dr. med. Ines Kappstein, hygienist, is a medical specialist for microbiology, virology and infectious disease epidemiology and a specialist in hygiene and environmental medicine. Her habilitation

in the field of hospital hygiene. From 1998 to 2006 she worked at the Klinikum rechts der

of the TU Munich. From 2006 to 2016, she was head physician of the Department of

Department of Hospital Hygiene at the Kliniken Südostbayern AG in the districts of Traunstein and 21

Berchtesgadener Land districts. Since 2017, she has been in charge of several acute, specialist and rehabilitation clinics in her

in an independent capacity.

The expert gave her expert opinion, which is inserted here in full, as follows:

I will comment on the evidentiary questions, as far as I can see them from my professional background of infection control - with special regard to the transmission of infectious

of infectious agents and the development of infections. This applies

questions 1. and 3., which are answered in summary in part A., part B. and part C. of the

of the expert opinion, as well as to question 4.

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

To facilitate understanding of the expert opinion, I would like to provide some information in advance:

1. for the activity in hospital hygiene (= prevention of infections in the in connection with the medical care of patients, so-called nosocomial or hospital-acquired or hospital-acquired infections), one must have knowledge of the transmission transmission pathways of infectious agents, from which the infection protection measures necessary in individual cases (so-called hygiene measures) can be derived from this knowledge. Hand hygiene (usually in the form of hand disinfection) plays the most important role.

Masks (as a so-called surgical mask) have been used comparatively seldom outside the operating theatre

used comparatively seldom outside the operating theatre and then only selectively for close face-to-face contact with patients with respiratory infections. FFP masks (usually as FFP2 masks) were used almost exclusively when patients with open respiratory tuberculosis entered the room.

tuberculosis of the respiratory tract (or also during bronchoscopy of patients with suspected tuberculosis).

patients with suspected tuberculosis).

2 The transmission pathways of infectious agents can be presented as a brief overview as follows (further explanations will follow in the course of the report) expert opinion):

(a) Contact. (1) Transmission of pathogens through direct contact (= body contact) between an infected and a non-infected person.

infected person with a non-infected person. (2) Transmission of pathogens through indirect contact via shared objects or surfaces with which an infected person has previously had an infected person has had contact with or which have been contaminated with infectious person and which are subsequently used by an uninfected person. used.

In the case of both direct and indirect contact, the pathogens usually only reach the skin of the (still) infected person.

only to the skin of the (still) uninfected contact person, especially to the hands.

Respiratory viruses must then reach their ports of entry in the area of the mucous membranes of the upper respiratory tract.

mucous membranes of the upper respiratory tract (eyes, nose, mouth). This

usually happens through frequent and mostly unconscious hand-face contact. Presumably, a rapid sequence of the various steps is usually required for effective

steps is usually necessary for effective transmission of infectious pathogens with subsequent infection of the contact person.

subsequent infection of the contact person. Such contacts characterise the

of people living together, especially in the private sphere, but also, albeit less so, in the public sphere,

in the public sphere. Whenever several people are together in a confined space for a long

together in a confined space over a long period of time (e.g. conversations between colleagues during breaks, celebrations), 22

direct and indirect contact as well as droplets (see below) have to be considered as

transmission routes must be considered.

(b) Droplets. Special form of contact transmission through droplets ($> 5 \mu\text{m}$ in

diameter) of respiratory secretions in close vis-à-vis contact ($< 1 - 2 \text{ m}$) with a duration of at least

duration of at least 15 min between an infected and a non-infected person.

person.

For example, it concerns situations in which two persons are in close vis-à-vis contact at a distance of less than

face-to-face or face-to-face at a distance of less than 1 - 2 m and talk to each other.

face to face and talk to each other. In principle, it is possible that the infected person's

respiratory droplets released by the infected person when speaking onto the mucous membranes of the face of the

mucous membranes (eye, nose, mouth) of the person opposite and not (yet) infected.

(eye, nose, mouth), i.e. that the pathogens are transmitted in this way.

For decades, contact transmission and droplet transmission have been considered to be the most

epidemiological studies as the decisive transmission routes for respiratory pathogens.

for respiratory pathogens.

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

Transmission of pathogens through the air (aerogenic transmission) was previously only considered to be possible in the case of

tuberculosis of the respiratory tract (lungs, larynx) and is in fact the only natural transmission

tuberculosis, but only if the infected person has a so-called open tuberculosis.

person has a so-called open tuberculosis of the respiratory tract, whereby the tubercle
tubercle bacteria are released via the exhaled air of the infected person. The person thus infected
with
air of the room contaminated with the tuberculosis pathogens is inhaled by the persons
persons present at the same time (or by persons who only enter the room after the infected person
has left it again),
after the infected person has left the room). Airborne tubercle
tubercle bacteria suspended in the air can penetrate into the alveoli (= alveoli of the lungs), and that
is
and this is exactly where these pathogens must reach in order to trigger tuberculosis in the first
place.

tuberculosis. However, whether other people who breathe this air in the room are exposed to the
contact with the pathogen required for an infection to occur depends, among other things, on the
the size of the room and thus its air volume, the ventilation of the room and thus the
ventilation of the room and thus on the dilution of the pathogen in the air, and last but not least on
the
the amount of the pathogen that the infected person releases (or has released), e.g. when coughing.
coughing) and thus on the probability that other people will come into contact with contaminated
inhalation come into contact with contaminated air.

It was precisely this transmission route that was identified in the spring of 2020 soon after the
appearance of

Sars-CoV-2 as a significant transmission route for this new pathogen. In the
2020, the idea of so-called aerosol transmission of SARS-CoV-2 has been
in the international literature as well as in the media - but not supported by corresponding
international health authorities - has become so dominant that for months now it has been
that for months now various 'hygiene measures' have been called for (e.g. air
(e.g. air purification devices, ventilation) to reduce this allegedly high risk (see part C.).
(see part C.). With regard to influenza viruses, it has already been discussed for years
whether they might also be airborne, but there was no confirmation of this.
no confirmation. De facto, no measures were ever taken in hospitals to protect
measures to protect against the transmission of the pathogen have never been established.
transmission via the air. The recommendations of the RKI, for example, did not and still do not
provide for this.

do not provide for this.²³

3 Very many results from studies on the effectiveness of non-pharmaceutical non-pharmaceutical interventions to contain the pandemic, such as masks in the public masks in the public, are based on mathematical modelling, the specifics of which are will be briefly described here:

Mathematical modelling (also known as mathematical estimation) is familiar from weather forecasting and climate research, but have also been used for many years to predict the for many years to predict the course of epidemics and the influence of various preventive measures. prevention measures. They are used especially when there is little meaningful data from direct studies. In a very large part of all studies on SARS-CoV-2 (e.g. effectiveness of masks) are mathematical mathematical modelling, which is of very limited value, because their results do not reflect 'real' life, but are based on assumptions.

are based on assumptions. The results depend on these 'adjusting screws' and therefore reflect a simplified picture of reality.

simplified picture of reality. Such studies can therefore always

only provide 'if-then' results. On the one side of the spectrum, there are purely theoretical theoretical modelling and, on the other, those that work with as much clinical epidemiological data as is available. However, the

results are very limited, and the quality of the scientific evidence is moderate at best.

evidence is moderate at best. The results of such studies in the context of

SARS-CoV-2 are often overestimated in their relevance to reality and, if positive

overestimated and, if the results are positive, taken as proof of the effectiveness of measures.

measures. This could be observed repeatedly in the course of the pandemic, and

even among scientifically active physicians and bioscientists.

Answering the evidence questions

1. can the wearing of different types of face masks reduce the risk of infection with the SARS-CoV-2 coronavirus (appreciably)? A distinction should be made between children in and adults in general, and between asymptomatic, pre-symptomatic and symptomatic patients, pre-symptomatic and symptomatic people. 3.

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

A. Masks

This section outlines the literature supporting the effectiveness of masks in public places (e.g. shops, public transport, schools, offices, etc.), which published studies exist that speak against the effectiveness of masks, and what statements are made about the transmission of pathogens from asymptomatic, pre-symptomatic and symptomatic persons. All statements apply equally to adults, adolescents and children equally.

The RKI's 'reassessment': What was the justification for masks?

The background and basis for the introduction of compulsory masks everywhere in Germany was the so-called 're-evaluation' by the Robert Koch Institute (RKI) [1].

The 're-evaluation' of the RKI led to the fact that masks are not required for the protection of the wearer (= self-protection).

self-protection, especially for medical staff during patient care in hospitals), but for the protection of other people (= source control, i.e. for the protection of other people).

control, i.e. to protect other people from the source of the pathogen), 24

but not by people with symptoms of an upper respiratory tract infection (sore throat, cold (sore throat, cold, cough), but by - clinically - healthy people (the people with symptoms should be people with symptoms should stay at home anyway).

The RKI recommends masks in public ('... as another building block to protect risk groups ...' [1]), so that the wearer of the mask, who is perhaps already unnoticed and already excreting the pathogen in the respiratory secretion, will not be able to release respiratory droplets unhindered, e.g. when speaking. The droplets are to be held back to a large extent by the mask, in order 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 (cannot) know it yet because they do not have any symptoms (pre-symptomatic).

(pre-symptomatic) or who will not develop any symptoms at all (asymptomatic), all other people they meet from possible contact with the pathogen by wearing a mask.

contact with the pathogen. Ultimately, this is intended to directly or indirectly protect in particular those

people who, due to old age and / or certain chronic diseases, are at a higher

chronic diseases, have an increased risk of severe infection by SARS-CoV-2.

because, as is well known, the virus does not pose a danger to anyone else (this also applies to (according to current knowledge, this also applies to the new variants), because they are either, as is typical for

either become more seriously ill for one to two weeks and have to stay in bed (e.g. with (e.g. with fever, aching limbs and cough), but in most cases they only develop mild respiratory symptoms.

develop only mild respiratory symptoms (as with a common cold) or even do not get sick at all. do not get sick at all.

About the possible benefit of masks for the protection of fellow humans (foreign protection) against clinically healthy, but already infected and thus potentially infectious people

In the spring of 2020, a discussion developed in the international professional public that masks should not be worn for self-protection, but out of 'altruism and solidarity' (= external protection) [2].

protection of others) [2]. This ultimately led to the mask recommendation of the of the RKI, which is therefore about 'protection of others' - and not about the protection, especially of persons from risk groups. This was true at least until January 2021.

The fact that self-protection also plays a role because of the new variants of the virus, was only then emphasised by the politicians, and the obligation was justified, to wear medical masks (surgical masks or FFP2 masks) instead of everyday fabric masks. masks). For all persons who do not have to deal professionally with the way in which infectious agents are transmitted, masks as protection against a respiratory virus are virus, whereby the idea of self-protection is certainly the leading factor.

is always leading.

At no point in the article about the 're-evaluation' does the RKI explicitly say that there is a scientific basis (in the sense of scientific proof or evidence) for the use of the virus.

= evidence) for the use of masks in public [1]. This conclusion is merely suggested by the ambiguous wording of the text. The

The RKI article was published online in advance, as is often the case in journals today, on 14 April, i.e. immediately after Easter 2020, so that the RKI's

RKI's statement was thus available for the federal government's decision on the the first lockdown measures, which were announced for one week after Easter 2020.

were announced, was available in good time. The statement did not appear in print until 7 May 2020, i.e. about a week after the introduction of the mask requirement (and this date is - see below - is still relevant). It is interesting that the president of the RKI on 28 April 25 2020, i.e. on the day of the German government's decision to make masks compulsory, in an interview with the 'Deutsches Ärzteblatt'.

the 'Deutsches Ärzteblatt' (German Medical Journal) about the 'low added value' of masks. which would only come into play if they were used 'correctly' [3].

The official presentation of the RKI's mask recommendation in [1] was soon modified somewhat. modified, because only six days after the print version of the article of 7 May 2020, the RKI commented on 13 May 2020 under the heading 'Answers to Frequently Asked Questions (FAQ)', the RKI was cautious about the protection provided by masks:

'A protective effect has not yet been scientifically proven, but it appears to be plausible.

However, this was not the end of the story, because since 15 July it now reads now reads:

'There are now first scientific indications for this external protection by MNB (= mouth-nose-covering).

first scientific evidence.

This description is still up to date, most recently in the version of 17.02.2021.

However, indications are not proof. The question arises: What are 'first scientific indications'? scientific indications' and moreover: why 'in the meantime'? The evidence should in itself already been given with the publication of the mask recommendation [1]. I have

e-mail dated 19.07.2020 to the RKI asking for the scientific literature on which this statement is based.

the scientific literature on which this statement is based and received a list of publications by e-mail of 21.07.2020.

of publications, which I will discuss in the further course of the expert opinion.

In the following, I would like to evaluate the recommendation of the RKI [1] on the basis of the literature cited therein.

literature cited therein. Subsequently, the more recent publications will be presented, which are thus which were published after the RKI's contribution and which are considered by scientists and the media as evidence for the effectiveness of masks in the public.

Finally, the publications that did not find any benefit of masks are listed.

of masks.

The RKI recommends in its paper

'a general wearing of a mouth-nose-covering (MNB) in certain public situations in public places as a further building block to protect at-risk groups and reduce groups and to reduce the infection pressure and thus the rate of spread of COVID-19 in the population'.

This recommendation is based on

'based on a re-evaluation of the growing evidence that a high proportion of the (emphasis added for this report) of transmission is undetected, even before disease even before the onset of disease symptoms'.

In its contribution, the RKI states that a 'high proportion of transmissions go unnoticed'. 'unnoticed', but does not refer to a source for this. In the literature list of the of the article, however, there are two publications to which the RKI presumably referred when the RKI's statement (and in the text, perhaps only the references to them were forgotten). One is a mathematical estimate according to which the pre-symptomatic transmission is very high.

pre-symptomatic transmission was very high, between 48% and 77% [4].

between 48% and 77% [4]. The result of the second publication is also based on a mathematical estimate with a very high pre-symptomatic transmission rate of 79% [5].

[5].

The RKI website states under FAQ > Infection protection measures > What is to be done What should be considered when wearing an MNB in public?' of 15 July and 21 August then then no longer 'high proportion', but only 'certain proportion', and finally in the FAQ since 7 September (most recently in the version of 17.02.2021) to speak of a 'relevant proportion'. (emphasis added for this report). Literature references are not available there (and are also not common in the FAQ).

However, the RKI makes a reference to this in a later article (online in advance on 23.09.2020) [6]. In this article entitled 'Weighing up the duration of quarantine and Isolation for COVID-19' it states:

'For example, He et al. demonstrated that presymptomatic transmission was responsible for a large proportion (44%) of SARS-CoV-2 transmissions, ...'.

In the cited publication by He et al. a mathematical estimation is made based on assumptions about how the viral load might be distributed in the respiratory secretions before the onset of symptoms [7]. This article was published on 17 August 2020 (i.e. a good five weeks before online publication).

weeks before the online publication of the new RKI article [6]).

which has since been referred to directly before the beginning of the text when accessing the article by He et al.

before the beginning of the text. 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 literature references in the cited article).

It follows: In the evaluation of real contact scenarios, significantly lower rates of pre-symptomatic rates of pre-symptomatic transmission were found, 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] cited by the RKI in [1, 6] are theoretical results, which are significantly higher than real results from reality (see below).

Evaluating contact constellations from contact tracing studies is tedious and lengthy.

tedious. However, when clarifying such questions, it is important to evaluate real-life scenarios, because then it also becomes clear what kind of contacts were involved.

contacts were involved. For example, in the study from Singapore it was determined that in 7

contact evaluations, 3 x (married) couples and 1 x a member of a shared apartment were affected by pre-symptomatic

pre-symptomatic transmission of the pathogen, i.e. situations with close, continuous

contact, in the case of the couples even with mucosal contact [10]. In such

situations, pre-symptomatic (as well as asymptomatic) transmission is to be expected.

(and yet they are rare; see below). The situation is different with contacts in public spaces between people who do not get (that) close to each other or at most close to each other or at most pass each other briefly or stand behind each other.²⁷

In its article [6], the RKI neither takes into account nor quotes the critical article [8] that which was published in mid-August long enough before the RKI's online pre-publication, nor does the RKI address the even earlier published studies from China (published in June 2020) [6]. (published in June 2020) [9] and / or Singapore (published on 1 April 2020) [10], which are cited in the critical article [8].

cited in the critical article [8]. The RKI therefore does not adhere to the rules of evidence-based medicine to include all available data from scientific studies in its considerations. scientific studies into its considerations. Instead, the RKI refers to only only one study, which theoretically determined a very high rate of presymptomatic very high rate of pre-symptomatic transmission. The rates determined from real scenarios in from real-life contact tracing scenarios, which are much lower, are not listed.

are not listed. This makes the risk of pre-symptomatic, transmission appears high, and according to the RKI, this was the reason for the 'reassessment' ("unnoticed").

for the 'reassessment' ('high proportion'). According to the rules of the (in Germany so-called) (in Germany so-called) evidence-based medicine, it is not comprehensible that the the critical statement [8] and the articles from China [9] cited therein, which had been from China [9] and Singapore [10] and thus did not discuss them. discussed.

The same can be observed in a review published in mid-September 2020 by other authors.

systematic) review by other authors published in mid-September 2020, which is cited by the RKI in the COVID 19

is cited [11]. Not only is the relevant literature on the topic in question missing (so that it is de facto not a systematic review), but it is also not a systematic review.

de facto it is not a systematic review), which reports much lower asymptomatic or asymptomatic or pre-symptomatic transmissions, but all the results are presented together without all results are presented together, without differentiating between epidemiological epidemiological context: There is, however, a significant difference between whether a transmission takes place in families, where close physical contact and mucous membrane

contact with the mucous membranes, or in public spaces, where such contact between people does not

people do not normally come into contact with each other. It is therefore important in such studies to evaluate the

settings separately.

In any case, it is inadequate in scientific discourse (and especially in systematic reviews) when selective

inadequate in scientific discourse (and especially in systematic reviews), because a selective, and therefore at least potentially

selection of publications is not part of today's established scientific principles.

scientific principles. Thus, the basis for the 're-evaluation' of the RKI is missing,

because the 'unnoticed transmission' has not been proven by scientific data.

and this was already true when the RKI article appeared online in April 2020 [1]. However

the same time, the topic was being discussed internationally (e.g. CDC), so that the

RKI may simply have joined this trend [12].

The fact that infected persons are potentially infectious even before the onset of symptoms (and in

infectious before the onset of symptoms (and usually even excrete more viruses than during the

phase of the disease), has been known for a long time from other viral infections whose

whose pathogens are also excreted in the respiratory secretions (e.g. influenza).

(e.g. influenza, measles). The fact that this is also the case with the new coronavirus was therefore

This was therefore nothing new or expected by experts. Since mid

February, there have been reports about the new coronavirus in the international literature.

international literature (compilation in [13]). This also applies to all

respiratory infections that are asymptomatic (e.g. influenza in approx. 1/3 of all cases; see

cases; see RKI guidebook), i.e. these people are also potentially or in principle infectious for those around them.

in principle infectious to their environment.²⁸

In reality, however, this only means that it is possible, but not that these persons will

necessarily spread the respective pathogen: The extent of ('unnoticed') pathogen

spread of the pathogen in the case of pre-symptomatic or asymptomatic excretion of the virus

there are now further data showing that this is only a small proportion (see below).

(see below).

A WHO scientist, Dr Maria van Kerkhove, made the following comments at a WHO press briefing in Geneva as early as 08.06.2020 [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 contact tracing studies, as discussed above. One

The day after, the same WHO staff member clarified [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 relativises her clear position of 08.06.2020 a little on the following day, but did not revise it, the WHO's statement remained the same, namely that that most transmissions come from people who have symptoms, and that it is not clear how many transmissions are due to people who do not (yet) have symptoms. have symptoms.

All in all, the excretion of the virus before the onset of clinical disease is nothing new.

new, but could also have been included in the considerations for the new coronavirus from the beginning.

could have been included in the considerations from the very beginning. However, it was implicitly presented by the RKI as if this had been

('growing evidence' [1]), and was picked up by the media, like so many other things.

media, like so many other things, without asking how it actually relates to other virus infections, which would have been obvious.

It has therefore been known for a long time that in the case of numerous viral infections (incidentally also in the case of

gastrointestinal infections, e.g. noroviruses, in which the pathogen is excreted via the intestine).

intestine), infectiousness does not begin with the onset of clinical symptoms,

Rather, infected persons can already excrete viruses at the end of the incubation period.

and in large numbers, if they do not even suspect that they have an infection (e.g. they are infection (and will be sick the next day, for example). For a numerically 'relevant' (according to the RKI since 7 September, however the term is meant) role of the asymptomatic persons in the transmission of the new coronavirus.

no evidence, however. This is most likely due to the fact that in infected individuals.

without the clinical symptoms of an upper respiratory tract infection, i.e. without coughing and sneezing.

coughing and sneezing, transmission of the pathogen occurs mainly in close contact, i.e. in particular mucosal contact, such as in couples and families, but not as a rule in the mostly very short the usually very brief encounters of people in public spaces, as well as in schools.

in schools. The theory of aerosol transmission is presented and discussed in Part C.29

As an important example of transmission from asymptomatic or pre-symptomatic individuals pre-symptomatic persons, the outbreak at the Webasto company near Munich was cited [16].

Munich [16]. The authors of the report - published in the New England Journal of Medicine (NEJM; one of the two most respected medical journals in the world, along with The Lancet)

journals), even if only as a 'letter to the editor' (but quickly because

without peer review) - assumed that the Chinese employee (the so-called

(the so-called index case or patient 0), who had arrived from Shanghai shortly before and was Shanghai and was already infected, had no symptoms during her stay in Germany.

symptoms during her stay in Germany. However, this turned out to be incorrect only a few days after the publication.

publication and was made public by a science journalist at the beginning of February [17].

by a science journalist at the beginning of February [17]. According to the state of health of the

Chinese employee's health, the authors had only asked the German employees of the

German employees of the company on site and not the employee herself. Only the Bavarian State Office for Health

and Food Safety (LGL) and the RKI contacted her directly shortly after the publication.

contacted her directly. During the telephone conversation (with a Chinese interpreter), it emerged that the

that the employee from China had already been (slightly) symptomatic during her stay in Germany.

was already (slightly) symptomatic during her stay in Germany and had been given a one-time pain and

anti-inflammatory drug (paracetamol) [18]. This first

publication on the case therefore had to be supplemented by a precise description of her state of health during her stay.

of her state of health during her stay in Germany. Since then

Since then, if you access the article at the NEJM, there is also a corresponding

supplement. The title of the article has remained the same and thus still suggests an

asymptomatic' transmission. Also and especially with this, i.e. only apparently

asymptomatic case, the compulsory use of masks in Germany was justified. In the full description of this

a few months later, there was no longer any mention of asymptomatic transmission.

asymptomatic contact [19].

In September 2020, a further article (systematic review with meta-analysis as a

December as the final publication) on the proportion of asymptomatic cases in all cases and the

of all cases and the extent of asymptomatic transmission [20].

According to this, asymptomatic transmission was very rare (between 0% and 2.2%)

and symptomatic transmission was more frequent (between 2.8% and 15.4%), but in 4

of the 5 studies, with a maximum of 5.1%, were also rare, and were thus in any case significantly less frequent,

than would be expected for symptomatic persons. The relative risk

of asymptomatic transmissions was not significant in the evaluation of these five studies, which reported on

secondary infections in asymptomatic and symptomatic individuals,

from asymptomatic cases was 42% lower than from symptomatic cases.

from symptomatic cases. The authors conclude that it is

unlikely that asymptomatic transmission is a significant driver in the emergence of clusters.

clustering (temporal and local clustering or outbreaks) or transmission of infection to the public.

transmission of infection in the general public, and therefore the importance of asymptomatic

asymptomatic cases in the spread of infection should be viewed with caution. The

authors also criticise the unclear definitions of asymptomatic cases in the studies they have

the studies they analysed. This could lead to asymptomatic cases being confused with

asymptomatic cases with mildly symptomatic cases (see above [16]). If this

frequently, the frequency of true asymptomatic cases would be much lower, and so would their

would be significantly lower, and so would their proportion of transmissions.

At the end of November 2020, a study was published from China that reported the result of a PCR screening programme.

of a PCR screening programme across Wuhan between 14 May and 1 June 2020

reported [21]. Almost 10 million (!) people were screened. New

symptomatic cases were not found, but 300 asymptomatic people were. At

No positive cases were found among the close contacts of these asymptomatic persons (N = 1,174).

positive case. Thus, there was no indication of asymptomatic transmission, even though

only close contacts were examined.

A systematic review with meta-analysis on Corona transmission in households was published in December 2020.

was published in December 2020 and, as expected, found a higher transmission rate

from symptomatic index cases (18.0%) than from asymptomatic index

asymptomatic cases, where the transmission rate was as low as 0.7% [22].

This result is of particular interest because (albeit for different reasons) there is a consensus that

reasons) that the risk of respiratory transmission of pathogens is higher indoors than outdoors.

transmission is particularly high indoors, and outside buildings, i.e. in the 'fresh' air, is too low.

air, but nevertheless the asymptomatic transmission rate in households was extremely low.

transmission rate in households was extremely low, despite the fact that in relatively close

with numerous direct (also via the skin and mucous membranes) and indirect contacts

and indirect contacts, and thus it is almost impossible to avoid contact with the pathogen if a

member of the

member of the household is infected. Therefore, if pathogen transmission starting from

asymptomatic persons should play a role, this should be particularly evident in the case of close skin contacts,

i.e. close skin and mucous membrane contacts in households (= indoors). How

the risk must be that a transmission of the pathogen from asymptomatic persons in the

asymptomatic persons during fleeting contacts in public spaces,

has never been investigated. Nevertheless, despite this data, almost 80 million people in

million people in Germany are still exposed to the virus on numerous occasions in public,

even outside enclosed spaces (and this is considered pointless even by aerosol physicists; see part C.).

even by aerosol physicists; see Part C.).

In January 2021, another mathematical estimate appeared on the question of how often

asymptomatic persons transmit the new coronavirus [23]. On the basis of their assumptions, the authors

based on their assumptions that at least 50% of all new SARS-CoV2 infections are due to contact with asymptomatic persons, a result as is

modelling studies: high transmission rates, but no real contact evaluations.

contact evaluations.

A further review (a so-called 'living systematic review', i.e. for which updates are planned on an ongoing basis) was submitted in September 2020.

planned) was submitted in September 2020 and accepted in January 2021 [24]. The

international team of authors wanted to determine the probability that infected

infected persons with different symptom statuses are infectious to contacts, so that there are

secondary cases with detection of SARS-CoV-2 occur. For the analysis of the rate

secondary cases from asymptomatic persons, 10 studies could be analysed.

were analysed, resulting in an overall transmission rate of 1%. For

the overall transmission rate was 6% for symptomatic cases and

pre-symptomatic cases, the transmission rate was 7%. This evaluation of real-life studies again showed that

again showed that starting from asymptomatic people results in significantly fewer secondary

secondary cases than from symptomatic or pre-symptomatic persons, who are also rarely associated with secondary cases.

were also rarely associated with secondary cases. Most of the transmissions could be

secondary cases lived together with the index cases or that the pathogens were

cases or that the transmission of the pathogens was due to group activities, such as

meals or board games, all of which are again direct contact situations with indirect

direct contact, indirect contact or droplet contact (vis-à-vis < 1 - 2 m).³¹

The probability of transmission presumably also depends on the virus concentration

respiratory secretions, as was shown in a study conducted in Spain in spring 2020 [25].

25]: the transmission rate ranged between 12% at a concentration of

a concentration of < 10⁶ RNA copies per mL and 24% at ≥ 10¹⁰ RNA copies per mL

in respiratory secretions. The duration until the onset of the first symptoms was shortened

successively with increasing virus concentration: 7 days in individuals with initially < 10⁷ RNA copies

per mL, 6 days in individuals with concentrations between 1 x 10⁷

and 1 x 10⁹

RNA copies per mL and 5 days for $\geq 1 \times 10^9$ RNA copies per mL. A large proportion (approx. two-thirds) of the cases included in the study were not associated with secondary cases. Transmission events were significantly more frequent from index cases with high virus concentrations in respiratory secretions. Similarly, exposure in a shared household was associated with a higher risk of transmission, although there was no association with the presence of cough in the index case. The authors conclude from the results of their study that the viral concentration in the respiratory secretions plays a more important role than the presence of typical respiratory symptoms such as cough in particular. A connection with the use of masks in terms of a reduced risk of transmission. (the authors of another study [26] came to the same conclusion). Due to the importance of the virus concentration in the respiratory secretions, the authors suggest that the risk of transmission should be assessed using the measured RNA concentrations.

The measured RNA concentrations into low to high risk.

They receive support for this in an accompanying commentary to their article [27]. There it is stated that the presence of low RNA concentrations in the respiratory secretion is a problem both for the person tested positive and for his or her contacts, because all of these persons are at risk.

contacts, because all these persons are threatened with unnecessary quarantine measures. If one had not only qualitative test results, i.e. 'positive' (= virus RNA detection) or 'negative' (= no viral RNA detection), but quantitative results (i.e. the number of RNA copies per mL of respiratory secretion of each person tested positive), the risk of transmission could be assessed in each individual case - and avoid unnecessary quarantine measures in many cases. The indication of the Ct values (cycling threshold: low values = high viral load in the initial sample) would be, only a semi-quantitative indication of the number of RNA copies per mL, would in any case be better than the purely qualitative results. However, since the Ct values are also dependent on the different PCR devices (cyclers) available in the different laboratories (cyclers) available in the different laboratories and the test reagents used in each case, the results from the same laboratory can be compared with each other, but they cannot be

with the results of other laboratories, as long as each laboratory does not use external calibration curve on the basis of external reference samples with a defined concentration. comparison of one's own laboratory results with the results of external laboratories. possible. The WHO also pointed out in its information of January 2021, that, on the one hand, the Ct values should be indicated in the findings and that, on the other hand the test results must always be seen in connection with the anamnesis and clinical findings [28]. clinical findings [28].

Since the appearance of the new coronavirus, PCR tests are increasingly being carried out on clinically healthy persons.

healthy persons since the appearance of the new coronavirus, contradicts an old rule in the (serological)

(serological) diagnosis of infections (antibody detection), which one learns in medical school, that one should not treat 'titres' but only patients, i.e. one should make a treatment

treatment should depend on whether the patient has symptoms that can be reconciled with the result of the laboratory examination.

the laboratory test, because laboratory results often have no meaning for the individual patient.

often have no meaning for the individual patient. This principle was abandoned with the new

coronavirus: people without clinical symptoms are examined and, if they are positive

positive PCR, they are declared 'infected' - and sent into quarantine, among other things, and this with a test, the

PCR, a test that is known to detect traces of nucleic acid in a sample.

in a sample.

Moreover, a PCR only ever detects the genetic material of the respective virus (in the case of RNA in the case of coronaviruses) is detected by multiplying (= copying) it until the PCR device indicates a positive result.

the amount of virus material in the initial sample. The relationship is

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

vice versa.

However, whether the RNA originates from viruses that are capable of infection and thus of replication (= replicable) or not.

replicable) viruses cannot be determined with PCR. In order to

infectivity, one would have to try to grow the virus in a cell culture from the same sample.

from the same sample in a cell culture. However, this does not mean that the detected virus

virus would be able to cause an infection in a person who is in principle susceptible (see part C).

infection in a person who is in principle susceptible (see Part C.). Therefore, if in connection with a PCR

virus detection', this is not correct in itself: it is a simplification (although one says 'virus').

simplification (one says 'virus' but only means the genetic material).

Summary of the 're-evaluation' of the RKI

The RKI gave as a reason for the 'reassessment' of masks for the population in the public space [1] was that there was 'increasing evidence' that infectious diseases could be symptoms appear, i.e. at a time when there is no evidence that one is infected.

there is no evidence that one is infected. However, this has long been known

other viral infections and does not mean that the pathogen is actually transmitted.

actually transmitted, but only that transmission is possible depending on many other

other factors. The RKI relied on the following as evidence of this

high risk of so-called unnoticed transmissions, the RKI relied on mathematical estimates

mathematical estimates that used their models to calculate a very high proportion of such

of such transmissions. However, the RKI omitted results from contact tracing studies published previously (i.e. before the publication of the RKI article), from which more realistic data were determined.

were determined, were omitted. This is not compatible with the principles of scientific work

and thus the RKI does not take into account the mandate formulated for all authorities etc. in § 1 (2)

IfSG, 'according to the respective state of medical and epidemiological science ...'.

epidemiological science ...'.

Significance of experimental mask studies

For as long as masks have existed, there have been studies on the filtering effectiveness of various materials (be it for the normal medical so-called surgical masks, also called surgical masks, or the surgical masks, or FFP respirators), and each manufacturer has to meet various testing and every manufacturer must fulfil various test criteria in order to be able to market the various masks.

We will not go into this in detail here, as the mask issue under discussion in this report is not about question under discussion in this report is not whether the masks themselves are effective in principle

material, i.e. whether they are effective in filtering larger and smaller to the smallest particles.

particles, but whether they are effective in the given epidemiological situation, for which 33

which the mask obligation was introduced at the end of April 2020 - namely for the normal population in the so-called public space, which soon also included schools - they have a benefit. Such a benefit, for example when shopping for groceries, looking for clothes in a fashion clothes in a fashion shop or when travelling by public transport, cannot depend on the respective the respective filter effectiveness of the masks used, but - on the basis of the possible the possible transmission pathways of the pathogen - but only from the concrete possible contact situations between people standing next to each other or behind each other, or people or passing each other from behind, even if the distance between them is very small (up to distance is very small (up to crowding)).

The most important criterion for assessing the associated risk of infection is that these contacts are short, even if the distance between them can be close, which can happen normal' times. In the epidemiological context of encounter of people unknown to each other in public spaces, sufficient contact with the contact with respiratory infectious agents sufficient for pathogen transmission is therefore almost almost always extremely unlikely. 'Almost always' here means: as long as someone does not directly coughs directly into the face of another person at a short distance (which is hardly ever public, other than perhaps in private) or as long as one does not have a (prolonged) as long as one does not have a (longer) conversation, i.e. of at least 15 minutes duration, and and do not keep at least 1 m distance from each other. This duration (as also stated by the RKI) is derived from epidemiological studies, in which it was recognised in the analysis of the contact situations, it was recognised that in the case of respiratory infections, it is important for an infected person and a non-infected person to be in face-to-face contact, but that this contact also requires a certain and not too short minimum period of time.

a certain and not too short minimum time for pathogen contact to take place at all.

can take place at all. A short contact, even if one should feel the other person's

breath of the other person as they pass, is not associated with a realistic risk of pathogen

transmission of the pathogen. However, if conversational contact of presumably longer duration should occur

of presumably longer duration should occur in a public space, one can simply keep an appropriate distance.

distance. It is therefore not necessary to make masks compulsory for all people in order to avoid such potential contact with pathogens, and all other risks of transmission ('unnoticed' transmission) can be

transmission ('unnoticed' transmission and 'aerosol' transmission) are not supported by the necessary

scientific data and thus remain hypotheses - if necessary until appropriate

evidence.

In this respect, when assessing whether masks are 'effective' in public spaces, the question is not the question of what filtering effectiveness professional or fabric masks are likely to have,

apart from the fact that one can never make an even remotely accurate statement about

(even self-sewn) fabric masks. There is also the question of whether

fabric masks can be made 'better' for the protection of public health does not arise either [29].

[29]. Similarly, the question of what improvement can be made with the use of medical

masks (OP or FFP2 masks), which have been compulsory since the beginning of 2021 for shopping and on public

is completely open, because the basic effectiveness of masks (of whatever type) is not

masks (of whatever type) depends on how they are used, i.e. whether they are worn correctly at all (see part B).

worn correctly at all (see part B.). In any case, the way the population has been

masks for a year (regardless of whether the - often self-sewn - fabric masks were worn for nine months or since the beginning of 2021).

masks or, since the beginning of 2021, medical masks), masks are ineffective because they do not

they do not fit tightly to the face and by no means always cover the mouth and nose, and

if not even adults can properly handle masks of any kind,

how can children? Masks that are not used 'correctly' (as the 34

President of the RKI), are also a potential contamination risk due to the frequent hand-face contact.

a potential contamination risk (see Part B.).

So if it is established that masks 'work' because the material can, in principle, retain droplets and particles, this is not a basis for proving that the masks are actually effective.

that the transmission of the new coronavirus is prevented or at least reduced and the 'infection

transmission of the new coronavirus and to reduce the 'infection pressure and thus the

spread of COVID-19 in the population' can be reduced [1].

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

This would require data from appropriately informative epidemiological studies.

studies.

The scientific basis of the RKI

Whether the RKI had such data or whether they were only presented by other authors after the publication of the RKI article, and which data are actually cited as evidence, will now be presented.

will now be presented in the following. These explanations are

necessarily extensive, because a substantial part of these publications by scientists and the cited by scientists and the media to prove that masks are effective.

masks has been proven. However, in order to be able to answer the question as to whether these these studies are actually suitable for this purpose, they must be examined in detail.

1st study from Hong Kong

In its article [1], the RKI attached a lot of importance to a study from Hong Kong, which was published in spring

published in spring 2020 and has since been widely cited internationally in the SARS-CoV-2 literature [30].

cited internationally [30]. It will therefore be presented here in detail.

In its paper, the RKI, in presenting the differences between medical

masks (mouth-nose protection = MNS) and FFP masks, the RKI referred to a 'current' study in which it could be shown that

in which it could be shown

'that (an) MNS also leads to a relevant reduction in the excretion of respiratory respiratory viruses via the exhaled air (...)' [1].

By 'recent' study, reference was made to the study from Hong Kong. This study was

as stated by the authors in their article, was conducted between 2013 and 2016 and was therefore and was therefore no longer up to date when the RKI article appeared:

The study was only published 'up-to-date' after the appearance of the new coronavirus, and the RKI therefore knew that.

the RKI knew that.

In this study, medical masks (professional surgical masks) were used.

were used. Primarily, 246 patients were selected for the study who had been admitted for respiratory symptoms of various causes in the outpatient department of a clinic in

Hong Kong. However, the study ultimately focused only on 111 patients

influenza viruses (N = 43), rhinoviruses (N = 54) or seasonal human coronaviruses (N = 54).

coronaviruses (N = 17), whereby three times two of the viruses were detected (all RNA viruses). The patients were asked to participate as subjects in a study,

in which the extent of the release of (1) respiratory droplets and (2) aerosol containing viral RNA in exhaled air. The RNA detection was carried out by means of RT-PCR (= real-time polymerase chain reaction).³⁵

In a randomised manner (= randomly assigned), the test persons were given either an operating mask

either an OP mask (which the study directors ensured was correctly fitted) or no mask.

mask, in order to determine to what extent the mask had an influence on the release of the (respective) viruses.

(respective) viruses, i.e. would reduce the release of viruses into the environment. In itself planned to study all subjects once with and once without the mask,

However, most of them (80%) refused a second examination for reasons of time.

the exhaled air was collected for 30 (!) minutes. The

particles were divided into two fractions (1) $> 5 \mu\text{m}$ (= droplets) and (2) $< 5 \mu\text{m}$ (= aerosol particles).

$5 \mu\text{m}$ (= aerosol particles). The results must therefore take into account

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

the same subjects in the two groups 'with mask' and 'without mask', although this was in intention.

A remarkable result of the study, which was not taken up by the RKI, is the following.

by the RKI is the following: Although all participants had an acute viral infection of the upper respiratory tract

respiratory tract (with concentrations of 10^7 - 8 RNA copies per sample in the nasal secretion and

of approximately 10^4 RNA copies per sample in pharyngeal secretions), without a mask only 6 of 23 (with influenza virus infection), 9 out of 32 (with rhinovirus infection) and 3 out of 10 (with corneal infection).

of 10 (with infection by coronaviruses) of the samples taken, droplets with evidence of viral

virus RNA were found. Aerosol particles containing viral RNA were collected under the same

conditions, i.e. also without a mask, only in 8 of 23 (influenza viruses), 19 of 34 (rhinoviruses) and (rhinoviruses) and 4 out of 10 (coronaviruses) of the samples.

So even without a mask, despite acute viral infection of the upper respiratory tract (with

(with high virus concentrations in the respiratory secretion), only a few samples showed any virus RNA detection at all. This result shows that - in contrast to what is commonly assumed - a

person with an acute upper respiratory viral infection does not necessarily release a high number of viruses.

a high number of viruses.

And with mask, the results looked like this: Virus RNA detection in droplets could be detected in 1 out of 27 (with influenza virus infection), in 6 out of 27 (with rhinovirus infection) rhinoviruses) and 0 out of 11 (with infection by coronaviruses) of the samples taken. samples. In aerosol particles, virus RNA detection was possible in 6 out of 27 (influenza viruses). (influenza viruses), in 12 of 32 (rhinoviruses) and in 0 of 11 (coronaviruses) of the samples. possible.

In its article, the RKI makes a 'relevant reduction' in the excretion of 'respiratory viruses' from these partial results.

excretion of respiratory viruses via the excretory air' by masks [1]. But the

However, the RKI does not indicate how low the virus concentrations in droplets and aerosol particles were even without a mask (see below). In addition, the RKI only singled out

the result in test persons infected with one of the seasonal coronaviruses, as if it could be

as if this could show that masks 'work' with coronaviruses and thus also with SARSCoV-2. In the subjects with the influenza or rhinovirus infections, there were

hardly any differences between the groups with and without masks.

The RKI also did not take into account that such an effect can only be achieved if masks are correctly if the masks are correctly fitted, which was ensured by the study leaders for each individual subject.

individual test persons. No one, however, is available to help the (completely untrained)

people in public (who are completely untrained) how to wear masks correctly so that they can

(have to be) worn correctly in order for them to be effective in principle. But even then, whether they are effective in the

epidemiological context (e.g. shopping, public transport, schools, offices).

would be effective in the given epidemiological context (e.g. shopping, public transport, schools, offices) would have to be shown by corresponding studies, which do not exist.³⁶

However, the results are also special due to the fact that in the samples in which

virus RNA was detected at all (both with and without masks), the RNA concentration in droplets and in aerosol particles was consistently extremely low (mostly only

100

1 RNA copy per sample and only occasionally somewhat higher values, which were also found in the samples with masks.

the samples with mask; the detection limit was 0.3 RNA copies per sample), so that only the few

only the few higher values ('outliers') could be compensated for by the mask.

very low values in view of the high values in the respiratory secretion.

secretion.

Considering the efficient collection technique and the (long) collection time of 30 minutes, the authors concluded that

the authors concluded from their results that a longer period of close contact was probably required contact would be necessary for pathogen transmission to occur at all.

However, looking at the results of the Hong Kong study, the question arises,

what practical relevance a mask is supposed to have: If (1) a large proportion of infected

of the infected persons did not release any viral RNA even without a mask, and if then

(2) those with viral RNA release, despite high viral concentrations in the nasopharyngeal secretion nasopharyngeal secretions, the RNA concentrations are extremely low, there is little to be said for the benefit of masks.

for a benefit of masks. However, despite their own clear analysis, the authors

that their results suggest that masks (as surgical masks as used in the study) should be

used in the study) could be used by sick people. However, they also speak only

of sick, i.e. symptomatic, persons and by no means of every citizen in the

public space.

In order to answer this question, i.e. whether the widespread use of masks in public spaces, if

even if only in certain situations, makes sense for every citizen, but this study was not

study - contrary to the impression one might get from reading the RKI article [1].

[1]. The authors are quite critical of their own results (this is, however, one of the

(However, this is part of the usual rules in scientific articles, i.e. that the

authors themselves must point out limitations of their study or of its validity, because no

study can never be perfect), because a large proportion of the subjects - irrespective of their

of the test persons - irrespective of the type of their viral infection - no viral RNA

RNA release could be detected, even without the mask, and this despite the (long)

measurement time of 30 minutes. They see a further deficit in the fact that only in individual cases and

and only in the case of influenza viruses, whether the virus RNA released (in low concentrations) from intact viruses was

virus RNA (in low concentrations) originated from intact viruses and whether 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 this is precisely what is cited as evidence in the RKI's article, the study does not provide any evidence that the general wearing of masks (whether professional or masks or so-called community masks) in public spaces (e.g. shops, public transport, schools, offices), schools, offices) can reduce the risk of infection for the people one encounters during people encountered during this time - but with contact times that are much longer than the in the study of 30 minutes are generally much shorter. The

results show, however, that the risk of coming into contact with excreted viruses of other people, even if they are acutely infected and have corresponding clinical symptoms, is symptoms, is much lower and probably negligible if you are not infected.

negligible if one is not coughed on directly, a situation that most people in the public eye people in public will hardly ever have actually experienced, even though just such a 37 such situation is cited as a risk and thus as (one) justification for masks.

Finally, it is incomprehensible that the RKI, starting from a study in which in which a maximum of 11 subjects with evidence of seasonal coronaviruses were examined and in which

and in which the study directors also checked the correct fit of the masks or corrected them if necessary.

or, if necessary, corrected the fit of the masks, that masks caused a 'relevant reduction' in the release of the virus. Only then was this partial result of the study, which was not very informative study into a justification for the fact that masks 'work'. But how does the RKI from a result of only 11 test persons (with an acute respiratory infection at that) to a similar infection) to a similar effect when masks are worn by a population of almost 80 million (without symptoms) is not to be questioned here.

Brief contacts. In terms of life experience, encounters in public spaces are only experience, close (< 1 m) and prolonged (≥ 15 min) face-to-face contacts are only made in a few cases.

face-to-face contacts, which (in contrast to patient care in a hospital) do not usually extend hospital) do not usually extend over 15 minutes or more. Mostly, people pass each other pass each other in public (e.g. in the supermarket) or stand one behind the other (e.g. at the one behind the other (e.g. checkout in a supermarket) or next to each other (e.g. public transport). And even

even if the journey by public transport takes more than a few minutes, experience shows that you can

experience shows that you can almost always position yourself in such a way that you do not have any face-to-face contact with other passengers, even if you are not on the bus.

face-to-face contact with other passengers, even if it is crowded.

(For the possibility of pathogen transmission through aerosol particles, see Part C.). Keep a distance during conversations

e.g. during banking transactions or during a consultation, e.g. in a bookshop, is always possible.

always possible - and makes masks unnecessary.

Distance. The fact that the face-to-face contact, which is crucial in droplet transmission, will at some point be 'lost' at some point in the course of the pandemic (at any rate, at the beginning the

At the beginning, at least, the RKI and in the media were still constantly talking about at least 15 minutes of face-to-face contact as a prerequisite for pathogen transmission) and was replaced by an all-round distance of at least 1.5 m (at the same time as the introduction of mandatory masks).

masks), is an important factor in the numerous misunderstandings and misinterpretations (see misunderstandings and misinterpretations (see evidence question 4.).

fearful when someone comes 'too close' from any side. Since the discussion about the

role of 'aerosols' only arose later, the RKI was not able to address this aspect, which was

1.5 m distance and the 'everyday masks', could not yet consider this aspect in its contribution [1].

not yet taken into account in its contribution [1].

2. assessment of the WHO from 2019

As a further source, the RKI has referred to the WHO (World Health Organisation). Therefore, their representations on the question should now follow here, what role masks could play in containing the pandemic.

In 2019, the WHO had published a review of so-called non-pharmaceutical measures.

measures (i.e. without drugs or vaccination) to contain epidemic and pandemic influenza.

epidemic and pandemic influenza, non-medical masks could only be used with reservations to protection of the general population during severe epidemics and pandemics, and surgical

masks are recommended for symptomatic persons in contact with other people [31].

At the same time, however, the WHO has stated that there is no scientific evidence for this.

i.e. that, based on the scientific data, it is not known whether this measure is effective in preventing effective in reducing the transmission of pathogens, rather the potential effectiveness is based on plausibility.

effectiveness is based on plausibility.³⁸

If a measure is only plausible, no scientifically substantiated effectiveness can be derived from it. Effectiveness can be derived from it. Plausibility can be described as something that is somehow plausible for most

most people who think about it, something that is somehow plausible and comprehensible - and therefore a plausible measure could perhaps be effective. Thus such a theory could give reason to test it in a scientific investigation.

However, plausibility cannot replace such an investigation. This is also comprehensible to a layman, otherwise one could do without any scientific investigation, because many things are plausible.

scientific investigation because many things are plausible. On the imposition of compulsory masks for (almost) the entire population in Germany, plausibility cannot be sufficient.

In the meantime, the WHO has published two updates, which will be presented later (see below). (see below).

3. assessment of the ECDC

The ECDC (European Centre for Disease Prevention and Control) is the scientific health authority of the European Union (EU). The recommendations of the ECDC have force for the individual European nation states, but also beyond the EU.

and, of course, the RKI also takes the ECDC's pronouncements into account.

ECDC.

In April 2020, the ECDC made a statement on the potential effectiveness of masks against the transmission of the new coronavirus [32] and has referred, among other things, to the WHO statement of 2019 [31]. According to ECDC, there is limited indirect evidence that non-medical evidence that non-medical masks (made of different materials) can reduce the release of respiratory droplets into the environment during coughing, but the available data suggests that non-medical masks can help to control the source of the pathogen ('source control'). However, non-medical masks are less effective than medical masks in controlling the source of the pathogen ('source control').

However, the ECDC also says that it cannot be concluded from the fact that in

Asian countries, where the wearing of masks in public is common,

that corona infection rates are lower in some of these countries because, in addition to the use of masks.

the use of masks, there are numerous other measures that are practised to reduce the risk of infection. For example, in these countries, awareness of respiratory etiquette and hand hygiene is higher than elsewhere. This is more pronounced in these countries than elsewhere.

The use of (non-medical) masks in public can primarily serve as a means of source control, but should only be considered as an additional measure, not as a replacement. It should only be considered as an additional measure, but not as a substitute for the central prevention measures,

which include careful hand hygiene and avoidance of own hand-face contact (eyes, nose, mouth). In its publication, the ECDC

numerous arguments for and against the use of masks.

In summary, in the April 2020 publication, the ECDC says that in the recommendation for the use of masks in public, the gaps in the scientific data and the possible negative effects.

They should only be considered as a complementary measure, but should not

lead to the established measures of, in particular, careful hand hygiene and avoidance.

hand hygiene and the avoidance of personal hand-face contact (eyes, nose, mouth),

where these measures are impaired. So here, too, there is no talk of a 39

scientific basis for the use of masks in public and no clear recommendation for the use of masks.

clear recommendation for the use of masks in the normal population.

In February 2021, the ECDC published a first update on this issue, expressing the same

same assessment as in spring 2020 [33]. Already in the first sentence of the

key messages states:

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

ECDC goes on to say in the summary:

1. the evidence for the effectiveness of medical masks in the population for the prevention of COVID-19

prevention of COVID-19 is consistent with a small to moderate protective effect, but there are still significant

significant uncertainties about the size of the effect. 2.

2. in relation to non-medical masks, face shields and FFP2 masks used by the public, the public, the effectiveness is sparse and associated with very low certainty. It studies are needed to assess the relevance of the use of medical masks in COVID. medical masks in the COVID 19 pandemic.

Ultimately, the ECDC nevertheless recommends the wearing of masks in certain situations in the public.

in public, e.g.: when there is transmission in the general public and in this situation when staying in closed public areas or also in households for symptomatic symptomatic persons and then also for the other persons in the household.

However, the ECDC also states that, due to the given (i.e.: lack of) scientific evidence scientific evidence, it is unable to recommend whether medical or non-medical masks should be used in public.

medical or non-medical masks should be used in public.

The ECDC further states that the very limited scientific evidence with regard to the use of on the use of FFP2 masks does not support their mandatory use by the public

instead of other types of masks. Although FFP2 masks are not expected to be inferior to other types of masks, they are not expected to be inferior to other types of masks.

masks would be inferior to other types of masks, the difficulties in ensuring their correct and use in public, as well as the potential disadvantages of difficult breathing, should be considered. disadvantages of difficult breathing should be taken into account.

Furthermore, as in the April 2020 report, masks should not replace other preventive measures.

preventive measures: (1) physical distance, (2) staying home when sick, (3)

(3) work via telecommunication if possible, (4) respiratory etiquette,

(5) careful hand hygiene, (6) avoiding contact of hands with the face (eyes, nose, mouth).

avoid.

And finally, the appropriate use of masks, and improving

compliance with their use, when recommended as a preventive measure for public health recommended as a public health prevention measure, are key to its effectiveness and can be and can be improved through education campaigns.

4. recommendations of the CDC

As another health authority of international importance, the RKI cites the US-American CDC (Centers for Disease Control and Prevention), but cites no publication on this.

no publication. The CDC's statements are similar to those of the WHO and the ECDC, but at the time they

scientific evidence at the time, except with regard to the early excretion of pathogens.

early excretion of the pathogen at the end of the incubation period [34].

there was no scientific support for the RKI's mask recommendation.⁴⁰

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

However, both the information contained therein and the scientific basis are very limited.

limited because there are no meaningful data for 'real-world effectiveness' [35].

Nevertheless, at the end of the paper, the CDC recommends the wearing of masks and even goes so far as to state that

go so far as to state that the use of masks in public may prevent future

prevent future lockdowns, especially when combined with other non-pharmaceutical interventions such as spacing, hand hygiene and adequate ventilation,

and adequate ventilation.

Thus, the CDC recommends a 'bundle' of measures, without evaluating the individual

measures of the bundle have been proven to be effective, as is also the case for ventilation (see also

masks, ventilation (see part C.) and distance (see evidence question 4). The

importance of hand hygiene is very likely to be high, although it must also be noted that in

that one can never wash (or disinfect) one's hands frequently enough in public to

disinfect) frequently enough for it to be effective, i.e. protective, which is why avoiding

hand-face contact when out and about is clearly more important than washing or disinfecting.

than washing or disinfecting hands.

Like all other international health authorities, the CDC also adheres to the mask recommendation, although on the one hand the necessary scientific data are lacking and on the other hand masks are not used by the people who are not in them.

on the other hand, masks are not (or cannot be) used correctly by people who are not trained to use them.

(can) be used correctly by untrained citizens, so that they become a contamination risk (see Part B.).

In view of these

considerable limitations, the CDC does not even begin to weigh up the

the measure with its potential disadvantages for all people and especially for children of all ages.

particularly for children of all ages.

5 Updated Cochrane Review

Cochrane reviews are current (or updated if the original work was published earlier) systematic reviews.

published earlier) systematic reviews (usually with a meta-analysis, i.e. a statistical statistical evaluation of different studies on the same topic) and are therefore of of importance for every author when it comes to the scientific basis of a question.

scientific basis of a question. Thus, the RKI also consults the relevant Cochrane review for its mask recommendation.

Cochrane review for its mask recommendation.

In a Cochrane review updated in 2020, studies on the effectiveness of masks in reducing the spread of respiratory viruses [36, 37]. As a review was available to the RKI for publication as a preprint [36], but the final final publication did not appear until the end of 2020 [37]. The studies evaluated in this review masks in public, as is the case in Germany for all citizens in certain situations (shops, restaurants, etc.).

made mandatory for all citizens in certain situations (shops, public transport, sometimes even outdoors).

outdoors).

Rather, studies in completely different settings were evaluated, and thus it is

misleading when the text of the RKI article, which is explicitly about the use of masks in public, refers to the use of masks in public.

masks in public, states [1]:

'In an update of their Cochrane Review from 2003, the authors, based on observational studies during the SARS outbreak, also recommend the the use of masks in combination with other measures'.

Included in the current review from 2020 was, for example, a study at a meeting in Australia to see if the use of 41 masks (professional surgical masks) could be used in combination with other

masks (professional surgical masks) on attendees with respiratory infections to reduce reduce pathogen transmission within such mass gatherings with close contact (e.g. (e.g. staying in tents) between participants.

In another study, general practitioners in France included households with influenza in home visits. households in which there were cases of influenza. The ill persons were to (professional surgical) mask, but the rest of the household did not.

not. The aim was to determine the rate of transmission to other members of the household. household. Similarly, another study from Australia was concerned with the effect of masks in households with sick members. There were also other studies in which the effect of hand hygiene together with masks, e.g. in two studies in student dormitories, i.e. in studies in student dormitories, i.e. in a kind of large shared shared accommodation.

All of these were studies that had nothing to do with the wearing of masks in public (shops, restaurants, etc.).

wearing masks in public (shops, public transport, schools, etc.). Most of the of the studies cited in the Cochrane review were carried out among medical medical personnel and therefore do not play a role in the question of whether masks in public have any meaning.

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

Masks not evidence-based. From the literature cited in the RKI's article there is there is no scientific evidence that masks (of any kind) worn by the normal worn by the general public in public places (shops, public transport, schools, etc.) reduce the transmission of pathogens in respiratory infections. Whether it is possible to achieve

'a sustainable reduction in the rate at which COVID-19 is spreading in the population and to reduce the number of new cases',

as the RKI article states, is unproven, and there is also a lack of scientific evidence that the additional that the additional use of masks in the population could have the effect of 'reducing several components'.

several components (...) complement each other' [1].

For even that, i.e. the claimed interaction of various measures (in a so-called 'bundle'), is not proven. measures (in a so-called 'bundle'), must be proven and cannot simply be assumed or considered plausible.

plausible. The so-called AHA formula was only developed later (by an advertising agency).

- similar to the 'baby elephant' distance in Austria).

In itself consistent, the RKI article states very cautiously [1], among other things:

'A partial reduction of this unnoticed transmission of infectious droplets

droplets through the wearing of MNB could (emphasis in this report) lead to a further contribute to a further slowing of the spread at the population level', a formulation that, in the scientific discourse, because of an apparent lack of evidence for the momentous for the RKI's momentous mask recommendation.

Unnoticed transmission. The RKI cites no evidence for the statement at the beginning of the that there is increasing evidence that 'a high proportion of transmissions go unnoticed'. transmission goes unnoticed'. It should be noted: It is precisely this alleged possibility of unnoticed transmission was the reason for the 'reassessment' of masks in the masks in public by the RKI. Even then, however, there was no evidence for this. 42

Normally, science evolves, and the measures derived from it are guided by these developmental steps. However, when it comes to the issue of unnoticed transmission

transmission, however, the RKI sticks to the description it gave almost a year ago, which even then was not exhaustive.

the scientific basis was not and will not be included in the spring of 2020.

not and will continue not to be included.

Epidemiological connection decisive. Although the RKI states in the article, that

'Outbreak investigations and modelling studies' (showed) that 'the rapid rapid spread of SARS-CoV-2 is due to a high proportion of illnesses that initially initially with only mild symptoms, without limiting the daily activity of the sufferers. activity. As early as 1 - 3 days before the onset of symptoms, there can be excretion of high amounts of the virus. A partial reduction

of this unnoticed transmission of infectious droplets through the wearing of MNB could (emphasis added for this report) lead to a further slowing down of the spread of the contribute to a further slowing of the spread.' [1].

However, as noted above, these are known facts that have nothing to do with the alleged new scientific evidence for the effectiveness of masks in public spaces. effectiveness of masks in public spaces.

Furthermore, outbreaks in circumscribed settings, e.g. in nursing homes or in accommodation for asylum seekers or for employees in slaughterhouses or farms.

farms, reflect a completely different epidemiological situation than the stay of people in public spaces.

in public places (they should therefore not be included in the total number of people tested positive).

tested positive in each case in the calculation of the incidence figures.

only one case of each outbreak, the so-called index case, should be counted,

but that is a different problem). Modelling studies cannot, as

described at the beginning, modelling studies cannot provide any insights into the expected reality [38].

Despite all these obvious limitations in the informative value of the cited

evidence cited, the RKI article ends with the statement [1]:

'In the system of different measures, (emphasis for this expert opinion).

a situation-related general carrying of MNB (or MNS, if production capacity

production capacity permits) in the population is a further building block to reduce

reduce transmission'.

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

with considerable consequences. After all, on the first two pages, the RKI is only

only rather cautiously about the possible positive effects ('could', 'may'),

in this last sentence with 'is', however, it speaks as if the wearing of masks is actually,

confirmed by the results of scientific studies, is such a building block.

but without citing any scientific basis for it.

(and could).

This formulation at the end of the article may have been chosen for all those readers (e.g. journalists) who only read the last sentence.

readers (e.g. journalists) who only read the last sentence (or paragraph) of an article, because there is often an

(easily readable) summary is often given there. This leaves the reader with the impression that

the impression that a positive effect of the mask recommendation for the public space is a 'fact' - but this is not the case.

is a 'fact' - which, however, is not the case, as has been shown and is

will be further demonstrated in later published literature. For policy makers, however, this

essential for politicians to be able to impose the mask requirement, because this would make the

RKI as the decisive scientific authority in Germany for the prevention of infections.

infections, to which at least the administrative courts as a rule attach great importance.

the administrative courts, has provided the decisive justification for the mask obligation.

Conclusion

At the time of the RKI's publication, neither the RKI, the WHO (2019) nor by ECDC or CDC scientific data for a positive effect of masks in the (i.e. a reduced 'rate of spread of COVID-19 in the population' [1]).

population' [1]), because - and this is still true at present, i.e. about one year later (see below) - such data do not exist.

(see below) - there are no such data [1, 31 - 35]. Similarly, the update of the of the Cochrane review does not support the use of masks in public places [36, 37].

This has already been confirmed by two other reviews of the relevant literature from April 2020 [39, 40].

[39, 40]. The same is even more true for the Hong Kong study conducted several years ago [30]. study from Hong Kong [30].

Further publications on the effectiveness of masks

Only after the 're-evaluation' of the RKI [1] did a number of publications appear, most of which were also published in the German language.

publications, most of which were also taken up by the media. They

They are discussed below.

1 The WHO assessment of 2020

The WHO recommendation of June 2020 on masks in public (as in a previous recommendation on this of

(as in a previous recommendation on the subject in April) that there is no scientific

scientific data that the use of masks (from medical masks to community masks) is not

community masks) by (apparently) healthy people, i.e. people without symptoms of upper respiratory

symptoms of an upper respiratory tract infection, in public settings against infections with

respiratory viruses, including those caused by the coronavirus [41]. The WHO

has once again not come out in favour of the general wearing of masks in public.

masks in public, even if this was interpreted differently in the media.

interpreted differently in the media.

However, in the recommendation of June 2020, the WHO for the first time (besides the use of masks in the medical sector), the WHO for the first time deals in detail with the use of masks by the by the population in public spaces and makes differentiated statements on this.

According to this, the wearing of masks should be encouraged in certain situations in public life. The WHO does not consider the use of masks to be 'mandatory' or 'compulsory'. It is important to note is that the WHO only makes this recommendation for areas (e.g. counties) with (1) known or suspected widespread transmission outside localisable outbreaks, so to speak. 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 spacing is difficult. Then this could be an additional measure and part of a comprehensive approach to suppressing coronavirus transmission. The WHO states, however, that there is no direct scientific evidence for this (i.e. as in the earlier (i.e., as in the earlier recommendation of 2019 [31], this is merely plausibility) and that in addition to possible advantages, disadvantages must also be considered. An update to the June 2020 publication appeared in December 2020 [42]. It is not fundamentally different from the June guideline. For the normal population 44 only non-medical masks are recommended. Medical masks should be people at increased risk of serious complications if a distance of at least 1 m cannot be maintained. of at least 1 m cannot be maintained. Those caring for persons who are suspected of having COVID-19 or who have been diagnosed with the infection should wear a medical mask while in the same room.

Regarding children, WHO comments are 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 risk.

risk: the child's ability to use the mask correctly, and the availability of availability of adults for supervision, local social and cultural environment, special settings settings, such as households with older relatives or schools.

From the age of 12 years, the same principles apply as for adults.

Special decisions are needed for immunocompromised children, for children with cystic fibrosis cystic fibrosis or with certain other conditions (e.g. carcinoma), and children of all ages with developmental delays, disabilities or other specific disabilities or other specific health conditions that prevent them from wearing masks. mask-wearing.

The WHO, like the ECDC, points out that the use of masks alone, even if

used correctly, is not sufficient to ensure an adequate level of protection for non-infected persons or to prevent transmission from an infected person (third-party protection). Hand hygiene, physical distance of at least 1 m, respiratory etiquette, adequate ventilation of enclosed spaces, testing, contact tracing, quarantine, isolation and other and infection control measures, whether masks are used or not, are critical to prevent human-to-human transmission of the pathogen. masks are used or not, are critical to prevent human-to-human transmission of the pathogen. human transmission.

WHO provides very detailed guidance on what to look for in the correct use of masks:

Perform hand hygiene before putting on the mask (no specification of what exactly is meant by this, i.e.

i.e. hand washing or hand disinfection).

Inspect masks for damage and do not use damaged masks.

Put the mask on carefully and ensure that the nose and mouth are completely covered

adjust the nosepiece and straps to minimise gaps between the face and mask.

face and mask are minimised. If ear straps are used, make sure that they do not cross each other, as this will increase the gap between the face (cheek) and the mask.

and the mask.

While wearing the mask, avoid touching it. If it is

However, if it is accidentally touched, hand hygiene should be performed.

Remove the mask using appropriate technique, i.e. do not touch the front,

Instead, loosen the straps from the back.

Replace the mask with a new, dry mask as soon as it becomes damp

Either discard the mask or place it in a clean, resealable plastic bag where it can remain.

plastic bag where it can stay until it is washed and cleaned. The

do not wear the mask by the straps around the arm or wrist or tuck it under the chin or neck.

the back of the neck

Perform hand hygiene immediately after disposing of the mask

Do not reuse masks after 1 use.

Dispose of disposable masks correctly after each use⁴⁵

Do not remove the mask when speaking

Do not share the mask with other people

Wash fabric masks preferably at 60°C at least once a day. If it is not possible to wash the mask in hot water, wash the mask with soap in cold water and then soap in cold water and then place in boiling water for 1 min.

Regarding the scientific evidence related to the protective effect of masks in the WHO states:

'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 report nos 88 - 93].

Despite the limited and conflicting scientific evidence cited by the WHO for the efficacy of evidence for the effectiveness of masks in healthy people in public, the use of masks in the public is the use of masks in the general public, in addition to all other (see above) in cases of known or suspected transmission in the population or in outbreaks. or in outbreaks. When decision-makers consider the use of masks for the general population, they should base their decision on the given risk. risk.

1. within enclosed spaces (indoor settings).

In poor ventilation regardless of physical distance; limited or no opening of windows or doors for natural ventilation; the ventilation system is not does not function properly or cannot be assessed

In the case of adequate ventilation, if the physical distance of at least 1 m cannot be cannot be maintained

In households, when there is a visitor who is not a member of the household and when the ventilation is poor, limited opening of windows and doors for natural ventilation or if the ventilation or if the ventilation system does not function properly regardless, 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 maintained

2. outside closed rooms (outdoor settings)

When the physical distance of at least 1 m cannot be maintained.

Individuals at increased risk of severe complications of COVID-19 should be treated in any setting where the physical distance cannot be maintained.

wearing a medical mask in any setting where the physical distance cannot be maintained.

mask in any setting where the physical distance cannot be maintained.

3. during sporting activities

Individuals who participate in sports should not wear a mask when doing so because masks interfere with the ability to

ability to breathe easily.

Indoors, good ventilation should be ensured and, in addition, careful disinfectant cleaning of the environment.

disinfectant cleaning of the environment, especially surfaces with frequent hand contact.

hand contact.

When recommending masks for use by the public in public spaces, decision-makers should consider the following points:

The purpose of the mask should be clearly communicated, i.e. where, when, how and which type of mask should be worn. It should be explained what can and cannot be achieved with masks.

and what cannot be achieved with masks. It should also be made clear that the mask is only one part of a package of measures.

part of a package of measures along with hand hygiene, physical distance, etc., all of which are necessary.

etc., which are all necessary and should reinforce each other.

People should be informed and trained on when and how to use masks safely.

used safely, i.e. put them on, wear them, take them off, clean them and dispose of them.

The practicability of use, supply and replenishment issues, social and acceptance (both of wearing and not wearing different types of masks under different conditions). types of masks under different conditions) should be taken into account.

Continuous scientific data and evidence on the effectiveness of mask use (incl. the use of different use of masks (including different types of masks or other facial face coverings such as scarves) should be collected.

The impact (positive, neutral or negative) of mask use in the general population should be general population (including behavioural and social science). social science).

Potential benefits of masks in healthy people in the general public

Reduced release of respiratory droplets containing infectious viral particles, including from infected individuals before they develop symptoms

Reduced potential for stigma and greater acceptance of mask wearing, to prevent infection of other people or in people who are patients with COVID-19 in non-medical settings.

People are made to feel that they can contribute to stopping the stop the spread of the virus

Promote concurrent behaviours to prevent transmission, such as

Hand hygiene and avoiding touching the eyes, nose and mouth

Preventing the transmission of other respiratory diseases such as tuberculosis and influenza, and reducing the burden of these diseases during the

Pandemic

Potential disadvantages of masks in healthy people in public

Headaches and difficulty breathing depending on the type of mask used

Development of skin lesions on the face, non-allergic contact dermatitis, or

Worsening of acne with frequent use for many hours

Difficulty in communicating clearly, especially with people who are deaf or hard of hearing deaf, hard of hearing or lip-reading

Discomfort

False sense of security, possibly leading to less adherence to other crucial preventive measures, such as physical distance and hand hygiene.

Hand hygiene

Poor compliance with mask wearing, especially among younger children

Waste management issues, inappropriate mask disposal, leading to increased public litter and environmental hazards.

harm and difficulty in wearing masks, especially for children, those with

with developmental delays, mental retardation, cognitive impairment, asthma or chronic respiratory or breathing problems, in

persons who have had facial injuries or recent maxillofacial surgery

and people living in hot and humid climates⁴⁷.

Summary of WHO pronouncements

Although the WHO also in its most recent statement of December 2020 (incidentally as previously in June 2020) explicitly states that the scientific evidence supporting effectiveness of public-use masks in preventing respiratory infections (including those caused by infections (including those caused by SARS-CoV-2) is limited and contradictory at this stage. and contradictory, it nevertheless recommends the use of masks in certain epidemiological settings. masks in certain epidemiological situations for the general population.

The WHO mask recommendation is therefore not a scientifically based recommendation.

scientifically based recommendation. Whether political lobbying was actually behind it does not need to be discussed here.

be discussed here, but it must be noted that the WHO, as the scientific health

WHO, as the scientific health authority of the UN for the entire world, did not make its mask on a scientific basis. This is shown by the results of the scientific

This is shown by the results of the scientific literature evaluated in this report:

According to this, there is no scientific evidence that masks worn by healthy worn by healthy people in public, e.g. when shopping, in public transport, in offices and schools, and schools, make a verifiable and quantifiable contribution to reducing the spread even reduce the spread of the new coronavirus.

The possible advantages that the WHO cites in connection with the wearing of masks

are therefore, on the one hand, the more or less evident (in the German sense of the word, i.e. obvious) finding that

obvious) that the spread of respiratory droplets containing viruses can be reduced.

respiratory droplets can be reduced. On the other hand, the potential advantages

potential benefits are only possible effects on a psychological level.

The WHO recommends only non-medical masks for the general population and still only in special epidemiological situations.

and still only in special epidemiological situations and thus only in defined

regions with high numbers of infections and locally in the event of outbreaks.

outbreaks, but without giving any indication of the extent of the case numbers, in any case

but not as a general (nationwide) mask requirement, as has been the case in Germany since the spring of

2020. The WHO recommendation can therefore also not be used as a basis for a general compulsory masking.

cannot be used as a basis for a general mask requirement.

Lancet review

The systematic review with meta-analysis published at the beginning of June 2020 in the journal 'The Lancet' does not provide any evidence for the efficacy of masks in public places [43]. masks in public spaces [43]. But it is precisely this publication that has been and continues to be cited as evidence when it comes to the question of whether masks are effective in public. For 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, incidentally, commissioned and sponsored by the WHO). In it it is a matter of masks - in addition to physical distance and eye protection - but not about the wearing masks in public spaces for the protection of others. In most of the comparative studies that could be included in the meta-analysis are more about SARS.

included in the meta-analysis are about SARS or MERS, in 7 of them about COVID-19, but - and this is decisive here

is decisive here (not the pathogens) - in no case was it a study that drew conclusions about the conclusions about the wearing of masks in public places for reasons of protection of others. protection of others.⁴⁸

If one reads the summary of the 'Lancet Review' and then looks at Figure 4 with the meta-analysis of the studies that evaluated the wearing of masks, one might

At first glance, one could say that masks are well proven to be effective.

However, if you take a closer look at the figure, you will see that almost all of the individual studies were conducted in a hospital setting.

individual studies were conducted in hospital settings and only three in non-healthcare settings (all on SARS-1) [44 - 46].

protection of others in public, but for self-protection in the family (1 x) [44].

(1 x) [44] or when leaving the home (1 x) [45]. As protective factors, the following were also factors identified in this study were visiting farmers' markets and owning pets.

factors that could be regarded as increasing the risk or, in other words, as having a protective effect, or, in other words, for whose protective effect there is no rational explanation. From this that so-called confounders were present, which incidentally also calls into question the other results of the study.

the other results of the study are also called into question. The third study [46]

could not show any effect of masks at all, because 95% of the participants stated that they never never worn a mask when in contact with SARS patients. So how does this study included in the Lancet review of mask effectiveness is unclear.

is unclear. At this point, it should be emphasised once again that these three studies were the only ones in the Lancet review that looked at mask use at all.

masks in the general population outside hospitals. This review

is therefore not suitable for making a statement about the effectiveness of masks for people in the public space.

public space.

All the other studies included in the review were from the field of

medical institutions. However, it is not possible to draw conclusions from patient care in

hospital, where the wearing of masks by staff in certain situations is necessary for

occupational safety reasons in the case of close and prolonged patient contact (self-protection =

no contact with blood and bodily fluids of the patients regardless of whether an

infection is known in the patients and, if so, which) has always been recommended,

the opposite effectiveness (protection of others) of masks in fleeting encounters in public spaces.

encounters in public spaces. In the case of patient care, there are

contact with pathogens is quite different from that of people meeting each other while

people shopping, in public transport, in schools or among colleagues in the office.

Medical staff who treat patients with respiratory infections or other potentially infectious

potentially infectious pathogens in the nasopharynx, on the one hand, have close

close contact (< 1 m), and on top of that, it is a vis-à-vis contact, i.e. face to face.

Another important criterion is that contacts in patient care typically last longer and take place repeatedly.

contacts in patient care typically last longer and take place repeatedly.

and also by the RKI, a duration of at least 15 min of such close vis-à-vis contact has been

prerequisite for a possible pathogen exposure of the staff. Such a

duration does not occur in public spaces with the short contacts that are customary there, and

and certainly not as vis-à-vis contact. If you want to have a longer conversation with someone you meet on the way, you can simply keep your distance.

you can simply keep your distance, and then there can be no contact with the respiratory secretion of the person.

with the respiratory secretion of the other person. It is the same with patient care: If you do not have to care for the patient with close contact but only want to discuss something with him, you stay a little away from his bed, you don't need to put on a mask and you can talk to them normally, even if they are having an acute an acute respiratory viral infection.⁴⁹

Mankind has always lived like this, even in seasonal influenza periods, and the question arises as to whether the

question arises whether everything should be different with the new coronavirus and, moreover, whether it is

only with this virus or with all other respiratory viruses. This new

virus is not even remotely comparable to a dangerous pathogen such as smallpox or Ebolavirus.

virus such as smallpox or Ebola, but according to current studies it is comparable to a more

influenza, as we have experienced several times in recent years (e.g. 2016 / 2017).

(e.g. 2016 / 2017 and 2018 / 2019) [47].

The 'Lancet review' adds nothing to the effectiveness of masks as third-party protection in public

(as well as self-protection), because this systematic review has also not

has not brought to light any studies that make any, or even any, supporting

statement on the wearing of masks in public spaces for reasons of protection from

protection of others - nevertheless, this publication has been cited in the media and by numerous

and by numerous medical experts. This may also be due to the fact that

in the summary of their results and their assessment, if this is read at all and not just the

and not just Figure 4, they did not really express themselves clearly and unambiguously.

clear and unambiguous. Thus they state:

'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'.

In plain language, then, the conclusion of the authors of this review is: There is no scientific scientific evidence for the efficacy of masks in public, and their use may depend on the epidemiological context.

their use could be made dependent on the epidemiological context, but in any case there is a lack of scientific

presented by the media in December as a new study, but in terms of the
it is not in terms of the subject matter.

The so-called Jena study - along with the 'Lancet review' - is often presented in the media as clear
evidence for the effectiveness of masks.

the efficacy of masks, and in fact - together with a study on golden hamsters
with a study on golden hamsters ('hamster' study; see below), i.e. an animal experiment.
animal experimental work.

The authors of the 'Jena Study' are all macroeconomists who used the same methodology ('synthetic
control method').

('synthetic control method') on behalf of policy-makers in order to assess the effects of
the effects of political decisions (so-called 'reforms') mathematically.

In the study, the development of the Corona case numbers after the introduction of the
mask requirement in Jena was compared with that in comparable cities (= synthetic Jena) without a
mask obligation. The authors come to the conclusion that the mandatory masking leads to
led to an approx. 40% reduction in the daily increase in corona infections.

However, the study does not take into account the epidemiologically decisive aspect that
that as early as 1 March 2020 (i.e. about 5 weeks before the introduction of compulsory masks in the
the city of Jena), the rate of spread of the new coronavirus decreased and that on
decreased and that on 10 March the R-value - according to the RKI - was already below 1.

[53, 54]. From the end of March, there were no more relevant infection figures in Jena. It follows
from this

that the introduction of compulsory masks (from 6 April, first in Jena, about three weeks later
later in the whole of Germany) coincided with a phase of the Corona epidemic in which there was
already a continuous

there had already been a continuous and marked decline in the number of infections, a development
that was

a development that continued thereafter. An effect of the
on the decline in the number of infections, because the two overlap,
because the two overlap, but this was not taken into account in the modelling study.

Particularly important for the assessment of the 'Jena Study' is that the

according to the data of the RKI was concentrated on only a few days in March and the majority of
the

March and the majority occurred before mid-March: There were (1) approx. 3 - 5 positive cases at
the end of February, (2) approx.

5 positive cases at the end of February, (2) between 43 and 53 positive cases on the weekend around 7 - 9 March and (3) between 59 and 73 positive cases in the period from 11 to 14 March, (4) then a marked decrease in the number of positive cases on individual days prior to the end of March and (5) another 3 - 5 positive cases at the end of March. The close temporal of events (2) and (3) indicates that these were outbreak situations and not outbreak situations and not a successive spread of infection 'in the area'.

the area'. At any rate, by the end of March, the infection in Jena had subsided to such an extent that that it was no longer possible to expect an effect from the compulsory use of masks as of 6 April.

because there was no longer any infection that could in principle be influenced by it.⁵¹

was no longer possible.⁵¹

In addition, it must be taken into account that the reporting date of the cases used in the study does not have any

the study does not allow for even an approximately reliable statement about the time of the infection, which can only be determined by the date of the infection.

infection, which can only be determined precisely enough by the date of the disease (= onset of clinical symptoms), as the

as practised by the RKI in its modelling studies [54].

According to the RKI, the time between infection and reporting date is 14 - 21 days, and

this period is composed of: (1) the incubation period, (2) the time delay until

the patient goes to the doctor because of increasing symptoms, (3) the time for carrying out the test test (including transport to the laboratory and evaluation in the laboratory), (4) the administrative administrative delays in reporting the test results to the RKI and (5) publication by the RKI [55].

by the RKI [55]. The 'Jena Study', however, only assumes a delay of about 8

days [50] or about 10 days [51, 52].

In other words: The effect attributed to the mandatory masking in this study

in the decrease in the number of infections is, on the one hand, overshadowed by the clear decrease of positive tests, which occurred everywhere in Germany a few weeks before the introduction of the in Jena and elsewhere a few weeks before the introduction of mandatory masks. On the other hand, it must be

that the infections reported to the RKI occurred 14 - 21 days earlier, so that the mask

the mask obligation had no influence on the number of infections for at least the first 2 - 3 weeks.

infection figures for at least the first 2-3 weeks.

Another important aspect for the assessment of an effect of the compulsory masking is that in the reported infection figures can always conceal infections that result from outbreaks, e.g. in outbreaks, e.g. in homes, hospitals or community accommodation, outbreaks. Institutional outbreaks, however, are not influenced by compulsory masking in public areas.

public spaces, so that a decrease in the number of infections in a town or region may be due to the fact that

region may be due to the fact that outbreak events previously increased the number of cases of infection

increased the number of cases, but afterwards the number of cases was lower than before the than before the introduction of compulsory masks. This seems to have played an important role in Jena

played an important role in Jena, if one considers events (2) and (3), as shown above,

in Jena: It is highly probable that these were temporary

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

However, outbreaks e.g. in institutions such as old people's/nursing homes always have individual causes that have to be sought in the specific epidemiological context, but they can be cannot be influenced by making masks compulsory when shopping or using public transport.

public transport. Thus, without taking into account the epidemiological context from which the the infection figures reported from the different locations (i.e. whether outbreaks were outbreaks), the effect of masks in public places on the incidence of 'new infections' remains unchanged.

The effect of masks in public on the occurrence of 'new infections' (= positive test results) remains necessarily unclear.

All in all, this modelling study does not produce any results that would support a compulsory use of masks.

because, in addition to the introduction of mandatory masks, the possible factors listed (probable outbreaks)

factors (probable outbreaks), especially from the time before, were not taken into account.

were not taken into account. With these limitations of the study, a circular

circular reasoning because the authors, as economists, do not have medical epidemiological expertise and therefore do not take into account important potential influencing factors,

factors, such as the question of outbreaks and their possible causes, in their considerations.

into their considerations.

There are numerous examples from other countries where, for example in Spain, despite the strictest Spain, for example, between July and the end of October 2020, the number of people tested positive increased dramatically between July and the end of October 2020, while in Sweden, where masks were not mandatory, the number of positive cases in the same 52 period was significantly lower [55]. period were significantly lower [55]. There are other examples of this from other countries: Despite mandatory masks, the numbers of positive test results rose sharply [56, 57]. One similar for Germany from the RKI data (introduction of compulsory masking on masks on 28 April) (e.g. in the daily situation reports). Likewise, the head of the Austrian AGES (Agency for Public Health) said that neither the introduction of the introduction of the mask obligation nor its abolition had any measurable impact on the incidence of infections in Austria have had [58]. In the last two months of 2020, also in the number of people tested positive has also increased significantly, but not to the same extent as in to the same extent as in Austria, where the mask requirement has been in force almost universally since spring 2020 [58]. has been in place [58]. Even with all this empirical data from numerous countries, influencing factors may have factors may have remained undiscovered, but it is striking that in none of the countries is there any effect of the mask requirement on the number of cases.

5 Mathematical estimation: Wuhan, New York and Italy

This is another modelling study that was carried out for Wuhan (China), but mainly for Italy and New York City, that with the introduction of compulsory the introduction of mandatory masks in public places, the number of new infections decreased significantly [59].

This study was apparently quickly criticised for lacking statistical methods (and the journal was asked to retract the article, which did not happen) [60]. A critical letter to the editor on this study was accepted and published by the journal [61].

From an epidemiological point of view, there are fundamental objections to this study which results are not meaningful, no matter how well they may have been calculated.

should have been calculated. As in the 'Jena Study', these authors (also not medical doctors or infection

epidemiologists, but chemists, including a co-chemist who was awarded the Nobel Prize in 1995, as well as physicists and geologists) have overlooked the fact that the effects of a measure are not the effects of a measure are not immediate, but rather, due to the interval between the

the date of infection and the date of notification, the effects of a measure may not be apparent for at least 2-3 weeks afterwards.

be noticeable.

Moreover, the authors thought that they could not only show that the mandatory masking had the greatest effect

of all the measures, but they are also convinced that their study is the

aerosol transmission of the new coronavirus as the dominant route of transmission.

transmission route. They do not specify from what they conclude this,

but possibly from the fact that masks mechanically stop respiratory droplets

respiratory droplets and thus prevent aerosol particles (i.e. from the smaller droplets that do not immediately

aerosol particles that are capable of floating and may contain viruses.

viruses. They also claim that the aerogenic route of transmission is the most efficient,

because aerosol particles enter deep into the lungs during normal inhalation.

and that this route of transmission typically requires a low 'dose of infection'.

infection dose. In addition, free-floating viruses have a high mobility and a sufficiently long 'survival time' for their transmission.

long enough 'survival time' for them to spread.

However, on the one hand, these are all unsubstantiated assumptions and no scientific evidence.

evidence and, moreover, assumptions that are not compatible with the knowledge in which anatomical regions the new

anatomical regions the new coronavirus must reach: because it multiplies in the upper

in the upper respiratory tract and mainly in the nasal mucosa, but not in the lungs [62].

lungs [62] (see Part C.). Furthermore, until then nothing was known about the so-called 'infectious dose' (i.e. with how many pathogens

(i.e.: with how many pathogens must a person who is in principle susceptible come into contact?

to become infected), and thus there was no evidence that a 53

virus is sufficient for an infection to occur (in the meantime, a little more is known about this; cf.

Part C.). Finally, as lipid-enveloped viruses, coronaviruses are among the most sensitive to environmental

sensitive to environmental influences, all in all not good prerequisites for even a somewhat prolonged

survive unprotected in the air for even a slightly longer period of time or, more scientifically

- more scientifically speaking: to remain capable of infection and replication.

remain. The authors are natural scientists and have obviously not asked themselves such questions or, as

or, as non-medical scientists, were unable to ask such questions.

Nor have the authors presented, for example, as in the critical letter to the editor

61], (1) the epidemiological context from which the infections originate, i.e. whether they are

i.e. whether they were acquired in the private sphere or in the course of patient care and, if the latter

and, if the latter, whether the staff had sufficient protective equipment at their disposal.

had. And they have (2) further failed to take into account that other factors besides the

factors other than the mask requirement may have played a role (so-called confounders), and (3) in addition

how the masks were accepted by the population in the first place, because

even if they were compulsory, it cannot be assumed that all people would use them and - also importantly

and - also important - wear them correctly.

6 Mathematical-theoretical study

Another paper is a purely mathematical-theoretical modelling study published at the end of April 2020.

mathematical-theoretical modelling study [63]. The authors (all mathematicians and statisticians) statisticians) are very cautious throughout - similar to the RKI in [1],

about the effectiveness of masks, but ultimately claim that masks, together with other

together with other interventions (so-called 'social distancing' and in particular hygiene

hygiene measures) could reduce mortality and the burden on the medical system.

burden on the medical system. According to the authors, masks are not a 'panacea', but they can have a

have a synergistic effect with other non-pharmaceutical interventions.

interventions. They go on to write that masks alone, if they are not very effective and are

used by almost everyone, would have only a small effect in more severe epidemics,

but still not insignificant in terms of the absolute number of lives saved.

is not insignificant. The relative benefit of general mask use could be combined with other public

for the public. Masks should therefore not be considered as an alternative,

but as a complement to other public health interventions. They then say

then go on to say that their simulations showed that even weakly effective masks, if

widely used, could help prevent many deaths.

Their theoretical results suggested a significant - though potentially highly variable - even when low-effectivity masks were used widely. widely used.

Towards the end of the 'discussion' they state that their 'theoretical results' must be interpreted with caution because of a combination of potentially high rates of non-compliance with the use of masks.

non-compliance with the use of masks, as well as uncertainty about their (intrinsic) effectiveness.

their (intrinsic) effectiveness (especially with self-sewn masks), respiratory droplet

droplets and/or aerosol particles, and finally because of, as they actually write

even surprising degree of uncertainty about the basic transmission mechanisms of respiratory mechanisms of transmission in respiratory infections.

Nevertheless, they conclude their paper with the statement that - despite uncertainty - (1)

the potential benefits, (2) the lack of obvious harms, and (3) the precautionary principle.

precautionary principle lead them to strongly recommend universal use of masks in the public

use of masks in public (i.e. everyday masks unless medical masks could be used without 54

medical masks could be used without compromising the medical system).

compromise the medical system). In doing so, the authors make surprising claims: (1) without

a potential benefit of masks is simply assumed, (2) that masks are quasi

are virtually free of side effects are among the other unproven assumptions, and finally

Finally, (3) the precautionary principle cannot be used as a justification for measures that are based only on plausibility.

based on plausibility.

Precaution, as opposed to aftercare, means that potential hazards or risks are not only

risks are not only recognised and their significance assessed before they occur, but also at this

risks at this point in time - despite possibly incomplete knowledge - so that they either do not

either do not occur at all or, if they do, then only in a weakened form. The

precautionary principle originates primarily from environmental policy and was

and was concretised in 1992 at the UN Conference on Environment and Development in Rio de Janeiro as follows

as follows:

'In view of the risk of irreversible damage to the environment, a lack of full scientific

scientific certainty should not be used as an excuse to delay measures that are in themselves

measures that are justified in themselves. ...'.

The idea behind the precautionary principle is that measures to protect against potential protection against potential risks even if it is not yet known exactly what these risks are based on, exactly what these risks are based on and whether they will materialise at all and, if so, to what extent [64, 65].

and, if so, how pronounced they will be [64, 65]. The precautionary principle has also been extended to health and

health and safety policy. It is always about

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

Acting according to the precautionary principle requires a strict risk-benefit assessment, risk assessment, so that the means or measures used to reduce or eliminate the potential or elimination of the potentially threatening danger do not lead to a burden on society that is possibly

more harmful than the realisation of the potential danger. Therefore, in the case of principle, not only the negative consequences of the potential risk should be taken into account, but also the

risk must be taken into account, but at the same time and equally the possible negative consequences of the means or measures to be applied must be included in the decision.

measures to be applied must be included in the decision. To this end, a solid scientific basis must be basis must be created on the basis of which both the benefits and the risks of the one and the other aspect can be assessed, even if not conclusively.

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

potential risk and as much scientific basis as possible in order to assess an effect of the of the envisaged measures on the imminent risk. Plausible

considerations as justification for the chosen measures are not enough if one wants to justify one's actions with the precautionary principle.

justify their actions on the basis of the precautionary principle. This is exactly what happens when the precautionary principle is

scientific justification and declares the wearing of masks to be a measure of masks as a measure that can protect against the spread of coronavirus [63].

[63].

It is not quite as simple as that, otherwise one could impose any measure with reference to the precautionary principle.

measure with reference to the precautionary principle. The federal government suddenly started at the beginning of 2021

began to justify the Corona measures on the grounds of the new virus variants with the

precautionary principle, after there was no mention of it in 2020. However, there were 55

However, there were no further explanations from the political side, as if the term 'precautionary principle' spoke for itself.

precautionary principle' speaks for itself and makes any justification superfluous.

This modelling study looks somewhat similar to the RKI's contribution [1].

At the end, there is a statement that is in line with the authors' previous considerations, namely that the validity of their theoretical results for reality is completely open.

can be reconciled. If one reads only the last paragraph of the publication, one learns nothing about the more differentiated

about the more differentiated considerations of the authors.

7 'Hamster study

The aim of an animal study with golden hamsters was to investigate the extent to which surgical masks could reduce contact with respiratory droplets [66].

This study was apparently taken seriously by the media as evidence for the efficacy of masks in public spaces and should therefore be mentioned here.

Without going into the details of the methodology, it proceeded as follows: One group group consisted of hamsters artificially infected with the new coronavirus.

group of hamsters was without infection. The respective cages were placed close to each other and were either

were either separated by a wall made of surgical mask material or not.

not. The mask material was used to simulate an infected person wearing a surgical mask.

surgical mask. There was therefore no direct or indirect contact between the animals in the two groups.

contact between the animals of the two groups, so that pathogen transmission, if it were to take place, could be

respiratory secretions or aerosol particles. In the

significantly fewer corona infections in the exposed patients when the surgical mask material was used.

infections in the exposed, i.e. primarily uninfected, animals, which led the investigators to conclude

investigators concluded that this protection was effective.

However, the question arises as to whether the results of such an animal study can be used to infer the

the effectiveness of (surgical) masks in humans, especially when they are worn by millions of people in public.

worn by millions of people in public, since the two settings are clearly not comparable.

obviously not comparable in any way. In public

In 2020, when the study was conducted, no surgical masks were worn in public,

but anything you liked, down to a scarf of some kind, was allowed. On the other hand

Secondly, the basic effectiveness of masks depends not only on their material, but also on how they are worn.

but also on how they are worn, i.e. how well they fit the face. In the

public space, it is easy to see that there are very different and, as a rule, no

and, as a rule, none of them is even close to correct. So even if under the

conditions in the animal study, it does not mean that the result can be extrapolated to other

does not mean that the result can be transferred to the population. The authors

surprisingly come to this conclusion themselves - and that is why journalists have also

journalists have also reported in this way, even though they too could recognise that

they are dealing with very different and not comparable conditions.

8. RKI: 'First scientific indications' for foreign protection

The RKI named the background of the 'first scientific indications' of 19 July 2020.

scientific indications' of 19.07.2020 in its answer of 21.07.2020, on the one hand, two experimental
56

laboratory studies (from 2008 and 2013, which have therefore been known for quite a long time), in which the

the principal ability of textile MNB to retain droplets, but with a large influence of the

with a large influence on the effectiveness by the material used [67, 68]. For

For indications of the 'infection prevention effect at the population level', the RKI has

modelling studies discussed here [50 - 52, 59, 63] (whereby [50 - 52], as explained above

above, are three publications on the same study).

With experimental and modelling studies, the RKI thus wanted (at the time of the

in July 2020) wanted to use experimental and modelling studies to support its then new statement, which is still in the FAQ, of 'initial scientific evidence'.

of the 'first scientific evidence' for the effect of masks as external protection.

substantiate.

At the beginning of 2021, a request from the public was made to the RKI in accordance with the Freedom of Information Act. In this request, the RKI was asked to provide the scientific (1) for the statement that asymptotically infected persons with SARS-CoV-2 have a relevant transmission from asymptomatic persons infected with SARS-CoV-2, and (2) for the mandatory to be stated. The RKI responded by listing a total of 8 citations: 2 for asymptomatic transmission and 6 for asymptomatic transmission.

asymptomatic transmission and 6 on the effectiveness of masks. Of these, the following literature citations are 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. on the filtration performance of aerosol particles by different substances is included in the review [29]). One of the literature references was not dealt with here because it is a study from the hospital sector on medical staff (fabric masks compared to (fabric masks compared to medical masks). All 6 citations on the effectiveness masks were obviously copied by the RKI from the BfArM's statement on the use of masks. masks (the same citation errors are present, and the order of the citations corresponds to that of the BfArM).

order of the quotations corresponds to that of the BfArM). The BfArM contribution is dealt with in Part B.

A little more than half a year after the July enquiry (see above) on the effectiveness of masks for external protection, the RKI's latest statement shows that there is no scientific scientific evidence for the effectiveness of masks for healthy people in the public for protection for healthy people in public and that there is no scientific evidence that pathogens are that the transmission of pathogens from asymptomatic persons is a relevant factor in the spread of asymptomatic persons have a relevant share in the spread of SARS-CoV-2.

Additional publications on the effect of masks

After having discussed publications up to this point, which have been mentioned in particular in the media,

but also by scientists, have always been mentioned when it came to the allegedly assured effectiveness of masks in the public, and which have thus achieved a relative popularity, the following section will present lesser-known publications.

will be presented below.

The publications were predominantly found via the bibliographies of other publications publications, e.g. also the current ones of the international health authorities, in order to use the the publications cited by the respective authors as evidence for their assessments.

as evidence for their assessments. They are listed in the chronological order in which they were submitted to or published in the journals,

order in which they were submitted to or published in the journals (depending on the information given).

discussed.⁵⁷

a) Publications 'per masks

A total of 17 publications are presented that found a positive effect of masks.

10 of which are mathematical estimates, i.e. modelling or simulation studies.

Modelling 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 field, submitted in April 2020) [69]: It is a small literature

small literature review, with most of the studies covered being from the clinical

clinical setting, if they are mask studies at all and not other questions or general

and not other issues or general pronouncements from international health

health authorities without reference to literature. Ultimately, masks are

are advocated by the authors, even though they have not cited any scientific data to support them.

scientific data.

2. mathematical estimation (submitted in April 2020) [70]: In this mathematical modelling study, the potential effectiveness of masks should be assessed.

modelling study was designed to assess the potential effectiveness of masks in combination with lockdown periods on infection.

lockdown periods on the infection dynamics of the new coronavirus.

The authors reached the following conclusions: (1) The baseline replication number

R_0 can be reduced to less than 1 if masks are always worn in public, i.e. not only when

in public, i.e. not only when there are signs of respiratory infection. (2) If

lockdown periods with 100% mask use are introduced, there is no longer any

spread of infection, secondary and tertiary 'waves' are 'smoothed'. This means that

epidemic is under control. This effect is also given if the masks used are only

masks are only 50% effective in stopping the exhaled virus (with an equal or lesser effect during inhalation).

effect during inhalation). (3) Even without lockdown periods, mask wearers have advantages, even if there is only a lower mask acceptance. Overall, the authors conclude that masks in combination with spacing or lockdown periods may be an acceptable way to manage the corona pandemic and reopen economic activity. A

'key message' of their analysis to support the widespread adoption of masks,

is: 'My mask protects you, your mask protects me'.

3. mathematical estimate (submitted April 2020) [71]: the paper was submitted to the journal at a time when masks were not being used.

submitted to the journal at a time when masks were in short supply in many places and not even available to

even for medical staff or staff in care homes. The

authors wanted to contribute to the investigation of the epidemiological significance of masks of masks in the public. According to the calculations made therein

masks can reduce both infections and deaths, even with a limited effect, and may

deaths and can delay the peak of the epidemic. They conclude

masks are an effective intervention strategy for a pathogen that is often asymptomatic.

asymptomatic, masks are an effective intervention strategy. It is important to distribute masks

distribution of masks so that they are available at all. Obviously

the authors assumed different mask efficacy in their calculations, without

without making it clear on which efficiencies they relied and on what basis they were assumed.

and on what basis they were assumed. These are therefore

calculations on a theoretical basis.

4. narrative review (version 1 submitted in April 2020, by the end of December 2020 as a

version 4 without completed peer review process, finally published in January

2021 [72]: 'Narrative' means that not all studies on the topic were searched for.

research on the topic was searched for. This publication, whose title suggests the efficacy

effectiveness of masks, is very frequently cited, but is not an evidence review due to the selective 58

literature selection, it is not an 'evidence review' as it says in the title. Scientifically sound conclusions cannot be drawn from it.

Conclusions cannot be drawn from it.

5 Mathematical estimation (submitted in May 2020) [73]: The authors highlight,

approach than most modelling studies, which focus mainly on the dynamics of virus transmission. mainly on the dynamics of the transmission of the virus and on the resulting reproductive number (R0). Rather, they wanted to include the people affected by looking at different groups of people (e.g. susceptible, symptomatic, hospitalised), symptomatic, hospitalised) to determine the optimal control of the infection with different non-pharmaceutical interventions. In the the following measures were most effective in their model: staying at home, washing hands stay at home, hand washing, early case detection (using PCR) and masks.

The introduction of all strategies at the same time for at least 50 days could greatly reduce the number of new cases.

greatly reduce the number of new cases.

6 Narrative review (submitted in May 2020) under the 'Viewpoint' section in the prestigious scientific journal 'Science' [74]: This publication was repeatedly referred to publication as a 'study' with evidence for the effectiveness of the masks. It is not a study, but a simple opinion piece.

opinion piece. It is a small review paper (of 2 ½ printed pages), in which mainly hypotheses and some questions, and only a few studies (including one animal studies (including an animal experiment with golden hamsters; see above) are mentioned, but not and certainly not

discussed exhaustively. The aim of this publication was obviously (which legitimate in a scientific context) was to raise some questions, but the authors do not do not attempt to give definite answers. This publication is therefore not suitable to prove the effectiveness of masks in the public.

7 Narrative review (submitted May 2020) [75]: The (very numerous) authors have prepared a very limited literature review, which, however, does not provide the effectiveness of masks in the public, as numerous experimental mask experimental mask studies and mask studies from the hospital sector were included. were included. Studies on the wearing of masks in public were not among them, but there are no such studies. Nevertheless, the authors conclude that masks conclusion that masks should be worn whenever spacing is not possible (e.g. in (e.g. in public transport), because this is very likely to reduce the spread of virus droplets and thus reduce the transmission of SARS-CoV-2.

could be reduced. Furthermore, the authors say that it is indisputable that infected persons can already be

can transmit the pathogen days before the onset of symptoms. This was in mid

May 2020, when the article was submitted, but even then it was without scientific

but even then it lacked scientific evidence and was based on assumptions and misleading publications [16].

misleading publications [16], but was already questioned or corrected at that time [17 - 19].

or corrected [17 - 19]. This article does not contribute to the effectiveness of masks for healthy people in the public.

masks for healthy people in the public (but is cited by the RKI and BfArM for this purpose).

BfArM; see above).

8. mathematical estimate (letter to the editor, i.e. no peer review, submitted in June

2020) [76]: 42 geographical regions on six continents were included.

The aim was to test whether there is a relationship between the use of the term "cigarettes", which is common in some,

use of masks in some countries, especially in Asian countries, as opposed to others, such as

European countries, where the use of masks in the early phase of the pandemic (from the 21st of the pandemic (from 21 January to 11 March) was not yet established or mandatory.

prescribed. The question of this investigation was whether the early use of

of masks in the Corona pandemic could have helped to contain the pandemic.

contain the pandemic. The authors' finding was that the number of cases in some 59

Asian countries (masks were used earlier) than in other countries (masks were used later).

countries (later mask use). According to the authors, masks were then an independent

independent factor in controlling the pandemic. They nevertheless

but only conclude that it is reasonable to assume that the use of masks

of masks could mitigate the pandemic because they could reduce the release of aerosol particles and droplets. They believe, they write, that wider

wider use of masks is the key to controlling the pandemic, and this is

regardless of hand hygiene, social distancing and other measures.

9. mathematical estimate (submitted July 2020) [77]: Among employees in shops with regular

regular customer contact, the use of masks was investigated, the use of

the use of masks in public, as it is compulsory in Germany, is not

is not comparable to this setting. The results cannot therefore be applied to the

the question of the effectiveness of masks in public spaces for almost every citizen. citizens. Moreover, the authors themselves say that their results should be interpreted with great caution.

10. mathematical estimate (submitted in August 2020) [78]: Basis were US states with and without mandatory mask use between April 8 and May 15, 2020. with the use of masks could not be determined, as the authors state, so it is unclear how often masks were worn (and whether they were worn correctly). worn at all). Moreover, only the 5 days before the the 5 days before the masks were made compulsory, which is far too few for a before and comparison, as it takes much longer for the effect of a new measure to become apparent (about effect of a new measure can be seen (approx. 10 - 14 days). For this reason alone the study would not be meaningful. However, the authors also only conclude, their findings suggest that mandatory mask use by the general public could help to could help to reduce the spread of COVID-19, so they are cautious about the of their study accordingly cautious.

11. mathematical estimation (submitted August 2020) [79]: all authors come from ophthalmology and included a wide range of countries from all over the world for their study. countries of the world and compared them with each other. Included in the study were. countries such as Africa, Latin America, Asia and Eastern Europe with very different infection rates, population structures and climatic conditions. Effects, however, which are based on regional geographic observations and associated characteristics (e.g. climatic (e.g. climatic) are not suitable for comparison with or among each other.

The corresponding limitations apply to this modelling study: There are different causes for increases in case numbers (e.g. outbreaks), a different compliance with masks, which cannot be retrospectively verified, and other factors (so-called confounders).

other factors (so-called confounders, i.e. variables that have an influence on both the on the occurrence of risk factors as well as on the outcome of an observation) that cannot be cannot be detected in such a study.

12. mathematical estimation (submitted in September 2020) [80]: The compliance with mask-wearing in compliance with mask-wearing in 24 countries was evaluated to determine the possible

influence on the number of cases. The authors themselves say in their summary, that it is possible that the estimated decrease in new cases is not due to mask-wearing but to other masks, but to other variables that could not be accounted for in the model. could not be taken into account in the model. As a result, the authors conclude very cautiously, that because of such confounders and also because of variations in mask types and their use and their use, randomised controlled trials on the use of masks in public spaces are masks in public spaces are needed to determine the true effect of mask use on attenuation. on attenuating the transmission of respiratory pathogens.⁶⁰

Mathematical estimate (preprint submitted to Science in September) [81]:

According to the authors, this study was intended to address the problem with the assumptions in complex mathematical modelling by simply estimating the disease. mathematical modelling by simply comparing the cases, hospital admissions and deaths deaths and the respective date were plotted against each other. However However, here too, possible other (confounding) factors were disregarded and only the political only the political measures, such as school closures, etc., were included. It is also not the source of the respective numbers of cases is not stated, and it is not known in which epidemiological epidemiological context in which the cases occurred, e.g. in the public in the public or in hospitals or nursing homes and, if the latter, whether the adequate protective measures, such as protective clothing, in the typically close typically close and prolonged care of patients, or what proportion of cases were or what proportion of cases originated from outbreaks. Furthermore, the authors assume that the virus was new to the population, which is immunologically incorrect, as we know. immunologically incorrect, as we know that more than 80% are only mildly ill or do not get ill at all, so we have a have a background immunity through contact with similar viruses or through our natural natural immunity. There has been no exponential growth anywhere, because such infections always spread in the form of a Gompertz curve (and exponential growth always growth always has a natural end, even e.g. bacterial growth in a nutrient solution). nutrient solution). Incidentally, this paper is one of the numerous pre-publications (preprints: as of the beginning of January 2021), i.e. the manuscripts submitted to the journal manuscripts submitted to the journal that have not yet gone through a peer review process, which

which may still change, because very few manuscripts simply pass through the manuscripts go through the peer review process and are published without the authors having to without the authors having to make any changes.

14 Systematic review (summary of a so-called 'rapid review' by authors of the RKI, published in September)

published on the RKI website in September 2020) [82]: In this paper, a total of

In this work, a total of 27 mathematical modelling studies were reviewed with regard to the efficacy of non-pharmaceutical interventions.

effectiveness of non-pharmaceutical interventions in controlling the COVID-19 pandemic. pandemic.

This work from the RKI has not yet been published in a scientific journal,

but also the entire manuscript has not yet been published as a preprint.

only a summary of it is available on the RKI website. On the other hand

numerous papers are cited in this review as preprints, which themselves have also not yet been have not yet been published in peer-reviewed journals.

Nevertheless, the RKI writes under the link on the corresponding website

The following (last viewed on 03.04.2021):

Within the framework of a rapid review, the Robert Koch Institute (RKI) has

journal on the effectiveness of non-pharmaceutical interventions (NPIs) for the prevention of interventions (NPIs) for the containment of ...' (emphasis for this expert opinion).

The RKI thus pretends that the studies discussed have already been published in

published in scientific journals. However, this is true of the 6 citations in which, among other things effectiveness of masks, this is not the case for 4 citations, because they are (also) still in the preprint stage.

are still in the preprint stage. This preliminary publication also lacks the citation of

citation of papers that critically discuss the Corona measures.

In addition, a conspicuously large number of preprints are cited. However, one only notices this

only when you look at the bibliography. With such not yet peer-reviewed

manuscripts that have not yet been peer-reviewed and thus not yet accepted by the journals.

literature review is not unproblematic, because significant aspects of a paper can change by the time it is 61

aspects of a paper may well change by the time it is finally published (if the paper is ultimately

accepted for publication at all).

In the media, for example, reference has already been made to these papers, which were previously not available as a complete manuscript, i.e. not verifiable in detail.

not available as a complete manuscript, i.e. not verifiable in detail.

that the recommendations of the RKI are based, on the one hand, on a comprehensive evaluation of the currently available scientific knowledge and, secondly, that available at the time, and that the recommendation to wear masks as a protective measure against SARS-CoV-2 was evidence-based. These conclusions are neither possible nor scientifically admissible on the basis of the RKI's rapid review. possible nor scientifically valid.

15 Mathematical estimate (summary, authors from the RKI, published in September 2020 on the RKI website) [83]: This RKI article also contains selective citations.

was also selectively cited. Although it has not yet been independently peer-reviewed by the journal 'Lancet Public Health', to which it was submitted, it has not yet been published.

peer-reviewed by the journal 'Lancet Public Health', to which it was submitted, it is, like [82], also available on the

RKI pages in an abstract. In it, a modelling study

modelling study using the publicly available databases, the effects of the non-pharmaceutical of the respective non-pharmaceutical measures used to contain the infection within the infection within the 37 OECD member states from January to July 2020.

were investigated. The authors conclude that restrictions on meetings and gatherings are the most effective. In addition, could masks, school and work closure policies, and testing volume could reduce the number of testing volume could curb the number of positive cases. However, the literature list lacks publications in which the Corona measures were assessed critically and without any influence on the incidence of infection. Upon request to the RKI with the request for request for the complete manuscript, the RKI was informed that there were numerous suggestions from the expert public' on the manuscript, which is why it will be revised and resubmitted.

revised and resubmitted. It remains to be seen whether the bibliography will be will be completed after the revision.

These two RKI publications by Pozo-Martin et al [82, 83] will help the

government to justify the Corona measures it has taken. Presumably they have already been published as an abridged version on the RKI pages, but without the full the full manuscripts as well. Readers who are not familiar with the with the rules of publication may not understand the problems associated with such incomplete pre-publications (e.g. journalists who publish them on the RKI pages). journalists, for example, who treat them as if they were completed publications). publications).

16 Mathematical estimation (preprint, submitted October 2020) [84]: All authors are from economics.

are from the field of economics. The subject of this mathematical of this mathematical estimate was the effect of the indoor mask requirement in Ontario, the most Canada's most populous province, between March and mid-August 2020.

the mask requirement was staggered over a period of about two months in a total of 34 regions. regions, so that the regions with earlier mandatory masking could be compared with those with regions where the mask requirement came later. In a second approach, for all the effects of all non-pharmaceutical interventions (NPIs), including the mask interventions (NPI) including masks. The differences between the provinces in terms of both mask effectiveness and the effectiveness of the other NPIs. of the other NPIs. The estimation of the differences between the regions with and (still) without masks in the province of Ontario showed (already) two weeks after the introduction of the mask requirement, there was a reduction of new positive 62 corona cases by 25 - 30%. This result was confirmed at the level of all provinces and was and was even higher at 36 - 46%. This time interval to the is very narrow, because the first effects of a measure only begin to show after about two weeks. the first effects of a measure, if there are any.

Apparently, however, there was no further reduction in positive cases in the period after that, otherwise the authors would have reported on it, and this makes the result even more epidemiological point of view even more questionable. As usual in mathematical modelling studies, possible other (confounding) factors could not be included. factors could not be included, but only the policy measures, i.e. in this case the mandatory in this case the compulsory masking.

17 Narrative overview (first submitted in October, revised version from November, published in December 2020) [85]: It is a review paper which predominantly looks at recent (rather than all) publications on masks. Therefore the authors refer to the work as a 'narrative update'. It is a text that one assertion after the other and cannot offer any new work because there is no there is no corresponding research.

b) Publications 'contra masks

In the following, 7 publications are presented that have not shown any positive effect of masks in the public, even though they have not shown any positive effect of masks in the public.

positive effect of masks in the public, even if they recommend the use of masks the use of masks (again, in the chronological order in which they were submitted or (again, in the chronological order in which they were submitted or published, depending on the information in the publication).

Systematic review (submitted in May 2020) [86]: 9 randomised controlled trials were evaluated.

randomised controlled trials conducted outside medical institutions (households, student

institutions (households, student dormitories). An efficacy of masks as a

as a sole measure for the prevention of influenza-like illness (ILI) was not found.

illness = ILI) was not found. In 6 of these studies, 3 groups were compared in each case: (1)

hand hygiene alone, (2) masks and hand hygiene, and (3) no intervention. There was a

significant reduction in ILI was found only with mask use in combination with hand hygiene, but not with

hand hygiene, but not with masks alone. The authors note, however, that the

protection of masks over and above other measures, such as hand hygiene, remains unclear.

remains unclear.

2nd Systematic review with meta-analysis (commissioned and funded by WHO in 2019.

and funded by WHO in 2019, to be published in May 2020) [87].

development of a guideline on the use of so-called non-pharmaceutical interventions in the general

in the general population for pandemic influenza. It included 10

randomised controlled trials of masks to assess their effect on the transmission of laboratory-confirmed

transmission of laboratory-confirmed influenza infections. There was

no evidence that masks are effective in reducing influenza transmission.

transmission of influenza, either when worn by infected persons for the protection of protection of contacts (external protection), nor when used by non-infected people used them for their own protection. The authors also note that the use of masks is essential, otherwise the risk of transmission may be increased. risk of transmission may be increased.

3rd 'Living Rapid Review' (first part published in June 2020) [88]: Subsequently, a total of five updates have been published.

five updates have been published (most recently in March 2021) [89 - 93]. Reviewed

The aim of this continuously updated review is to examine the effectiveness of masks in reducing respiratory

respiratory viral infections, including SARS-CoV-2, in the context of patient care in medical in the context of patient care in medical facilities on the one hand and in the 63 population. So far, no evidence has been found for the effectiveness of masks outside the outside the medical field.

4 'Umbrella Review' (published July 2020) [94]: This paper reviewed all available systematic reviews of randomised controlled trials.

available systematic reviews of randomised controlled trials were analysed together.

(in contrast, in usual systematic reviews, the original studies are evaluated).

evaluated). The object of investigation in each case was the use of masks to respiratory infections in medical personnel and the general public.

normal population in public. No evidence was found for masks as an external protection, and even for the wearers themselves there was only a possible reduction in the risk of infection.

reduction in the risk of infection (self-protection).

Mathematical estimation (preprint, submitted in October 2020) [95]: Eight different so-called non-pharmaceutical

non-pharmaceutical measures (in addition to the wearing of masks, e.g. limiting e.g. restricting gatherings, closing shops, closing schools)

in 41 countries were investigated for their effect on the reduction of the R-value. However masks were included in the evaluation (together with the other measures).

measures) did not result in a further reduction of the R-value, i.e. masks have no have no effect.

In December 2020, the study was published in Science, but since then the evaluation of masks is no longer available.

evaluation of the masks is no longer available [96]. The article does not explain this. If the preprint, one does not notice that the measure listed in the first place in the is missing in the final publication. The only mention at the end only that it is difficult to estimate the effect of masks in public spaces, because of the limited public life created by the other measures in force. life was there. The preprint 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 to its comparatively low economic and social costs. Its effectiveness may have increased as other NPIs have been lifted and public interactions have been recommenced'.

6 Randomised controlled trial (conducted in April and May, published in November 2020) [97]: In Denmark, this study investigated whether the recommendation, in addition to the other known protective measures (keeping distance distance, etc.) to wear a surgical mask every time one leaves one's home. infection with the new coronavirus in a population with moderately high infection rates. infection rates. At the time of the study, in Denmark, the wearing of wearing masks in public was rare in Denmark and was not publicly recommended. The study was open to anyone who did not wear masks for work and spent at least three hours a day outside the home and among people. Through

randomisation, a total of 3,030 study participants were assigned to the mask group 64 and 2,994 participants to the control group. Infection with SARS-CoV-2 could be detected by antibody detection, PCR test or hospital diagnosis. In the mask group, 42 participants (1.8%) were found to be infected with the new coronavirus. In the control group in 53 participants (2.1%), so the difference was 0.3%. The difference of 0.3% was small (and not statistically significant). The study was aimed at self-protection and was therefore - in contrast to the masks in Germany until January 2021 - was not aimed at the protection of others. The study was aimed at self-protection and was therefore - in contrast to the masks in Germany until January 2021 - was not aimed at the protection of others. protection, so that this study cannot make a contribution to answering the question whether the wearing of masks by healthy people has a protective effect on other protection, i.e. whether other people can be protected from contact with pathogens. from contact with the pathogen. However, the study is equally unsuitable to support the self-protection provided by medical masks.

masks, which politicians in Germany have been calling for in the wake of the the new variants ('mutants') since January. Also for this decision to use OP or FFP2 masks (in Bavaria only FFP2) for shopping and public (in Bavaria only FFP2), there is no scientific basis for this decision. basis.

7. experimental study (published in December 2020) [98]: By the Deutsche Bahn AG (DB) and the German Aerospace Center (DLR) launched the project 'Corona Pandemic'. Corona pandemic, the project 'Air quality in rail vehicles' was carried out. In this experimental procedure in a stationary test carriage (type ICE 2) to determine the dispersion paths of particles in the order of magnitude of aerosol particles (simulated through the release of CO₂ as a tracer gas or artificial saliva particles with a diameter between approx. 3 - 4 µm from a source at head height of a seated person into the sitting person in the train carriages). The measurements were without and with (surgical) mask. The result (already) without a mask was that the dispersion takes place mainly directly and immediately at the source. A spread throughout the wagon or indirectly via the ventilation system. was not found. Interesting is (1) the result that a passenger sitting at a table directly the source of the pathogen (i.e. close face-to-face contact at a distance of approx. 1 - 2

m distance) comes into contact with only 0.2% of the released particles.

in front and next to it on the other side of the aisle, only 0.01% arrived. With

other words: even for the person sitting directly opposite, there would be practically no risk of being

risk of coming into contact with a released pathogen. Another important

point is that (2) the ventilation system operates at a very high air exchange rate and also

with a high proportion of fresh air, so that the entire air in the wagon is exchanged once every 5 minutes.

air in the wagon is exchanged once every 5 minutes (i.e. 12 air changes per hour). This in turn

means that, in view of the constant dilution by the supplied air, there is no relevant excitation for the passengers.

no relevant pathogen contact could occur for the passengers, also because the

the contact time is far too short for the particles to spread away from the

the particles away from the source of the pathogen to lead to an infection,

if they were infectious particles.

DB and DLR could have deduced from their results (which apply very well to the ICE 1/2 fleet, but could also be applied to many other types of rail vehicles).

that masks are not necessary in trains because (1) there is hardly any aerosol dispersion and

aerosol dispersion and (2) the ventilation system changes all the air in the wagon within a few minutes.

of the carriage is exchanged within a few minutes, so that potentially infectious particles are

particles are removed in the shortest possible time. This means that the concentration

of infectious particles is constantly and very effectively reduced by the high air exchange

effectively, i.e. a dilution of the particles in the air of the carriage takes place, which

which continuously, very quickly and to a high degree reduces the potential risk of transmission. 65

and to a high degree. The mask reduces this risk only insignificantly and only for the person

and only for the person sitting next to him. For these reasons, this study was

included in the group of contra-mask studies, contrary to the interpretation of DB and DLR, because the results speak against

because the results contradict that masks have an effect in the sense of protection against

effect in terms of protection against infection. However, whether the 'aerosol' transmission assumed in the

assumed in the study, plays a role at all in the transmission of the coronavirus

transmission of the coronavirus plays a role at all, is the crucial question that will be discussed in Part C.

Summary of the scientific basis for masks

Despite the lack of scientific evidence, in the first half of 2020 both.

WHO, ECDC, CDC and RKI - all generally highly respected national and

international scientific health authorities - have more or less recommended the wearing of masks in

more or less recommended the wearing of masks in public spaces, albeit, as with the WHO [41, 42],

limited to specific epidemiological situations, but with clear 'warnings' from all

with clear 'warnings', with the result that policy-makers rely on these assessments, which are made scientific basis, but the 'warnings' point to the need to keep their distance.

but limits the 'warnings' to the need to keep their distance.

It must be noted that all national and international health authorities, albeit

and international health authorities have, albeit cautiously, issued an assessment of the wearing of masks in public spaces with great implications, contrary to the scientifically established standards of evidence-based medicine.

have issued an assessment on the wearing of masks in public spaces of great significance, based only on so-called plausible considerations,

which, however, cannot be sufficient to provide policy-makers in such a situation, i.e. for the use millions of people, a scientifically sound basis for decision-making.

convey. A clear scientific opinion, as one can expect from these authorities, looks different.

looks different.

It is therefore not surprising that the technical literature published since the spring of 2020

has not shown any evidence for the wearing of masks by the public in public

has shown any evidence for the wearing of masks by the general public, even if the authors of mathematical estimates claim this and the authors of

of opinion pieces in e.g. narrative reviews do not (cannot) present any data for this.

Numerous physicians in various fields and scientists from other disciplines like to

disciplines like to refer to such 'positive' publications, and in particular often to modelling

often to modelling studies that are not particularly mathematical for those with a sound

mathematical background (not uncommon among physicians), and are therefore

and thus have a deterrent effect, but perhaps precisely by suggesting that they are particularly

suggest that it must be particularly meaningful 'science'.

The scientific quality of the pro-mask publications is (very) low, because they are

mainly mathematical estimates, narrative reviews and opinion pieces, but meaningful systematic but there are no meaningful systematic reviews. In contrast, the quality of the evidence of the contra-mask publications is high because of several systematic reviews (incl. meta-analysis).

As far as the frequency of its citation for confirmation of mask efficacy is concerned, the so-called 'Lancet Review' is at the top [43]: Since its publication at the beginning of June 2020, this

publication at the beginning of June 2020, this publication has been cited as evidence by countless medical

as evidence. They believe they are on the safe side, probably because this journal journal (together with the NEJM) is one of the two most highly ranked medical journals in the world. This means that physicians can be sure that what is published there is well-founded. is rigorously peer-reviewed and can be taken over with confidence. 66

can be accepted with confidence. This assessment is clearly not appropriate for this article.

obviously not appropriate for this article. What's more, it is easy to see that, and without need to know how meta-analyses work mathematically. The WHO had commissioned this WHO had commissioned (and funded) this 'urgent review' because they obviously needed the results urgently (hence an 'urgent' review) for a new evaluation of the mask issue for the new coronavirus. In 2019, the WHO had already issued a similar

pandemic influenza, the WHO had already commissioned a similar review [87]. However, since influenza

influenza was not considered sufficient or informative for decisions on the new coronavirus.

and perhaps also because this review did not show a protective effect of masks.

protective effect of masks, the WHO requested an 'urgent review' in which only

only publications on the three special, because non-seasonal coronaviruses

SARS, MERS and SARS-CoV-2 (with SARS-CoV-2 likely to become a seasonal one).

will probably become a seasonal one).

For this, the WHO needed a publication in a journal that was beyond reproach. The

journal, the more easily the messages of the articles published in it are accepted and disseminated by the readership.

accepted and disseminated by the readership. But to what extent the result of the

of the literature search corresponded to the WHO's expectations is unknown. One can

put it this way: both the authors of the Lancet review and the WHO with their

WHO with their mask recommendation of 5 June 2020 have at least attempted to to a certain extent with scientific decency. What remains, however that the WHO has bowed to political pressure, as has been reported, but then makes the clear statement that the scientific evidence for the effectiveness effectiveness of masks worn by healthy people in public is lacking. The Lancet review also says this, albeit somewhat hidden.

The WHO had commissioned a review on non-pharmaceutical interventions incl. masks in autumn 2019.

masks, which showed no effectiveness of masks [87]. In addition

In addition, a systematic review with meta-analysis had already been published in 2017.

the effectiveness of hand hygiene and masks [99]. This meta-analysis

only indicates a significant protective effect for hand hygiene, but not for masks.

masks. The studies evaluated in this meta-analysis were conducted in the so-called community setting.

families with people suffering from influenza. And also the 'Lancet Review'

[43] was also unable to show efficacy. Even the studies or opinion pieces published in the

published in the period since then have not been able to show any evidence of the effectiveness of masks in public (see above). Thus, according to the scientifically

criteria, there is no evidence that masks worn by healthy people in public have a positive

have a positive effect on the incidence of infection (but possibly a negative effect; see above).

(but possibly a negative effect; see part B).

The fact that masks were nevertheless made compulsory in Germany is not consistent with the requirements of the IfSG in § 1 (2), according to which

infection control measures should be evidence-based. Political decisions are not

IfSG does not provide for policy decisions, and yet, since the first lockdown in March 2020, political decisions have been made that have no scientific basis.

It is clear that due to the global shortage of professional masks (of which there will be

there were nowhere near enough in clinics and nursing homes in spring 2020, so that they were not available for

use by the population in Germany anyway), the general mask

masks could only be introduced in Germany with the indication that

self-made masks or even just a cloth in front of the mouth and nose were also sufficient.⁶⁷

Naturally, no statements can be made about the quality of non-medical masks, because every citizen could use whatever he wanted. For this reason alone there can be no data on this, as stated in the RKI article [1]. It would have been transparent to explicitly point out the lack of scientific data for the general use of masks in public spaces.

At least the last sentence of the sentence of the RKI article [1], as everywhere else in the text, should only have mentioned that the masks

that the masks could be a building block to reduce transmissions, but not to state this as a fact.

Any extensions of the mask requirement, such as in schools, in parliaments and on hiking trails (e.g. as through the Höllentalklamm gorge in the Zugspitz region because of bottlenecks on the

the path), in pedestrian zones in city centres or on car parks in front of shops because of possible crowding, or even in some municipalities when cycling in town centres

are based not least on the unscientific 'aerosol' discussion propagated by bioscientists and propagated by aerosol physicists as well as by manufacturers of air-conditioning systems ('air pollution').

manufacturers of air-conditioning systems (see part C.).

At the beginning of September 2020 an article (in the political magazine Cicero) dealt with the fate of schoolchildren wearing the masks [100]. The author (social scientist

and educational researcher) considers it certain that no study in which children were to wear masks for hours, days

days and weeks would have been approved by an ethics committee in Germany.

would have been approved. However, even paediatricians have spoken out in favour of schoolchildren wearing masks.

wear masks, or can wear them without harm, even during lessons [101].

even during lessons [101]. In an 'open letter', a pharmacist took a stand on this and expressed his expressed his lack of understanding that the opinion of the paediatric

paediatric societies lacks any scientific and ethical quality [102].

quality [102]. He asked whether the mask was not rather a political instrument than a sensible medical measure and whether the

medical measure and that the authors and signatories are not so much medical

medical practitioners, but more as political functionaries fulfilling a political mandate. Then,

the author continues,

'it would, however, be appropriate to present this mandate transparently and to that the wearing of masks for children is politically desirable and that the possible risks that may be involved'.

A few months earlier, this author had already published an article in the *Deutsche Apotheker* in which he criticised, among other things, that all the standards that have been important for the effectiveness of masks

masks have been invalidated, and only some piece of fabric in front of the mouth and nose is and nose, without taking into account the filter effectiveness (in view of the different particle sizes) and the

particle sizes), the correct use of masks, or the actual risk of transmission.

or the actual risk of transmission [103].

Since the introduction of compulsory wearing, masks have been the only visible measure used by the by politicians and the scientists advising them, and most of them have been strictly enforced, although they have had no discernible effect over the months. Instead of them - as obviously as obviously useless, potentially harmful and not confirmed by any data that can be described as scientific data, the obligation to wear masks was successively extended to extended to, for example, the irrational obligation to wear masks outdoors in busy squares or in pedestrian zones (which virologists and aerosol physicists also oppose), the compulsory wearing of masks by schoolchildren, even during the entire school day, and the FFP2 masks in shops and on public transport in Bavaria.⁶⁸

The fact that pupils are now forced to wear masks for hours on end, and that even during breaks in the schoolyard and in sports lessons, is not justified in view of the the complete lack of medical evidence. In addition, there are

there are no systematic studies on possible harmful side effects, and

and that such studies are not even demanded by the paediatric associations.

are not even demanded. The fact that the side effects are by no means harmless or rare is shown by (already published in December 2020 as a preprint and in the meantime as a final publication)

of the University of Witten-Herdecke, in which preliminary results from an online

online register in which parents, teachers or doctors, for example, enter the complaints of children in connection with the wearing of masks.

children's complaints in connection with the wearing of masks [104]. The

data from approx. 18,000 parents participating at this time (within 1 week of the start of the register) on

about 26,000 children, with an average wearing time of 4.5 hours.

4.5 h per day, the following complaints (with the respective percentages of frequency)

frequencies): Irritability (60%), headaches (53%), concentration difficulties

(50%), dejection (49%), dislike of school or kindergarten (44%),

malaise (42%), learning difficulties (38%) and sleepiness or tiredness (37%).

S3 guideline of the AWMF. Despite a lack of confirmation of the effectiveness of masks in the public from scientific studies, the guideline was published on 1 February 2021 with the participation of numerous

S3 guideline was published by the AWMF on 1 February 2021, which recommends the use of masks.

masks with the recommendation grade 'Strong Recommendation A' as an 'evidence-based recommendation'.

recommendation', although the quality of the evidence was rated as 'low' [105].

low' [105]. The preamble of this S3 guideline states, among other things:

'(...) The aim of this guideline is to provide all stakeholders with scientifically sound and and consensual recommendations for action.

The guideline recommends adaptable and suitable packages of measures to

reduce the risk of infection and to enable the safest possible, regulated and continuous school operation,

and continuous school operation in times of pandemic. (...)

These recommendations were drawn up by a representative group of experts from scientific

scientific societies, school stakeholders and decision-makers following a structured

decision-makers in accordance with a structured procedure. They

based on the currently available studies on the effectiveness of measures for the 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, a package of measures is always necessary: Measures

measures must be implemented in a coordinated manner in order to be effective. The starting point

The starting point is a standard package of measures that is based on the AHA+L rules

AHA+L rules that apply to the general population and that specifically provide for distance, hygiene, wearing an appropriate mask and ventilation.

wearing an appropriate mask and ventilation.

(...)'

'Evidence base. The evidence on the effects of the measures with regard to transmission of SARS-CoV-2 was systematically reviewed in a Cochrane Rapid Review [Ref]. was systematically conducted [Ref]. The evidence obtained is largely based 69 based on modelling studies with quality deficiencies [Ref]. For the possible effects of of specific interventions, particularly informative individual studies from the Cochrane from the Cochrane Rapid Review [Ref]. For all effects considered the confidence level of the evidence is very low or low'.

The recommendation on 'Ventilation and reduction of aerosol concentration in classrooms' shows a very low level of evidence, but the level of recommendation is, as for the Mask recommendation 'Strong recommendation A'.

The claim formulated in the 'Preamble' to the scientific basis of the guideline is - as usual for scientifically based guidelines - high. In addition, the recommendations of the guideline stand in stark contrast to this, because despite the lack of meaningful

scientific evidence (quality of the evidence: 'very low' or 'low'), both masks and low'), both masks and ventilation are given a recommendation grade of 'Strong recommendation A' with a high level of consensus (100% for masks and 93% for ventilation). recommended. Contrary to the description in the 'Preamble', both recommendations are not 'scientifically based'.

recommendations are not 'scientifically founded (...) recommendations for action', only the only the degree of consensus among the participants was high, but this cannot compensate for the lack of scientific

of the recommended measures. Otherwise we would be back in the time before evidence-based medicine (around the beginning of the 1990s, i.e. about 30 years ago), where the experts would present their opinions and then they would vote on them if necessary. there was no agreement anyway. At that time, scientific principles hardly played a role

scientific bases hardly played a role at that time, but rather the 'experience' of the individual experts and their

group of colleagues. However, the S3 guideline follows this old pattern almost exactly.

pattern. The only difference is that the underlying scientific evidence has been taken into account and its significance has been assessed. It is astonishing that the recommendation was not influenced in any way (possibly in the discussions, but not in the outcome). discussions, but not in the outcome, and that is the only thing that counts for a guideline). As a result, the AWMF's S3 guideline is not compatible with the requirements for such guidelines. such guidelines, but rather represents a perversion of what constitutes a scientifically sound guideline. Ultimately, it is a misdirection of those who are not familiar with the meaning of (high-quality) guidelines (S3). The It is very much in line with the decisions of politicians and is possibly due to subjective subjectively perceived political pressure.

In July 2020, a study by the University of Leipzig on cardiopulmonary adverse effects by masks in adults was published [106]. The authors concluded that respiratory function, cardiopulmonary performance and well-being when wearing surgical masks. well-being were reduced when surgical masks were worn. Significant limitations were observed in this respect in connection with FFP2 masks. were observed. These negative effects must be weighed against the potential protective effect of masks against virus transmission.

masks against virus transmission and should influence medical recommendations and policy decisions.

medical recommendations and policy decisions.

A further study (conducted in the first half of June 2020, i.e. within the the first six weeks or so of compulsory mask use in Germany) looked at the psychological, psychosocial and psychological, psychosocial and psychovegetative effects of mask-wearing [107]. [107]. The author comes to the following conclusion: The very fact that approx. 60% of the (approx. 1,000) study participants were already suffering from severe (psychosocial) severe (psychosocial) consequences, e.g. severely reduced participation in life in society (due to the effort to avoid wearing masks), social withdrawal, 70 reduced health self-care (up to and including avoidance of doctor's appointments) or the exacerbation of pre-existing health problems (post-traumatic stress (post-traumatic stress disorder, recurrent herpes simplex, migraine), indicate that the results of the study

The results of the study urgently call for a review of the risk-benefit ratio of the mask regulation.

The use of masks by policy-makers as an important measure to contain the pandemic, and the observations made in the media among politicians and the (normal) public on the use of the masks show that it is probably

neither that the effectiveness of the masks must be scientifically proven, nor that they should be handled in such a way,

nor is it about handling them in such a way that they do not pose a risk of contamination.

The RKI could and should have pointed out long ago, or repeatedly, what should be done for infection control.

what is meant by the correct handling of masks for reasons of infection control, but only occasionally

but there is only an occasional brief reference to this. This aspect

shows that the mask requirement is less about the claimed benefits in terms of infection

protection against infection, but rather its (psycho)social function, as it is very clearly stated in a

publication from the time of the so-called Spanish flu [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.'

Today, too, the mask seems to have the crucial function of showing the population that the government is doing something.

that the government is doing something to protect them from the presumed danger of infection.

infection. On the other hand, it is supposed to represent a kind of reassurance to the population,

that by wearing the mask they can contribute to their own well-being...

of others. The mask is thus needed by both the policy and the population,

and by the population, which trusts the measures of politics, in order to stabilise the mental

stabilise their mental and spiritual condition - including, of course, that of the politicians, who are quasi naked, i.e. without a 'protective measure'.

for the population in times of pandemic, if they did not have the mask,

even though experience since the spring of 2020 has shown

cannot have the desired effect, because the number of people testing positive is

uninfluenced high, or has risen and continues to rise from time to time even to unprecedented

unprecedented heights - despite the maximum extended mask obligation. The fact that compulsory masking for

psychological reasons and because of its symbolic significance, have already in July 2020 on the reintroduction of the strict mask requirement in Austria. independently of each other, both the Federal Chancellor and the Minister of Health of Austria on 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 hygiene', which means (1) coughing or sneezing into the crook of your arm and (2) washing your hands often and

and thoroughly for at least 20-30 seconds. Missing is (3) the

correct handling of masks. Until the introduction of the AHA rules, about six

weeks had passed since masks were made compulsory, and by then enough was known about the inadequate and

known about the inadequate and therefore potentially infectious handling of masks by the

with the masks. This section therefore discusses the risks from the point of view of

risks associated with the compulsory use of masks for almost the entire population.

the entire population, if the policy is already based on this.⁷¹

Use of masks not self-explanatory

The population has never learnt to use masks correctly, and has not been taught to do so after the and were not trained to use masks even after the masks were made compulsory. The RKI has never made any concrete statements on this, e.g. in press conferences.

press conferences, for example. It always stuck to formulations that were rather meaningless for the the population that they had to be used 'correctly'. Instead of the constantly

Instead of the constantly repeated request to stay at home, people should have been given

people should have been offered continuous training in the use of masks, explaining to them that that certain rules must be followed when using masks and why.

must be followed. Besides the lack of a scientific basis for mandatory mask use (see

A.), this aspect is important: if masks are to be used, then their correct use must be given a central role.

masks must be given a central role, so that the masks themselves do not increase the risk of spreading the pathogen.

the risk of spreading the pathogen. It is difficult enough to communicate the necessary rules

the necessary rules to the medical staff or to anchor these rules in their minds in a way that

so that hospital hygiene staff do not have to be reminded of them repeatedly (but they do have to be reminded).

reminders (but you have to). Why this is important will be explained in the following will be explained below.

In two passages of the (short) article with which masks were justified in public, the RKI urgently points out the need for masks.

masks in public, the RKI points out the problems associated with the use of masks.

of masks (MNB) [1]:

1. ... that 'the use of MNB would undermine the central protective measures, such as the (self-)isolation of sick people'.

(self-)isolation of sick persons, the observance of a physical distance of 1.5 m, the coughing rules and hand hygiene to protect against infection. These central

These central protective measures must therefore continue to be strictly observed'.

2. 'Hygienic handling and care of MNB must also be observed. For

For this reason, care must be taken to ensure that the MNB is not touched, especially when being put on and taken off.

and setting down - is not touched (emphasis added for this report), in order to avoid contamination by the hands. In general, a longer wearing time

is also associated with an increased risk of contamination'. (here the RKI refers to the

BfArM = Federal Institute for Drugs and Medical Devices; see below

[111]).

However, the correct handling of masks is not a matter of course for the population. It

rather confusing when the RKI writes that one should not touch the masks, even

not - or even 'especially when putting them on and taking them off'. In this brevity it does not sound

comprehensible. Only experts know what is meant by this. The BfArM provides more

more detailed explanations (see below). The citizen would therefore have to gather the important information

from the announcements of various higher federal authorities.

Correct handling of masks is important

The obligation to use masks exists according to the RKI, which made the obligation to use masks in public possible in the first place through its publication [1].

public in the first place through its publication [1], because every citizen can

new coronavirus in the nasopharynx and because this allegedly leads to 'unnoticed' transmissions.

'unnoticed' transmission of the pathogen to fellow human beings during encounters in the in public spaces (see Part A.). Almost all people in Germany have to wear masks because we cannot know if we have the virus in our nasopharynx, even if we have nasopharynx, even if we do not have any symptoms of an upper respiratory infection 72 and therefore, i.e. because of this lack of knowledge, we cannot stay at home to protect other people from contact with 'our' virus.

other people from coming into contact with 'our' virus. The mask - of whatever type, i.e. originally only the so-called everyday mask made of fabric (MNB), since January 2021, the medical mask as an OP or FFP2 mask - is intended to prevent the virus that from being released into the environment.

What all types of masks have in common is that they must be used correctly in order not to from becoming a risk of infection themselves. Because if we harbour the virus undetected or if it multiplies in our nasopharyngeal mucosa without causing any symptoms, then we are at risk of mucous membrane without causing symptoms, then we are, according to the theory of

According to the theory of 'unnoticed' transmission, we are a potential source of the pathogen with our nasopharyngeal secretions,

from which the virus could spread from our bodies to other people...

to other people. So the mask, in order to prevent just that, cannot be the only protection because, for whatever reason, people very often touch their faces with their hands.

hands to his face, which is a well-known fact that everyone can see at any time in himself which everyone can check at any time on themselves and on their fellow human beings in daily life.

[112]. And if one wears a mask, the hands are even more frequently in the face, because the mask is a nuisance. For example, you sweat underneath it, it itches, your glasses fog up, the mask gets

or you don't get enough air (even with everyday masks, not only with masks, not just FFP2 masks). So people are always with their hands on the hands on the mask, which according to the RKI - correctly - should not be touched.

Either way, you yourself or your fellow human beings can get into contact with the mask via the mostly unnoticed hand-face contacts.

contact with infectious agents in the very places where the pathogens of respiratory respiratory infections must reach in order to produce an infection, namely the mucous membranes. the mucous membranes of the upper respiratory tract, including the eyes (or where they are

if you are already infected). Incidentally, it has been known for decades that respiratory viruses (whether enveloped, such as rhinoviruses, or enveloped, such as influenza and coronaviruses) can also survive outside the body for a certain period of time (depending on the extent of their in cell cultures and thus remain potentially infectious. remain potentially infectious [113 - 115].

Thus, because people are almost constantly exposed to infectious agents on various occasions (in their own households, at work

work and in public), one can contaminate one's hands almost constantly.

hand-face contact, handwashing is, in the view of all health authorities in the world

the opinion of all health authorities in the world, as well as according to the results of the Cochrane Review Update [1, 33, 35, 37, 42, 111], handwashing is recognised as one of the most measures to reduce the transmission of respiratory infectious agents.

transmission. However, this is precisely what people cannot do when, for example, they are out shopping

or using public transport. Similarly, hand disinfectant is not always available.

Hand hygiene: hand washing

When all the health authorities in the world point out the importance of handwashing

hand washing, this always means thorough hand washing with soap and water for 20-30 sec.

sec. For the general education of the population about individual protection against infections - in addition to emphasising the general

the general necessity of frequent handwashing - it is also necessary to point out that

it is also necessary to point out that one should not touch one's face with one's hands as long as one as long as you have not washed your hands. This is exactly what the

international health authorities clearly say, and the RKI says it too, but less frequently and not

in a prominent place and also not in the AHA rules. However, it is not easy, you 73

but it can be trained: If you know that it's important, you can observe yourself and reduce your own hand-face contacts.

Therefore, information campaigns for the population should not only focus on the

the need for frequent handwashing, but also to explicitly point out

why handwashing is so sensible and important: so that people do not catch contaminated

contaminated hands to your eyes, nose and mouth. Only then can the call to

then the call to wash hands can really be understood and not (so easily) dismissed as an annoying rule of hygiene. For this reason, all health authorities in the world point out the great importance of hand hygiene.

importance of hand hygiene to prevent the transmission of respiratory viruses by indirect respiratory viruses through indirect contact or hand-face contact (the same is true for the prevention of gastrointestinal

The same applies to the prevention of gastrointestinal infections, whose pathogens, e.g. noroviruses, can also be acquired through contaminated hands and subsequent oral contact).
contact with the mouth).

For the prevention of the transmission of respiratory pathogens, this means that one should not to touch or go under the mask, because this would contaminate your hands and thus and thus expose other people to the risk of coming into contact with their own pathogens. with their own pathogens and thus to get an infection, which is precisely what the mask is which is precisely what the mask is supposed to prevent.

Hand hygiene: hand disinfection

The correct use of hand disinfectants must be learned, because hand disinfection is by no means trivial (and is trained repeatedly with the medical staff, e.g. in repeatedly, e.g. also by using a UV lamp in order to be able to see the fluorescent hand disinfectant to see under the UV light whether the entire the entire skin of the hands and in particular the finger syringes incl. thumbs were included in the disinfection).

thumbs have been included in the disinfection). The agents used for hand disinfection are alcohol-based.

used for hand disinfection are alcoholic solutions usually containing 60 - 80

so that the skin does not become too dry, as alcohol would otherwise dry out the skin (as would handwashing).

the skin (washing hands also dries the skin). They are usually very well tolerated (alcohol is not toxic). alcohol is non-toxic), but despite the addition of lipid-replenishing substances, it is still important to skin care is important if you have to disinfect your hands frequently, as is the case with medical as is the case with medical staff. Properly carried out, hand disinfection is more effective hand washing (eliminates or reduces more potential infectious agents in less time), but in time), but in normal life, hand washing is the method of choice, whereas in the medical sector

in the medical sector (partly for skin protection reasons), hands should only be washed when they are

hands should only be washed if they are visibly soiled.

If you are out in public, e.g. shopping, you usually have no opportunity to wash your hands.

to wash one's hands. That is why grocery shops, for example, have had

since the early summer of 2020, for example, have provided hand disinfectants at the entrances to the shops

alongside other disinfectants intended for surfaces (i.e. in particular around the

(i.e. especially for wiping down the handle of the shopping trolley), but which do not contain any

if they are also alcohol-based, because this is not necessary for this purpose.

not necessary for this purpose. Hand disinfectants should therefore not be confused with

hand disinfectants with surface disinfectants, especially if these products contain other

agents contain other active substances and not alcohol, because other active substances must not be

other active substances must not be used on the skin because they are toxic to humans or 'only' have an

have an allergenic effect. In this respect, the provision of 74

disinfectants can lead to incorrect use by the general public, who cannot

the difference between hand and surface disinfectants (and normally does not

normally do not need to know). The shelves on which the disinfectants are offered for self

disinfectants for self-application usually look untidy and do not give the

and thus do not give the impression that all this is supposed to be about cleanliness per se.

But assuming that the right hand disinfectant is being used, there is another difficulty for the people involved.

hand disinfectant is used, there is a further difficulty for the untrained population.

It is not enough to simply take any amount of disinfectant solution,

It has to be a sufficient amount to wet the entire skin of the hands.

the entire skin of the hands. This varies somewhat depending on the size of the hand.

usually about 3 mL, but this is necessary even for smaller hands (for larger hands it is

correspondingly more). With this amount, you have a puddle in the palm, and that means

also means that a smaller quantity or even just a little spray will not lead to an

effective disinfection of the hands. This puddle must then - not

washing hands, i.e. in the truest sense of the word according to the principle: 'One hand washes the other'.

hand washes the other' - over both hands so that the entire skin of both hands is wetted with the disinfectant.

skin of both hands is wetted with the product. On the other hand, you have to rub the

the product all over until the hands are dry again. This takes a total of 20

- 30 seconds, which only seems short, and only then can one speak of an effective hand disinfection.

effective hand disinfection. Spreading the agent everywhere must also be done consciously, because it is not enough to just

because it is not enough to just rub the palms together. Rather

that the fingertips and thumbs in particular are included, because they are

because this is where the decisive contact with objects or surfaces takes place.

Of course, effective hand disinfection also includes the spaces between the fingers and the folds of the palm.

the palm of the hand, but in normal life (as in the case of medical care of patients), the fingertips and the thumb

medical care of patients), the really important contacts are with the fingertips.

the fingertips (which is why long fingernails are an obstacle to effective hand disinfection).

hand disinfection, because unlike when washing your hands, if you don't use a nail brush

nail brush, you cannot get the product under the fingernails). Contact with the

contact with the flat of the hand or the spaces between the fingers is much less frequent.

The population does not know about this (they do not have to), but it was not explained to them.

explained to them. So it can happen that people who work in the field of medicine themselves

and therefore know how to disinfect their hands properly, i.e. effectively, may be reprimanded by fellow

people tell them not to use so much of the product and to hurry, because other people

and to hurry because others wanted to disinfect their hands too.

In summary, it can be said that with some certainty the possibility for hand disinfection is not the washing of hands.

hand disinfection cannot replace washing hands with soap and water, where at least some mechanical

you at least have some mechanical wash-off effect from the water,

even though you may not actually spread the soap all over the skin of the hands.

In addition, no matter what one has done before, i.e.

washing or disinfecting your hands, they are immediately contaminated again when you touch the mask or other objects.

the mask or other objects. The population is not aware of this either because they have not learned (and do not have to learn) that even a proper hand disinfection that even proper hand disinfection does not protect the hands from being contaminated in the next the next moment, i.e. the next time they come into contact with an object or a surface, the next moment, i.e. the next contact with an object or a surface.

But that is what medical staff learn. In this respect, the hand disinfectant 75 provided in front of the shops does not help.

hand disinfectant provided in front of the shops does not help, but only leads to more deception and provides

(once 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 and on the necessary handling of masks and the essential hand hygiene, which is essential to prevent the spread of SARS-CoV-2 through their use. of SARS-CoV-2 [1, 33, 35, 37, 42, 111].

Contamination. Masks become contaminated from the inside when the wearer exhales or speaks and can be

and can be contaminated externally by hand contact and respiratory droplets from other people.

respiratory droplets from other people. Masks worn in public places

The theory is that masks worn in public spaces should serve as 'source control'.

in the case of mask wearers who are (still) undetectably infected, the excisers released in pots when speaking etc. are to be used as a 'source control'.

released into pots when speaking, etc., should be caught by the mask so that they are not (or at least not in large numbers) into the environment.

With this assumption, the inside of the mask is potentially (because you don't know if you are already infected) contaminated with the pathogen.

you are already infected) is potentially contaminated with the pathogen. This means that with the inside of the mask, you will contaminate your hands with the pathogens from your (still) unnoticed infection from your own nasopharynx (NRR).

similar to what happens when one touches the mucous membranes of one's own eyes, nose or mouth.

eyes, nose or mouth. With hands that may have been contaminated in this way public surfaces (e.g. the handle of a shopping trolley or the handrail of an escalator).

or the handrail of escalators). These surfaces are then also touched by other other people also touch these surfaces, which can lead to a spread of the pathogens from the mask of the mask wearer.

Soaking. Every mask (including professional medical masks) will sooner or later become sooner or later become soaked through by the exhaled air and become permeable. permeable and no longer constitutes a barrier. Rather, the potential infectious infectious agents from the NRR (these can also be bacteria, such as Staphylococcus Staphylococcus aureus, one of the most frequent pathogens of purulent infections of e.g. accidental wounds.

e.g. accidental wounds) are not only found on the inside of a soaked mask, but also on the outside.

As a hospital hygiene staff member, one points this out to the clinically active personnel, medical staff are reminded of the correct use of masks.

masks, e.g. to avoid getting their hands contaminated with the potential infectious infectious agents from their own NRR if the mask is hung around the neck against the rules. worn hanging around the neck to put it back on later.

RKI, ECDC, CDC and WHO strongly emphasise that extremely careful hand hygiene and avoidance of hand-face contact are essential.

and avoidance of hand-face contact are essential and should not be discouraged by the use of masks in public.

masks in public are essential and must not be neglected.

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

In the spring of 2020, the BfArM explicitly stated that wearers of community masks cannot rely on the masks protecting them or others from transmission of the new coronavirus.

transmission of the new coronavirus, as no corresponding protective effect has been protection has been demonstrated for these masks. Since November 2020, this (correct) representation 76

is no longer available on the BfArM website. Instead, it stated there with the date of 12.11.2020:

'Irrespective of normatively defined proof of performance, as is the case for medical face masks and particle-filtering half masks, the BfArM has in the meantime the efficacy of the mouth-nose mask has now been confirmed on the basis of

the effectiveness of face masks in terms of general population protection.
protection of the population has been confirmed in numerous scientific publications
(Ref.). The protective effect of masks depends on the tightness and quality of the material used
quality of the material used, the adaptation to the shape of the face and the number of layers.
number of layers. For example, tightly woven fabrics are more suitable than lightly woven fabrics.
than lightly woven fabrics. By wearing good 'everyday masks' in the right way
the risk from droplets containing pathogens can be significantly reduced.
droplets can be significantly reduced'.

However, after it was decided in January 2021 in the federal government that only medical
masks (mouth-nose protection = MNS or surgical masks or FFP2) may be worn,
the text was adapted accordingly and now reads (last viewed:
29.03.2021) [111]:

'Everyday masks do not provide the performance evidence defined in the technical standards as
required for medical masks.

standards as required for medical face masks and particle filtering half masks.

half masks. They therefore generally provide less protection than these
regulated and tested mask types. However, this does not mean that they
protective effect. Internationally, there are numerous scientific

publications that confirm the experience gained about the effectiveness of the
effectiveness of mouth-nose coverings in terms of general population protection (Ref.).

(Ref.). The protective effect of the masks depends on the tightness and quality of the material used.

and quality of the material used, the adaptation to the shape of the face and the

number of layers of fabric. In this context, tightly woven fabrics are

are more suitable than lightly woven fabrics. So the correct

masks can reduce the risk of exposure to droplets containing pathogens.

by droplets containing pathogens'.

(The references given do not confirm the effectiveness of masks; cf.

above under the heading RKI: 'First scientific indications' for the

external protection, p. 32 of the expert report).

The BfArM formulated the rules for the use of masks in the following way

(summarised here for the different mask types) [111]:

The masks should only be used for private use.

The tips on hygiene as given in the recommendations of the Robert Koch Institute (RKI, www.rki.de) and the Federal Centre for Health Education (BzgA, www.infektionsschutz.de) should be followed. This is the only way to protect others from the spread of the coronavirus.

Even when wearing a mask, the safety distance of at least 1.5 m from other people recommended by the RKI should be maintained.

m from other people, as recommended by the RKI.

MNB. The mask must fit well and fit over the mouth, nose and cheeks. The

The edges of the mask should fit snugly so that as little air as possible is breathed past the mask. is breathed past the mask. It is best to try out different mask shapes until you find one that fits find one that fits.⁷⁷

MNS. The mask must fit well and sit over the mouth, nose and cheeks. The

The edges of the mask should fit snugly so that as little air as possible is inhaled past the mask. is breathed in. Adjusting the length of the ear loops (e.g. knots) can improve the seal. improve the tight fit.

FFP2. The mask must fit snugly and sit over the mouth, nose and cheeks. The

The edges of the mask should fit snugly and not allow air to flow past the mask. past the mask. An FFP mask can only provide its full filtering performance when it is tightly fitted.

When first used, the mask should be tested to see if it allows sufficient air to minimise obstruction to normal breathing.

A wet mask should be removed and replaced.

When putting on and taking off the mask, it should only be touched by the straps of the mask. the straps of the mask.

After removing the mask, hands should be washed thoroughly in accordance with the general rules of

hands should be washed thoroughly (at least 20 to 30 seconds with soap).

After removing the mask, it should be stored in an airtight bag or similar, or washed immediately. or washed immediately. The storage period should be as short as possible shortest possible time, especially to avoid mould growth.

MNB. Masks should ideally be washed at high temperatures. At

best at 95 °C, but at least at 60 °C. Do not use short wash programmes and then allow to dry completely. Be sure to follow all other manufacturer's instructions, e.g. the number of washes the mask can withstand without losing its function.

MNS / FFP2. The masks are intended by the manufacturer to be disposable. They should be changed regularly and disposed of after use.

Reality when handling masks in public

Correct handling of masks is not always easy to achieve among medical staff, as mentioned earlier, not always easy to achieve. For the general public, however, all these requirements, considered indispensable

requirements that are considered indispensable are not even remotely achievable. When shopping shopping, for example:

The mask is often adjusted with the hands.

It is often worn so that the nose is uncovered.

It is particularly problematic for spectacle wearers because the spectacles fog up, as

Unlike a professional surgical MNS, the community mask usually lacks a slightly bendable a slightly flexible temple that can be easily adapted to the anatomy of the nose.

to the anatomy of the nose. So you have to take off and put on the glasses repeatedly and inevitably get your hands on the outside of the mask.

Even if the weather is not particularly warm, you sweat under the mask and therefore and therefore your hands will always be on the outside of the mask or even underneath it.

Outside the shops, the mask is often only partially removed and then hangs over an ear with a sling. over an ear, is pushed under the chin, is worn on the wrist or forearm, or is taken off.

worn on the wrist or forearm, or it is removed and simply placed in a handbag, trouser pocket or jacket pocket. Furthermore, it can be observed that the mask (sometimes

(sometimes more than one at a time) in the car on the rear-view mirror so that it is always ready for the next use.

on the rear-view mirror in the car.

However, one must also ask oneself how one is supposed to do it differently on the road, even if one even if you try not to contaminate your hands on the mask:

You can't wash your hands when you get out of the car and put on the mask before entering the shop.

before entering the shop, and you can't wash your hands after leaving the shop, when the 78
the shop, when the mask has been taken off again, you cannot wash your hands.
wash your hands.

Hand sanitizers are not always available either.

The next question is how to manage contamination-free mask care after each use when in the shop.
after each use if you have to go to several shops:

One possibility would be to simply leave the mask on after leaving a shop,
as you've seen some people do. Then one could do all
errands (and the paths in between, if they are footpaths) with a single mask.
mask. People then walk around outside with a mask where it is
is usually not compulsory.

It is likely that the mask material will get
soaked through.

In everyday life, this is an impossible task if one wants to get tens of millions of citizens to take these
necessary precautions in the use of masks when it is not easy to do so with
medical staff is not easy, but where with the hygienic
hygiene specialists (hygienists, hospital hygienists), there are always people on the spot who can
can remind people of the correct way to use masks: It is unrealistic. Therefore, the RKI's mask
recommendation cannot be justified by pointing out the necessary precautionary measures.
precautionary measures, because they are unrealistic requirements that are inevitably
unrealisable requirements that inevitably and for all professionals cannot be implemented.
(can) be implemented.

A compulsory mask for many millions of citizens in Germany could result in tens of millions of
contaminations every day, which could be avoided to a large extent, because the already
avoidable, because the already frequent hand-face contacts of people would become even more
masks, but hand-washing on the road is only possible in exceptional cases.
and for a correspondingly frequent hand disinfection, every citizen would have to carry hand
hand disinfectant with them. There is a risk that the - already inevitable
inevitably - improper handling of the mask and the increased tendency to touch one's
face while wearing the mask may actually increase the risk of spreading
spread of pathogens and thus transmission of pathogens, a risk that the mask is intended to reduce.
the mask is intended to reduce. The increase in positive test results since the

can therefore also be attributed to the mask requirement itself.

itself.

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.

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 of the so-called transmission, as well as for the distance requirements, is of great importance. importance.

Almost all 'hygiene measures' used by policy-makers have aerosol transmission as their basis, even if they are not (always) explicitly justified on this basis:

However, there is no other explanation for measures such as the all-round distance or the FFP2 mask obligation or

ventilation. As will be shown in the following considerations

the theory of aerosol transmission is neither medically plausible nor scientifically proven.⁷⁹

scientifically proven.⁷⁹

The increasing importance of aerosol transmission in Germany

A mixture of airborne particles is called an aerosol. From

from media reporting to specialist articles, the term 'aerosol' is often reduced to the

reduced to the particles in suspension. The correct term is aerosol particles.

These do not have to be infectious agents, because all airborne particles can form an aerosol.

can form an aerosol.

In the case of SARS-CoV-2, many now consider the aerosol route of transmission (i.e. airborne or aerogenic transmission) to be the most likely route.

aerosol transmission (i.e. airborne or aerogenic transmission) is relevant. According to the latest

WHO's most recent description of the transmission pathways (dated 01.12.2020), the new

coronavirus (like all other respiratory viruses) is transmitted via (large) droplets of

respiratory secretions and via direct and indirect contact with respiratory secretions of infected

infected people [42, 116]. Aerosol transmission outside of medical

medical care (where aerosol-producing measures may be used, such as the

aerosol-producing measures are used, such as open endotracheal suctioning of intubated patients).

the possibility of aerosol transmission outside medical care (where aerosol-producing measures are

authors postulated aerosol transmission, or at least considered it probable, suggested that the authors postulated aerosol transmission or at least considered it probable, suggested, according to the WHO, that transmission via so-called droplets and / or contaminated objects (i.e. contact) could also increase transmission within these clusters [116].

The other international health authorities (ECDC, CDC) also agree that the pathogen international health authorities (ECDC, CDC) agree that the COVID-19 pathogen - like other viral respiratory pathogens

is mainly transmitted via large droplets and contact [117, 118]. The RKI and considers aerosol transmission to be possible in principle, but does not emphasise this route [119].

but does not emphasise this route of transmission [119]. The role of aerogenic transmission in SARS-CoV-2

is therefore at least scientifically unclear.

Nevertheless, shortly after the start of the pandemic in the spring of 2020, different scientists (especially virologists, but soon also aerosol physicists).

aerosol physicists) placed aerosol transmission in the foreground (also with regard to the claimed asymptomatic

transmission (also with regard to the alleged asymptomatic / pre-symptomatic transmission) and subsequently

subsequently in the public eye through the media as at least as important a transmission as the transmission through (large) droplets ($> 5 \mu\text{m}$).

In the meantime, transmission by aerosol particles is considered so important in politics and in the public that the German government included 'ventilation' in its AHA in September 2020.

ventilation' in its AHA rule. For the same reason, in numerous

hospitals, the use of FFP2 masks was made compulsory for staff on the initiative of the respective masks for the staff - but without the RKI having recommended it,

because there - so far at least - the recommendation remains unchanged to use FFP2 masks

only for close patient contact (= requirement of occupational health and safety) and for so-called aerosol-producing measures [119].

However, even if, for example, the viral RNA of the new coronavirus (or the nucleic acid of other virus (or the nucleic acid of other respiratory viruses) from the air, it cannot be concluded that it is cannot be concluded from this that they are viruses capable of reproducing and viruses capable of infection [42]. Likewise, the release of already

droplets when speaking, sneezing, coughing or singing is no proof of transmission by aerosol particles.

transmission by aerosol particles, because the occurrence of an infection depends not only on (1) the defence

(1) the immune system of the persons in contact and any predisposing chronic diseases, (2) the type and duration of contact, (3) the stability of the virus in the air, (4) the quantity of the pathogen and (5) the number of susceptible cells (= cells with a susceptible cells (= cells with ACE-2 receptors).

The result of the constant mention of 'aerosols' is, on the one hand, that indoor spaces are now be ventilated frequently and not only briefly, despite the cold, so that schoolchildren are children had to sit warmly dressed in class during the cold season, or, for example, during a long for example, you start to freeze during a longer dental treatment because the windows are permanently open. It

seriously thought about (or demanded by politicians and aerosol researchers)

expensive high-performance air purification devices with HEPA filters (class F 14, i.e. a filter with a class F 14, i.e. a filter material that is capable of separating even tiny particles such as viruses.

viruses, which are many times smaller than bacteria, for the elimination of which, e.g. in operating theatres

only' class F 13 filters are used, e.g. in operating theatres), e.g. for schools or restaurants.

restaurants, but without solid scientific evidence. Because

WHO also demands high-quality scientific studies to determine the transmission

the transmission routes, the infectious dose and the settings under which transmission with transmission of SARS-CoV-2 occurs [42].

Behaviour of aerosol particles in the air

Respiratory droplets consist of glycoproteins and salts in aqueous solution,

and infectious agents may be dispersed in them. Potentially infectious aerosols are formed

outside the body, if the water content of small respiratory droplets in the

in the dry ambient air (compared to the respiratory tract) is reduced by evaporation and thus

and floating particles are formed in this way [120 - 128]. Such

tiny droplets are also exhaled from the deep airways [123,

124]. If, for example, a cloud of larger and smaller droplets is released when a person coughs

the larger droplets sediment close to the point of release, and the smaller droplets rapidly become

droplets quickly become smaller and smaller due to evaporation, and some of them disappear completely,

if they did not have a pathogen trapped inside them, i.e. if they did not have a 'core'.

For this reason, international infectious disease literature has for decades referred to the droplet nuclei (aerosol particles). The initially released cloud does not simply remain in the air in front of the person, but in addition to the reduction by sedimentation and evaporation, it is also broken up by the air movements, so that it is diluted by the air until individual particles float freely and are distributed in the room air with the air movements.

Larger and thus heavier droplets disappear from the air shortly after they have been released after they have sedimented onto some surface. What remains are the smaller droplets which sediment much more slowly and evaporate very quickly, and thus rapidly become successively smaller, and also the tiny droplets that are already in the exhaled air, i.e. are already released as aerosol particles from the (deep) respiratory tract.

(deep) airways [123, 124]. The extent and speed of

evaporation depend (1) on the relative humidity: the lower the humidity, the faster

(2) the air temperature: the higher, the faster, and last but not least (3) its initial size: the smaller, the faster.

initial size: the smaller, the faster, up to lightning-like [127].

When coughing and sneezing, a particularly large number of droplets are released, which, in addition to the force of the coughing or sneezing, are virtually hurled into the air by the force of the coughing or sneezing, and therefore can therefore travel greater distances (several metres) [120, 121].

have a diameter of $< 100 \mu\text{m}$ (for comparison: $1 \text{ mm} = 1,000 \mu\text{m}$). This size

is the size of approx. 80 - 95% of the droplets released during coughing and approx. 99% of the droplets released during sneezing. 81

When coughing, almost 50% of these droplets are smaller than $4 \mu\text{m}$ and when sneezing, almost 20%, and thus they are already initially capable of floating, but also immediately become even smaller through

immediately by evaporation until they may have disappeared (if no 'nucleus' was present).

The remaining, somewhat larger droplets also dry up quickly and can thus also become particles, but again only if solid particles are formed after the evaporation of the

solid components remain after the evaporation of the water content, e.g. salt crystals or dried protein.

dried protein, or if the droplet contained an infectious agent as a 'core'.

However, if such a nucleus was not present, it follows that no potential

no potentially infectious aerosol particles can be formed from such droplets after evaporation.

Even if aerosol physicists can produce droplet clouds, e.g. when coughing, or with artificial

aerosol particles, most of the droplets released by humans are within the shortest

released by humans disappear from the air within a very short time (due to rapid evaporation and

evaporation and sedimentation). Only that part of the droplets can lead to the formation of

infectious aerosol particles which, when released, contained a nucleus of infectious

infectious agents, which remain in the air as suspended particles after evaporation.

remain in the air.

Aerosol physicists also always emphasise that an aerosol can, in principle, 'stand in the air' for hours

in the air for hours if it is not dispersed by air movements and

natural ventilation through windows or mechanical ventilation through air-conditioning systems.

systems (so-called air-conditioning systems). In principle, this also applies to droplet nuclei,

e.g. after a cough. If droplet nuclei consist of

infectious agents, their potential infectivity depends largely on three factors (see below).

(see below): (1) How long can the pathogens remain freely suspended in the air?

capable of causing infection? (2) Can the pathogens reach the specific target sites (more precisely:

(2) Can the pathogens reach the specific target sites (more precisely: cells) in the respiratory tract where they have their port of entry, i.e. where they must

where they have to reach in order to trigger the respective infection? (3) Do

sufficient pathogens reach the target cells of a person who is in principle susceptible, so that an infection can

can occur?

Aerosol particles, e.g. after coughing from the respiratory secretion released in the process

respiratory secretion released by coughing, or are released as particles that are already in suspension.

not all contain the pathogen that can be detected from the respiratory secretion.

from the respiratory secretion. This is true even if a person has an acute respiratory infection, i.e. a high

respiratory tract infection, i.e. has a correspondingly high pathogen concentration in the respiratory

secretion. Thus, for example, a viral infection of the upper respiratory tract is not necessarily a so-called 'respiratory infection'.

virus infection of the upper respiratory tract (this is also shown, for example, by the results of the Hong Kong study [30]). A large proportion of the larger and smaller droplets, and even tiny ones, that are released

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].

For example, one article shows that with 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

(still $3 \mu\text{m}$ in size when released with a water envelope) contains a virus particle [129]. For a $50 \mu\text{m}$ droplet, the probability before evaporation is approx. 37%, for a $10 \mu\text{m}$ droplet

reduced to 0.37%, and that such a droplet contains more than one virus particle

(assuming homogeneous distribution in the nasopharyngeal secretion) is negligible [129].

negligible [129].

In the meantime, it has become known to a broad public through the countless media reports,

that airborne particles are dispersed with the air movements (with or without mechanical 82 ventilation, so-called air conditioning).

ventilation, so-called air conditioning) can spread over many metres in the room air, but that they can also be massively diluted.

but that they are also massively diluted the further they move away from the source is usually not mentioned, although this aspect is crucial.

is usually not mentioned, although this aspect is decisive for the risk of infection. Even with

the obligation to wear masks outdoors, which - unspoken - just like the all-round distance

(see Evidence Question 4), the aspect of dilution in the air, which is the most

dilution in the air, which is very effective in the outdoor air, is given far too little attention.

this factor is essential and would help to reassure people who are afraid of the virus.

of the virus. It follows that compulsory wearing of masks outdoors, whether in

whether in pedestrian zones or at a farmers' market, for example, is an irrational measure with no infection control effect.

Behaviour of aerosol particles in the respiratory tract

Since so-called large droplets ($> 5 \mu\text{m}$) sediment shortly after being released, they can only be

in close face-to-face contact ($< 1 - 2 \text{ m}$) and only possibly (because not all of them land

but only on the skin of the face, for example) they can reach the mucous membranes of the eyes, nose or mouth.

mucous membranes of the eyes, nose or mouth, i.e. they can only reach the upper respiratory tract, if at all.

reach the upper respiratory tract. The smaller the particles, the further they penetrate into the deep airways.

Aerosol therapies make use of these properties [122]: (1) In the case of

(1) For diseases of the nose, particles $> 5 \mu\text{m}$ in diameter are used,

(2) for diseases of the trachea and large bronchial tubes, particles of 2 - 5

μm , and (3) for pulmonary diseases, particles of 2 - 0.5 μm are used, which reach into the smallest bronchi and alveoli.

bronchi and alveoli. From simulation models

the deposition rate of aerosol particles in the respiratory tract [123]: According to these models, 94% of

According to these models, 94% of 1 μm particles are deposited in the lungs and only 6% in the upper airways, including the trachea.

including the trachea. Particles with a diameter of 2.5 μm are deposited in the nose in

only 4% are deposited in the nose.

However, very small aerosol particles can not only be inhaled into the lungs from the ambient air, but they are also

lungs from the ambient air, but they are also produced and exhaled there, i.e. in the lungs [123].

exhaled [123]. Using laser technology, these particles were measured in test subjects [124].

124]: It was shown that no particles $> 5 \mu\text{m}$ were released when breathing calmly.

were released, but that many very small particles of about 0.4 μm in diameter were exhaled.

were exhaled, i.e. the lungs were a kind of 'aerosol generator' (special breathing manoeuvres showed that these tiny particles were produced in the lungs and not in the upper respiratory tract).

not in the upper airways).

From this it can be concluded that these aerosol particles can only be infectious when a person has pneumonia,

if a person has pneumonia, which is known to happen with SARS-CoV-2.

infection with SARS-CoV-2 - and if you do have pneumonia, you are (and have been)

pneumonia, you are (1) seriously ill and therefore (2) cannot go out among people (restaurant, public transport).

people (restaurants, public transport, shops, etc.). Therefore, for these reasons

therefore cannot be considered as a source of pathogen transmission in public spaces. As

decisive prerequisite for an infection to occur at all through the inhalation of aerosol particles, the released particles must contain the pathogen.

and for this to happen, the particles must originate at the site of infection [128].

For aerosol-physical reasons, it is precisely the very small particles (produced in the lungs) that accumulate in the room air.

(produced in the lungs) particles of about 0.4 μm in size accumulate and can remain in the air for a very long time.

remain in the air for a very long time, while the larger and even smaller ones disappear [124]. A 83 particle of this size could presumably hold at least one virus particle, and thus

the author (an aerosol physicist) concludes that persons infected with

SARS-CoV-2 release airborne particles containing the virus when they breathe,

and that these infectious particles remain in the air for a long time.

could be inhaled by other people [124]. For this to happen (see above), an infected person would have to

have pneumonia, because these tiny particles are formed in the lungs.

The majority (70%) of inhaled respirable particles between 0.1 and 0.5 μm

is exhaled again, i.e. only about 30% of these smallest particles are

in the deep respiratory tract (= lung), the larger part penetrates only briefly during inhalation, but then leaves the respiratory tract.

but then leaves the airways again with the next exhalation [123, 124].

In order for respiratory viruses to cause an infection of the respiratory tract, infectious

infectious particles must land (impaction) on the special cells of the mucous membrane, where the

where the pathogens find their specific binding sites, i.e. not just anywhere in the respiratory tract on any cells.

on any cells in the respiratory tract. In the case of SARS-CoV-2, these are primarily the cells

with so-called ACE-2 receptors, which are particularly pronounced in the ciliated cells of the nasal mucosa.

cells of the nasal mucosa [62]. Cells with ACE-2 receptors are found descending in the

successively rarer in the deeper airways [125]. So for the new

infection, the new coronavirus must reach the ciliated cells of the nasal

ciliated cells of the nasal mucosa and bind to the specific receptors. With reduced

of the ciliated cells (= reduced so-called mucociliary clearance, e.g. in heavy smokers or with

smokers or with diabetes mellitus), the time for the pathogens to remain there is prolonged.

and thus the chance of binding to the receptors is increased [120].

Typically, the patients infected with the new coronavirus primarily develop an

upper respiratory tract infection, if they develop symptoms at all. Pneumonia, i.e. infection of the deep respiratory tract, only develops secondarily, if at all, with a delay of about 7 days after the onset of the initial symptoms in the upper respiratory tract. Therefore, even in patients who develop pneumonia in the course of the disease pneumonia in the course of the disease, the disease does not primarily affect the lungs. This probably occurs in healthy people during deep sleep), whereby infectious secretions from the nasopharynx enter the lungs and can lead to secondary infection, especially in old age and chronic diseases. secondary to infection, which makes the course of the disease severe and life-threatening [122]. life-threatening [122].

The new coronavirus must therefore settle primarily in the upper respiratory tract in order to cause an infection [62].

infection [62] and therefore initially only causes an upper respiratory tract infection of the upper respiratory tract and only secondarily (after a latency period of about one week) in

with certain risk factors (after a latency period of about a week).

pneumonia. In most people, the symptoms of the upper respiratory tract are harmless, with or without a cough.

upper respiratory tract symptoms with or without cough.

This means for the theory of aerosol transmission: Since aerosol particles are in particles penetrate immediately into the deep airways, an infection there, if it were to occur at all, infection, if it were to occur at all, would not lead to the symptoms of an upper respiratory tract respiratory tract infection, but would lead to pneumonia on the spot if cells with ACE-2 receptors are reached (but this course of infection with primary pneumonia does not occur).

pneumonia does not occur), the aerosol transmission of SARS-CoV-2 can de facto play no role from a medical point of view.⁸⁴

Significance of airborne viral RNA detection

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

nucleic acid (RNA in the case of coronaviruses) by PCR outside the body, e.g. from air samples, means that the found

nucleic acid originates from an intact (and thus in principle infection-capable) virus particle

The question of whether the nucleic acid found comes from an intact (and thus in principle infectious) virus particle cannot be answered with pure RNA detection.

because it is relatively time-consuming. However, the confirmation of an intact (i.e. capable of virus by means of cell culture cannot be compared with proof of the infectivity of these viruses under normal living conditions.

of these viruses under normal living conditions. For the so-called

inoculation of a cell culture is a procedure under laboratory conditions, in which the virus is

is artificially and ideally brought into contact with its target cells, because it is (1)

directly and (2) in unchanged concentration on the cells. With

virus contact in normal life, on the other hand, potentially infectious droplets or aerosol

aerosol particles released by an infected person must first find their way - 'by themselves', so to speak - to the mucous membranes of the upper respiratory tract.

mucous membranes of the upper respiratory tract of another (and still) non-immune person.

person. Once there, if that comes about at all, the number of potentially

viruses must be high enough for at least some of them to make it through the protective respiratory tract.

to pass through the protective respiratory secretion to the surface of the mucous membrane cells and

mucosal cells through the protective respiratory secretion and adhere there, in order to subsequently penetrate the cells and multiply.

cells and multiply.

In addition, there is the following: Coronaviruses have a lipid envelope and thus belong to the so-called enveloped viruses.

As such, they 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.

but from a medical point of view, the most important question is whether such viruses in an aerosol, unprotected in the air, can remain infectious for a longer period of time.

for a longer period of time. The detection of viral RNA is neither proof that this RNA is

viruses that are capable of replicating (in a cell culture), nor that they are (which is by no means directly comparable with cultivation in a cell culture) from viruses that are capable of intact viruses that are capable of infecting humans [42, 116].

The detection of viral RNA in air samples is not sufficient to confirm aerogenic transmission.

transmission, nor are the results of studies in which aerosols were experimentally

aerosols are experimentally generated, counted and measured and their residence time in experimental

in experimental situations. All in all, this is a complex

infectious and epidemiological factors, and the various environmental conditions (indoor

It must include the various environmental conditions (indoor rooms, outdoor air) as well as aerosol physical peculiarities (see above). Thus, from an

infectiological point of view, it would have to be clarified, for example, whether infectious aerosols are actually

infectious aerosols can 'land', i.e. adhere, in sufficient numbers at the decisive points in the upper respiratory tract where

where SARS-CoV-2 must reach, because it is primarily found in the epithelial cells of the nasal mucosa.

epithelial cells of the nasal mucosa, i.e. also in the upper respiratory tract [62].

[62] - and not in the deep respiratory tract, where aerosol particles almost exclusively reach.

Number of pathogens required for an infection

For any infection to occur, contact with a certain (and often unknown) minimum number of pathogens is required.

(and often unknown) minimum number of pathogens, and this contact, in order for an infection to be successful for an infection to occur, it must occur at the sites in the body where the

pathogens need to penetrate in order to multiply. This is, as already 85

the nasal mucosa [62], and to a lesser extent the pharyngeal mucosa.

mucous membrane of the throat, but not the lungs (otherwise pneumonia would occur primarily in SARSCoV-2 infected persons, which is not the case). With

The approximate number of coronaviruses with which a person must come into contact for an

infection is not (yet) known exactly, although a study published in December

2020 shows that, according to a mathematical estimate based on 39 transmission events, a person

based on 39 transmission events, the average number of virus particles transmitted from one person to another is more than 1,000.

virus particles must be transmitted from one person to another to cause an infection [130].

infection [130].

If the pathogen contact were to take place significantly, or at least to a relevant extent, through the air,

air, i.e. via inhalation, one would have to assume a relatively high number of secondary

infections (triggered by an infected person), because the air surrounds all air surrounds all people and no one can escape it [116, 131]. The basic reproduction number (R0) of approx. 3 (i.e. approx. 3 subsequent infections by an infected person in the absence of immunity of the

of the population against the pathogen) would be low for the new virus.

would be low for the new virus; because of the unavoidable exposure of all people to the airborne transmission of the pathogen, one would have to reckon with considerably more subsequent cases. However

R0 could also be so low for the new coronavirus because the number of pathogens required for an number of pathogens (so-called 'infectious dose') is rather high for this virus, so that, despite relatively few secondary infections despite airborne transmission, because mucosal contact is mucosal contact with sufficiently high numbers of pathogens rarely occurs [131].

Outbreaks as evidence for transmission by aerosol particles

In 2020, there were several publications on outbreaks purporting to prove aerosol transmission of the new coronavirus, but in all of these outbreaks, no or only limited evidence of aerosol transmission was found.

outbreaks, no or only marginal consideration was given to the fact that instead of aerosol transmission, the other transmission routes via (large) droplets and / or (direct and indirect) contact are also possible.

(direct and indirect) contact are also possible and their significance would first have to be importance in order to attribute a significant role to aerosol transmission. In the

media that contact transmission (usually referred to with the unscientific term

term 'smear infection') does not play a role in SARS-CoV-2. Instead

one would have to say that this route of transmission has not been investigated or not

sufficiently taken into account, because it is not enough for such a statement that the virus is not was not or rarely found in environmental examinations.

One of the most important of these publications for Germany was certainly the

outbreak investigation at Tönnies in North Rhine-Westphalia [132]. The authors state,

that the cause of the outbreak was the special working conditions of the workers in this (and other) meat (and

(and other) meat (and fish) processing factories, where low temperatures (10°C) and hard

temperatures (10°C) and hard physical work (with heavy exhalation) on the one hand and

air-conditioning systems without fresh air supply on the other hand (low air exchange rate and constant recirculation of air in the factory).

recirculation of the air in the work hall), efficient pathogen transmission via aerosol is obvious.
is obvious.

The common (close) accommodation of the workers in their living areas and
and sleeping quarters, and the shared use of trucks - and thus the multiple
direct and indirect contact possibilities, including droplet contact - have, according to the
According to the authors of the study, these did not play a major role in the occurrence of the
infections.

in the occurrence of the infections. As limitations of their study, the 86
authors state that (1) all information about the accommodation of the workers and the
trucks came from the employer (and not from their own inspection of the housing conditions) and
that
conditions) and that (2) all air tests were only qualitative (i.e. only evidence of
(i.e. detection of viral RNA in air only), but not quantitatively (i.e. number of copies of RNA
per m³ of air) were carried out. Finally, the authors themselves state that their
study should not be regarded as an epidemiological study. The authoritative
authors of the study are predominantly virologists and geneticists, but not
population-based epidemiologists, the last-named (in the list of authors) of the
the last-named) so-called senior author is a biologist. Thus, all in all, the authors are predominantly
bioscientists, not epidemiologists trained in medical and infectious diseases.
epidemiologists.

There have been other publications on outbreaks, which are always cited as proof of aerosol
transmission.

aerosol transmission, e.g. a restaurant-associated outbreak in China [133] and a choir rehearsal in
[133] and a choir rehearsal in the USA [134]. However, a transmission route cannot be proven with
outbreak investigations cannot be proven, because there is always the important question whether
whether all possible transmission routes have actually been adequately tested (or retrospectively).
possible transmission routes have been adequately examined (or could be examined retrospectively
in the
events) before concluding that aerosol transmission is the most likely mode of transmission.

aerosol transmission was the most likely route of transmission. The restaurant-associated outbreak
was attributed by the authors to an air conditioning system that had a
had faulty airflow [133]. If this had been proven to be the cause of airborne transmission in this

case, then it would be open whether, for example, in a room without air-conditioning, transmission through

air transmission in a room without air conditioning, for example, so it would not be possible to that the new coronavirus is transmitted quasi-naturally via the air, but perhaps only in the case of faulty

but perhaps only in the case of faulty air circulation through an air-conditioning system.

In the report on the choir rehearsal in the USA [134], it is noticeable that 9 of the 10 authors are not medical doctors, but e.g. (heating-ventilation) technicians, engineers, chemists, only one co-author was a medical doctor.

only one co-author was a medical microbiologist. The article was published (logically)

in a technical journal ('Indoor Air') and not in a medical journal. From the

peer reviewers' reports, all of which are available for inspection, indicate that

critical comments were made from an epidemiological point of view: For example

For example, 3 choir members became symptomatic 24 h after the choir rehearsal and 7 others within 48 h afterwards [135].

within 48 h thereafter [135]. This suggests that not only the so-called index case from the article could have been infected.

infected, but also up to 10 other choir singers who, however, developed symptoms

developed symptoms later (and possibly already had very slight symptoms at the choir rehearsal, which they

symptoms at choir rehearsals, but which they did not notice or which they were told about during or which they did not remember when they were later interviewed as part of the outbreak investigation

a common problem in the clarification of outbreaks, which always has to be done retrospectively).

must be done retrospectively). Another question is whether there were in fact no indirect contacts via contaminated

contaminated objects, since the singers were together for 2.5 hours and also had a break together.

and also had a break together. From the original report of the

CDC's original report also shows that the singers had very close contact, because they were sitting

only at a maximum distance of approx. 15 - 25 cm, so that in addition to direct and

indirect contact, contact with large droplets (< 1 - 2 m) seems possible [135].

However, this was not addressed accordingly in the outbreak investigation [134].

Masks as protection against the generation or release of aerosols⁸⁷

As so-called community masks, i.e. everything from purchased masks similar to medical mouth-nose protection to (self-sewn) cloth masks and cloths in front of the mouth and nose, were used to protect against aerosol formation and release [134].

and nose, was possible and 'allowed' from the end of April 2020 (start of the mask obligation) until the end of January 2021.

anything was possible and 'allowed', as long as something was in front of the mouth and nose [103].
Only

such masks and cloths do not offer any protection against the formation of aerosol particles in the air or their release.

particles in the air or from their release from the deep respiratory tract, but can merely only reduce the formation of aerosol particles somewhat (but how much is unknown) by the larger droplets are trapped by the fabric and therefore no longer get the smaller they are, the quicker they form so-called droplet nuclei within seconds. droplet nuclei, if they contain a 'nucleus' at all (see above).

(see above).

However, no one can say how much retention of droplets is necessary to prevent the formation of infectious aerosol particles. The RKI's statements on this are also not

conclusive, but in the public discourse, masks are 'effective' in the public because they can retain can retain droplets. However, this is unscientific. What is probably true for (large)

droplets does not apply to the smaller droplets and certainly not to aerosol particles.

for aerosol particles. Humans normally emit aerosol particles in addition to larger droplets (see aerosol particles (see above), but these not only penetrate the mask material directly,

but can also escape laterally or from above and below, i.e. everywhere where the mask mask does not lie close to the face (but even there, of course, although not as many).

numerous). This is true not only for the so-called community masks (made of cotton or other fabrics), but also for the medical mouth-nose protection (surgical mask), whose

function is 'only' to protect against droplet contact (i.e. to act as staff or self-protection during patient care with close face-to-face contact) or to prevent the release of droplets.

to prevent the release of droplets (i.e. to protect the open surgical wound from droplets from the nose and throat).

from the nasopharynx of the surgical team during surgery = protection of the patient).

patient).

So if aerosol transmission were really as important as it has been portrayed for months in

Germany, all people would have had to wear respirators long ago, so-called FFP masks.

FFP masks (at least FFP2), because only these masks are suitable in principle for the material and design are suitable for separating free-floating particles, so that the wearer can neither inhale nor release them. However, this could only apply if such masks are worn correctly, i.e. if they fit snugly against the skin and have no exhalation valve. and have no exhalation valve, and then it is difficult to breathe through them because the mask material is very dense.

mask material is very dense. FFP masks (almost only FFP2, very rarely FFP3) are only used in the medical field only to protect personnel from inhalation of potentially airborne inhalation of potentially airborne infectious agents (in the case of open tuberculosis of the respiratory tract tuberculosis) and, if necessary, by very immunocompromised patients for their own protection.

to protect against inhalation of mould spores that are always present in the air.

(they can have exhalation valves for both indications). FFP masks are never used in the in the medical field to protect other people from exhaling aerosol particles, i.e. to protect others. However, this would be the very indication for

people in public, because masks are supposed to be worn there to protect other protection (but they should not have exhalation valves). This was

Since then, FFP2 masks have been compulsory in Bavaria (and in the federal government the obligation to wear a medical mouth-nose protection, i.e. a so-called OP mask or FFP2 mask). or FFP2 mask).⁸⁸

The ability of different types of masks to reduce the aerosol concentration in room air (i.e. to protect others) has been investigated several times in experimental studies.

One of these studies used volunteers, almost all of whom (N = 208) wore a laboratory mask.

(N = 208) had a laboratory-confirmed acute influenza infection, and 6 of them had a suspected acute COVID infection.

COVID-19 was suspected [136]. It was tested whether there was a difference in medical and homemade cotton masks in how many aerosol particles (20 - 1,000 nm) are (20 - 1,000 nm) are released during coughing and sneezing and are thus measurable in the room air. are measurable in the room air. The test subjects were given a medical mask and then a 3-layer cotton mask.

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 subjects, i.e. each with masks or without masks at all, were taken in a mechanically ventilated (= with so-called

air conditioning) room (with closed windows) and in a car (also with air conditioning).

air conditioning). The aerosol concentration in the room air in the room and in the car was also in the room and in the car without the test subjects wearing any of the masks.

All test subjects had an acute upper respiratory tract infection with the typical symptoms (coughing, sneezing).

symptoms (coughing, sneezing). According to the results of this study, there were no significant differences in aerosol concentration between the medical mask and the cotton mask.

cotton mask. The authors concluded that cotton masks are a substitute for medical masks in infected (i.e. symptomatic) individuals.

(i.e. symptomatic) individuals, could be a substitute for medical masks in rooms with

air-conditioned rooms (air-conditioned rooms because that is how the studies were

were conducted and it is therefore not known what the results would have been without air-conditioning).

would have been without air conditioning).

In another experimental study, a result was found that rather speaks against so-called community masks.

community masks, which are usually made of cotton [137].

cotton masks (in comparison to masks without masks), there was an increased release of (very small) aerosol particles ($< 0.5 \mu\text{m}$), which are tiny cotton fibres. These

cotton fibres, according to the authors' interpretation, could be used in asymptomatic or pre-symptomatic

infection of the carrier with the virus, and thus could cause the release of potentially contaminated

even increase the release of potentially contaminated aerosols.

Another experimental study showed that all mask types (surgical,

FFP2/N95 and cotton masks), while providing some protection against the transmission of infectious

infectious aerosol particles [138]. However, in this simulation model

that even with optimally fitting FFP2 masks, viral RNA was released.

was released. FFP2 masks in particular are seldom worn correctly by medical staff, because these masks

worn correctly by medical staff, because these masks hardly erode when worn for hours (as has been

in many clinics for months) are hardly tolerable. Therefore, it can be deduced from these

results, it can be deduced that the viral RNA in real life in clinics and of course

and of course even more so when FFP masks are worn by untrained persons in public.

which has become more and more frequent over time, despite the masks - and possibly to a possibly to a not inconsiderable extent - is released. But it is precisely FFP masks suggest increased safety, which they do not offer if worn inadequately, i.e. all masks (types), but especially FFP masks, convey a deceptive feeling of safety. deceptive feeling of safety, thus tempting people to wear them carelessly (and, by the way (and, incidentally, to particularly frequent hand-face contact) and are thus more counterproductive than counterproductive rather than protective.

An article (an opinion piece) in the renowned NEJM in September 2020 hypothesised that because wearing masks reduces the release of 89 aerosol particles, there would be less contact between other people and the virus, i.e. contact with low virus counts [139]. This could lead to mild forms of the virus, which is equivalent to a kind of 'vaccination'. The authors used the historical term 'variola' for this, a method that was long used in East Asia to immunise children against smallpox by extracting secretions from smallpox blisters. secretion from smallpox vesicles of a sick person and applying it to the nasal mucosa of the 'vaccinated'. the nasal mucosa [140].

The theory of variola in connection with the new coronavirus is a hypothesis, as the authors themselves write several times in their article [139]. This hypothesis is not supported by anything. You can put it this way: the authors think it is conceivable. There is no scientific background of any kind for this, because there is not even any evidence that the possibly smaller number of potentially infectious and potentially infectious aerosol particles released by masks leads to a reduction in the severity of the of the infection of people in contact with the result that the supposedly (mildly) (mildly) infected persons subsequently have a protective immunity.

Compulsory medical masks

In January 2021, a compulsory FFP2 mask was initially introduced in Bavaria for shops and public transport. Shortly thereafter, the federal government (federal government and minister presidents)

that when shopping and using public transport, only medical masks, either a medical

medical masks, either a medical mouth-nose protection (MNS or so-called OP mask) or FFP2 mask, may be worn when shopping and using public transport. The reason for this is medically medical reasoning, because both types of masks are designed for different purposes. purposes, but have now become interchangeable as a result of the policy decision. medical basis has been lost.

From the end of April 2020 (start of the mask obligation) until mid / end of January 2021 (in Bavaria Bavaria a little earlier than in the federal government), the so-called everyday mask made of cloth (or even just a cloth

mouth and nose) was considered adequate for the implementation of the mask obligation. It was supposed to

It was supposed to serve as 'foreign protection' (see above) to prevent the release of larger droplets, from which smaller inhalable aerosol particles could be produced. So for about nine months the everyday mask was correct, because in the view of the Federal Government and the RKI it was the so-called unnoticed transmission, or at least to limit it to such an extent that the wearing of the mask was

that the obligation to wear it seemed justified to the politicians. In the new year

2021, the transmissibility of the new virus had not changed. In particular, there were no new insights into the transmission routes, as the aerosol theory had been around almost theory had been around almost since the beginning of the pandemic in the spring of 2020.

change came with the increasing reports of the virus mutations from the

South Africa and Brazil, which are supposed to be more 'contagious', i.e. easier to transmit. more transmissible (and may in fact be).

The reason given for the compulsory FFP2 masks in Bavaria was that in view of the virus mutations, 'self-protection' was now also important. So what must be meant by the protection principle of FFP2 masks had to mean protection against the inhalation of aerosol particles, while the FFP2 mask also provides 'external protection'. The remaining

Länder can decide whether they want to make the FFP2 mask compulsory or whether they want to or limit themselves to the medical MNS. The justification for this was

limited to the fact that medical masks are 'better' effective. For what or against what, was not made clear. An MNS offers no more protection against inhalation 90

of aerosol particles than the everyday fabric mask, so it cannot guarantee improved 'self-protection'.

The MNS has other functions: (1) it can act as

(1) it can protect against the release of larger respiratory droplets, but it is not intrinsically more suitable for the public than fabric masks have been up to now, especially since it is not worn better, i.e. 'correctly', as the RKI always says, and (2) a MNS can provide 'self-protection' against respiratory droplets from another person in close face-to-face contact (< 1 - 2 m). In principle, the previously the usual fabric mask.

There is no medical reason for the new obligation to wear an MNS or an FFP2 mask, therefore does not exist. According to press reports, both the ECDC and the EU's EU health commissioner explicitly do not support the use of FFP2 masks in the population 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. (e.g. offices or even classrooms), it is always a good idea to let in a lot of fresh air, because we are constantly constantly breathe out carbon dioxide and need to breathe in oxygen, and we give off body odours and heat, so rooms where several people are present at the same time and for hours, such as people at the same time and for hours, such as classrooms in particular, undoubtedly benefit from benefit from ventilation. However, the fact that airing rooms is now considered a 'hygiene' measure The fact that airing rooms is now regarded as a 'hygiene measure' is a step backwards to the time of earlier centuries, where the development of diseases was attributed to 'disease-causing air' (miasma theory [142]). (miasma theory [142]), because no infectious agents were yet known. At that time hospitals were therefore built in such a way that the wardrooms were not only large in area but also were also high, i.e. had a very large air volume, and everywhere there were large windows through which the 'disease-causing' air could be expelled and fresh air introduced (but also sophisticated (but sophisticated air supply and exhaust ducts were also used as early as the 18th century) [143]. were already in use in the 18th century) [143]. These times, with their state of the art medical science the development of transmissible diseases are long gone. long gone. Today we know much more about the development of infections, and there is the principle of evidence-based medicine.

the principle of evidence-based medicine.

Summary: Aerosol transmission and scientific evidence

The public and the media say that aerosol transmission is now 'recognised'.

and even the Society of Virology has already claimed this in its ad hoc statement of 06.08.2020 [144]:

'One of the important new findings on SARS-CoV-2 that needs to be considered in the school opening school opening, concerns the now recognised possibility of aerosol aerosol transmission, i.e. transmission through the air, especially indoors in indoor environments with inadequate air circulation.'

The WHO publication of July 2020 is cited for this statement [116]. However, such a such a statement does not emerge from the WHO text, because it states:

'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 91 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.

small number of cases to many other people (e.g., superspreading event), especially if hand hygiene was not performed and masks were not used when physical distancing was not maintained.

distancing was not maintained.(Ref) (Where 'Ref' is used, literature references are given in the WHO article)

It is therefore not clear that aerosol transmission is a recognised way of transmitting the new coronavirus.

of the new coronavirus is mentioned in the WHO article, which explicitly deals with the transmission of the virus and the resulting preventive measures,

so that one must assume that the authors of the GfV statement have not read the WHO contribution they cite. This also applies to the WHO contribution of

December 2020 [42].

In this context, the question should also be raised immediately as to what is actually to become of the rule if aerosol transmission should actually play an important role (see evidence question 4). Should it play an important role (see evidence question 4). Would 1.5 m or 2 m then still be sufficient or not? How much distance would we need to protect ourselves from the aerosol particles of our fellow humans? And: Does the aerosol theory apply only to the new coronavirus or also to the other respiratory viruses? If you think it through to the end of the aerosol theory, i.e. the transmission of respiratory infectious agents through the air (because this pathway is not limited to the new coronavirus but could also apply to other respiratory infectious agents through the air (because this mode of transmission could not only be limited to the new coronavirus but would at least have to be relevant for all coronaviruses). This would have to result in a radical change in the way humanity lives together, and therefore it would have to be clarified with the necessary scientific precision to what extent, if at all relevant, pathogen transmission via aerosol plays a role in the new coronavirus. But why aerosol transmission should be important for SARS-CoV-2 but not for the other coronaviruses or respiratory viruses is biologically and medically incomprehensible. Such considerations require a differentiated presentation, which has so far been lacking in the aerosol theory for the new virus. One of the questions that would have to be asked is the question of what role masks (see above) and distance (see below) would play if aerogenic transmission were to be considered a relevant fact, i.e. whether the mask would continue to be a matter of protection for others or perhaps self-protection would have to be placed in the foreground. For this, however, only (but then also only) FFP2 masks (which, by the way, is not possible for people with full beards). Normal medical masks would not be suitable to protect against the inhalation of aerosols. As a result, people would have to wear FFP2 masks (and

all the time, because respiratory viruses are on the move all year round) to protect others from releasing their own (= 'foreign protection') and themselves from inhaling aerosol particles.

aerosol particles (= 'self-protection').

All these crucial questions are as yet completely unresolved (perhaps because the dimension of aerosol

the dimension of the aerosol theory, what consequences would result from it) and are still

would result from it) and are not even being discussed. Above all, the media 92

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

aerosol transmission (e.g. Christian Drosten in the NDR podcast of 12.05.2020 [145]:

'When I put it all together, my gut feeling is: almost half of the

transmission is aerosol, almost the other half is droplets and maybe ten percent is

percent of transmission is smear or contact infection.'

Firstly, 'gut feeling' has nothing to do with science, and secondly, aerosol transmission has also been turned into a (but only) scientific phenomenon by such statements from a scientist who is recognised in his field.

in his field has made aerosol transmission a fact (but only an apparent fact). Equally unscientific

scientific is his statement about 'bad breath' and 'aerosols' [146]:

'This bad breath, these are aerosols. There are also gases in it - these are not

not only vapours, not only small droplets of liquids - but now for our simplified discussion it is enough

discussion, it's enough to think of it like this. Can you imagine,

the same situation, you're standing at the same cake counter talking to someone

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

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

Exactly, you will no longer notice that. And this "no longer noticing",

can also be translated as "I won't get infected so quickly".

infected". And that is something that those who have doubts about the efficacy of everyday masks

of everyday masks should perhaps take home with them as an everyday example.

example.'

Contrast this with information on bad breath from a dental perspective [147]:

'Bad breath is caused by volatile sulphur compounds (sulphides) that mingle

mixed in with the exhaled air. They are caused by gram-negative

anaerobic bacteria decompose organic material, e.g. food residues, proteins, in the oral cavity. decompose in the oral cavity. Hydrogen sulphide is the best-known representative of the sulphides. It smells like "rotten eggs". Another group of sulphur compounds are the methyl mercaptans. They are considered to be the main causes of bad breath. They produce an odour like rotting cabbage or a musty, rancid smell. smell. If the breath smells of fish, rotten meat or faeces, then biogenic amines are responsible. biogenic amines are responsible. They are formed from amino acids by by the bacterial splitting off of carbon dioxide.'

'Aerosols' therefore have nothing to do with bad breath. Similar to the WHO (see above and [116]) other scientists [131]: Based on the (in comparison to measles

12 - 18) of SARS-CoV-2, such situations seem to be the exception rather than the rule.

such situations seem to be the exception rather than the rule. Furthermore, it is retrospectively difficult to determine the potential interactions between individuals that took place before, during and immediately after the event,

during and immediately after the event. The possibilities for viruses to

and far - but not necessarily via the air, but primarily via direct and indirect

and indirect contacts - in premises with large numbers of people should not be underestimated, should not be underestimated. Experimental studies with labelled

bacteriophages (= special viruses that are pathogenic only for bacteria but not for humans) have shown that viruses

viruses) have shown that viruses can spread within hours from a single contaminated door handle or the contaminated hands.

from a single contaminated door handle or the contaminated hands of one person to other persons and

and objects within hours. These, too, are speculative considerations that do not take into

aerosol transmission, but they are 93 possible alternative explanations for the occurrence of the virus.

possible alternative explanations for the occurrence of such clusters - and must therefore also be considered [131].

must therefore also be taken into account [131].

The CDC also state that the epidemiology of COVID-19 indicates that most of these infections occur through close contact.

infections arise from close contact - and not aerogenically [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, were 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 (e.g., less than six feet). There is no evidence of efficient spread (i.e., 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. This statement is consistent with the WHO's assessment and the CDC's statements [42, 116, 118]. Transmission via aerosols is merely an unlikely possibility, as described above.

improbable possibility. Therefore, no necessary protective measures can be derived from this on an approximately scientific basis.

necessary protective measures, such as compulsory FFP2 masks or special 'air purification devices or special 'air purification devices' or air handling units with HEPA filters or even frequent ventilation. frequent ventilation. Nor is there currently sufficient evidence from careful studies, that, for example, singing in choirs poses a risk of transmission through aerosols or that contacts between people

between people over distances greater than 1.5 m (WHO: 1 m) due to the aerosol aerosol particles released when speaking etc. can pose a risk of infection. One cannot deduce from aerosol-physical studies on the spread of artificially generated aerosols.

aerosols to a risk of infection. Whether aerosol transmission actually plays a relevant role in the acquisition of this pathogen could only be determined by carefully epidemiological studies in different settings, including randomised controlled trials. controlled studies.

In general, one can state on the question of aerogenic transmission of infectious agents, that whenever the possibility of transmission through the air is considered, transmission through large transmission through large droplets and / or through direct or indirect contact.

direct or indirect contact.

This corresponds to the fact that an aerosol physicist (who, by the way, considers outdoor transmission to be virtually ruled out) recently stated that the

outdoor areas) has stated that even indoors the greatest risk of transmission is in the vicinity of an infected building.

risk of transmission is in the vicinity of an infected person, because then one is in the in the still undivided cloud of aerosol particles released by the infected person [148].

released by the infected person [148].

From my professional point of view, I also see the greatest risk of transmission when one is in the vicinity of an infected person.

infected person, but for other reasons, namely because, on the one hand, one is exposed

because, on the one hand, you are exposed to possible droplet contact,

but also because you're much more likely to have direct and indirect contact...

standing a few metres away in another part of the room.⁹⁴

The aerosol theory has nowhere near sufficient scientific basis, and there is no

evidence that this route of transmission is relevant to the natural course of SARSCoV-2 infection. At the same time, this theory is extremely detrimental for the

for human coexistence as a whole and has a destructive effect on contact between

between people of all ages. Therefore, in appropriately planned

epidemiological investigations, direct and indirect contacts - via (large) droplets

and/or contact (especially hand contact) - would have to be reliably ruled out in order to be able to consider

aerogenic transmission can be considered.

Summary assessment of the scientific data on masks

The effectiveness of masks for healthy persons in public is not supported by scientific evidence.

scientific evidence. Likewise, 'external protection' and 'unnoticed transmission', which the transmission', which the RKI has used to justify its 'reassessment', are not

scientific facts. Plausibility, mathematical estimations and subjective

assessments in opinion pieces cannot replace population-based clinical epidemiological studies. Experimental studies on the

masks and mathematical estimates are not suitable for proving effectiveness in real

effectiveness in real life. The international health authorities

advocate the wearing of masks in public spaces, but they also say

there is no evidence from scientific studies. On the contrary all the scientific evidence currently available suggests that masks have no effect on have any effect on the incidence of infection. All publications that are cited as evidence for the efficacy of effectiveness of masks in public spaces do not support this conclusion. conclusion.

Any mask must be worn correctly in order to be effective in principle. Masks can become a contamination risk if they are touched. But they are worn incorrectly by the general public and are very often touched with the hands. touched with their hands. This is also the case with politicians who appear on television. on television. The population has not been taught how to use masks properly, it has not been explained how to wash their hands on the way or how to disinfect their hands effectively. hand disinfection is carried out. It was also not explained why hand hygiene is important and that one must be careful not to touch the eyes, nose and mouth with the hands.

eyes, nose and mouth. The population was virtually left alone with the masks. alone with the masks.

The transmission of SARS-CoV-2 through 'aerosols', i.e. through the air, is medically implausible and scientifically unproven.

plausible and scientifically unproven. It is a hypothesis that is mainly based on aerosol aerosol physicists who, understandably, are not able to assess medical are unable to assess medical correlations. The 'aerosol' theory is extremely harmful for human coexistence and means that people can no longer feel safe people can no longer feel safe indoors, and some even fear infection from indoor of infection from 'aerosols' outside buildings. Together with transmission, the 'aerosol' theory means that every fellow human being can be seen as a infection risk in every fellow human being.

The change in policy on masks, first fabric masks in 2020, then since masks or FFP2 masks since the beginning of 2021, lack any clear line.

Even if OP masks and FFP masks are both medical masks, they have different functions and are therefore not interchangeable.

different functions and are therefore not interchangeable. Either the policy 95

who made these decisions did not understand what each type of mask is suitable for.

which type of mask is suitable in principle, or it is not important to them, but only the symbolic value of the mask.

value of the mask. From my professional point of view, the mask decisions made by the politicians are not

incomprehensible and, to put it mildly, implausible.

A brief digression on masks in Japan

As early as spring 2020, media reports in this country repeatedly referred to the fact that in Japan and other Asian countries, masks are being used,

that people in Japan and other Asian countries have known for a long time about the benefits

masks have in public. Therefore, I would like to give some information

why the Japanese in particular wear masks so often and how the wearing of masks

and how the wearing of masks has developed there. This question was raised in two

articles (long before the current corona pandemic) [108, 149].

According to these, masks were first used in public in Japan (as, for example, in the USA)

at the time of the influenza pandemic of 1918 / 1919. While the other countries in

quickly abandoned masks in the 1920s, they persisted in Japan to a certain extent

Japan they continued to be used to some extent (but nowhere near to the extent seen in the last 10-20 years).

over the decades, but not so much to protect against infection, but rather as a traditional

the traditional symbolic order of 'purity' and 'impurity' and a notion of 'miasmas'.

a notion of 'miasms' (see above [142]) rather than viruses or other infectious agents.

infectious agents. In the 1970s (as a medical problem new to Japan to the extent observed), heusiasis emerged.

Japan to the extent observed), hay fever emerged, which was associated with cedars

cedars, which had only been planted there after the Second World War.

Masks were then worn during the pollen season in spring. Then it became

then became rather quiet again until the 1990s, when mask-wearing in Japan

became a socially accepted general protective measure, through a combination of influences from

through a combination of influences from (massive) advertising by the leading mask

mask manufacturer, as well as social and political pressures due to the increasingly

increasingly widespread neo-liberal ideology, according to which, among other things, everyone is responsible for their own

health protection ('self-healthcare'). The 2000s saw the emergence of SARS (2003), avian flu (2004), MERS (2006) and swine flu (2009).

epidemics in quick succession, and the swine flu in particular again promoted the use of masks. use of masks, so that the sale of masks increased enormously. Mask-wearing became a social norm, especially on commuter trains, so that those who did not wear a mask were conspicuous. In addition, sneezing and coughing in public has always been considered impolite in Japan.

In retrospect, the authors see 2009 as a kind of turning point: For

On the one hand, masks maintained a certain level of fear among the population and on the

On the other hand, they established themselves as the front line of protection for people. Added to this was the

the probably very crucial aspect of employers being expected by their employees

that employers could require their employees to wear masks and henceforth be under

and henceforth one was under pressure to comply or risk losing one's job.

jeopardise one's job. The wearing of masks was again revived after the nuclear disaster of

Fukushima nuclear disaster in 2011, because masks were also used to protect against radioactive were used. In the spring of 2013, air pollution coming from China was reported to have reached the southwest of Japan.

from China had reached the southwest of Japan, and the population was advised in the media to wear masks,

to wear masks that can filter microscopic particles (i.e. FFP masks). All

All in all, the whole development led to a consolidation of masks as an all-purpose means of personal protection.

as a general-purpose means of personal protection.⁹⁶

The mask ('safety blanket') in Japan, according to the authors [108, 149], is to be seen as one aspect of a broad-based type of risk culture.

of a broad type of risk culture: It is, however, more a ritual of

self-protection ritual rather than a selfless communal practice, and thus has little in common with the in this country for the compulsory wearing of masks,

and finally, it is obviously not only intended to protect against infectious pathogens

infectious agents, but in addition to (still understandable) protection against pollen exposure and

and air pollution, it is even supposed to include protection against radioactive radiation.

Finally, women allegedly like to use masks in order to avoid having to put on make-up when to avoid wearing make-up when they leave the house, or to be able to hide skin blemishes skin blemishes, and by men when they could not shave [150].

shave [150]. Other motives were that one could withdraw behind the mask and thus signal signal that one does not want to be approached, and that with a mask one can be undetected in public.

mask, one could remain unrecognised in public.

So there is a conglomerate of very different reasons for wearing a mask in Japan (and presumably also in other East Asian countries).

reasons for the mask in Japan (and presumably in other Asian countries).

among several, but perhaps not even the leading one.

Evidence question 4

Can the risk of infection, especially among children, be reduced by observing distance regulations? children in particular?

Spacing is particularly emphasised in the government's Corona rules

and is therefore probably also at the beginning of the so-called AHA rule (distance - hygiene - everyday masks).

everyday masks or, since the beginning of 2021: everyday with mask). It has always been emphasised that despite

masks, it is most important to keep a minimum distance of 1.5 m from other people.

to other people. According to the original AHA rule, masks should only be worn if the minimum distance is not maintained.

only be worn if the minimum distance could not be maintained (this restriction no longer exists).

restriction no longer exists). In reality, however, the masks seem to be more important, because their use has been extended more and more.

The distance requirement was introduced in Germany at the same time as the mask requirement, i.e. at the end of April 2020,

Since then, a distance of 1.5 m has to be maintained in public places.

in public. However, there is no international agreement on how great the distance from other other people should be. The WHO, for example, speaks of 1 m, as does Austria in 2020.

('baby elephant'), but since the beginning of 2021 it should now be 2 m there. The CDC speak of six feet', and that is about 2 m. So in Germany, 1.5 m is a kind of middle ground.

The difference between these specifications alone shows that there is no scientific

scientific basis.

For decades, there has been a rule for the medical care of patients in hospitals that in the case of patients in hospitals, to maintain a distance of at least 1 m for face-to-face contacts, if this is possible.

m, if possible (e.g. if there is only something to discuss), but only if the patient is respiratory.

if the patient has respiratory symptoms. If, however - as is so often the case

patients - the medical staff should use a medical mask (OP) for this purpose.

medical staff should wear a medical mask (surgical mask) to protect themselves from direct contact with respiratory droplets.

respiratory secretions on the mucous membranes of the face (eyes, nose, mouth),

nose, mouth).

This long-established distance rule is based on the transmission of respiratory

respiratory pathogens through so-called large droplets ($> 5 \mu\text{m}$) from the nasopharynx of infected persons.

infected persons, which fly only a short distance through the air due to their weight (e.g. when speaking) and then fall to the ground.

when speaking) and then fall to the ground. Once sedimented, they no longer pose

no longer pose a risk of infection. If one remains at a corresponding distance from a person with

respiratory infection, you have no contact with the droplets. That, at any rate

is the rule. Particularly when sneezing vigorously, but also when coughing, the droplets can be

droplets can also be propelled through the air over a longer distance. If then

person was standing there, he or she could possibly be hit by such far-flying droplets on the mucous membranes of the face.

the mucous membranes of the face.

A situation such as this, that other people can be considered as a potential

respiratory symptoms as a potential risk of infection was never considered before 2020 in the

infection control measures in hospitals, even during the influenza season.

season, because patients with respiratory infections do not cough and sneeze all the time.

cough and sneeze all the time. The fact that it is appropriate to keep a certain distance from other people

respiratory infection was also known in the general (non-medical) population.

(non-medical) population, if it was then explicitly said to the people they were talking to that they were

people to stay a little further away from each other so as not to infect the other person with the pathogen.

the other person with the pathogen (and also did not want to shake hands in greeting).

hand in greeting).

However, these precautions only ever applied when dealing with symptomatic people, even in hospital.

people, even in hospital. Never, for example, in the influenza season were non-symptomatic patients or even colleagues treated simply because it was the

season were regarded as potentially infected, and therefore no prophylactic distance was

prophylactically kept at a distance if there was no obvious respiratory illness.

was present. In the past few years, there have repeatedly been very severe influenza seasons in which the hospitals were overcrowded.

hospitals were overcrowded and patients had to lie in the corridors.

had to lie in the corridors. It was then no longer possible to keep a distance.

Keeping your distance is a plausible measure if you or someone you want to talk to has a respiratory illness.

person you want to talk to has a respiratory infection, even if it is

even if it is probably just a common cold. A cold is also unpleasant

a cold, and you want to spare others or yourself (if the other person has the symptoms) and symptoms) and therefore keep their distance.

For about a year now, however, people are supposed to keep their distance from each other all the time, even

even if no one has respiratory symptoms. This has been linked to the so-called unnoticed

transmission in the case of asymptomatic or pre-symptomatic transmission by the SARSCoV-2 virus.

The fact that this risk hardly plays a role in reality - unlike in mathematical

mathematical modelling - has already been explained in Part A. above.

The requirement introduced by politicians in 2020 to maintain an all-round distance of 1.5 m

has no rational basis because, if at all, only a vis-à-vis distance makes sense.

is sensible. Droplets fly forwards, but not to the side and to the rear, so this

distance to the side and to the rear has nothing to do with droplet transmission.

droplet transmission. If, however, the 'aerosol' theory was already in question, a distance of

a distance of 1.5 m would not be sufficient. At that time 98

aerosol' transmission was not yet an issue in Germany. Perhaps it seemed

easier for the politicians to talk about an all-round distance than to apply the distance

distance to vis-à-vis contacts. One can only speculate about this

because the politicians have not explained themselves.

There is no scientific research on keeping a distance outside of medical patient care.

In summary:

1. keep a distance of about 1.5 m (1 - 2 m) for vis-à-vis contacts if one person has symptoms of a cold can be considered a sensible measure.

can be described as a sensible measure. However, it is not scientifically proven,

There is only evidence, or it can be said to be plausible, that it is an effective measure...

an effective measure to protect oneself against contact with pathogens through droplets of respiratory secretions if the person in contact has signs of a cold.

cold. In contrast, an all-round distance is not useful to protect oneself if the contact has a cold. person has a cold. 2.

2. keep an all-round distance or even just a vis-à-vis distance of about 1.5 m (1 - 2 m)

distance if none of the people present has signs of a cold is not supported by scientific data.

not supported by scientific data. However, this does not make it easier for people to live together and especially the carefree contact between children is severely impaired.

3. close contacts, i.e. between people with a cold.

3. close contacts, i.e. less than 1.5 m (1 - 2 m), among pupils or between teachers and

or between colleagues at work, etc., do not pose a risk even if one of the two persons

even if one of the two people in contact has signs of a cold, because the duration of such

of such contacts at school or with adults somewhere in public is far too short for it to

is far too short for droplet transmission to occur. This is also shown by

studies from households where, despite living in close proximity with numerous

skin and mucous membrane contacts, only a few members of the household fall ill if

one of them has a respiratory infection.

Summary answer to the evidence questions

On the basis of the foregoing descriptions of the scientific literature, the evidentiary questions posed by the court can be

the evidentiary questions posed by the court can be answered as follows:

1. can the wearing of different types of face masks reduce the risk of infection with the coronavirus SARS?

with the SARS-CoV-2 coronavirus (appreciably)? A distinction should be made between

children in particular and adults in general, and between asymptomatic asymptomatic, pre-symptomatic and symptomatic people.

and symptomatic people.

There is no evidence that face masks of different types reduce the infection risk 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 people.

asymptomatic, pre-symptomatic and symptomatic individuals.

symptomatic people.

On the contrary, it is more likely that the even more frequent hand-face contacts when wearing masks could

the risk of coming into contact with the pathogen oneself, or of infecting fellow contact with the pathogen itself or to bring other people into contact with it. 3.

3. is there a risk of infection at all that can be reduced by wearing face masks?

(or other measures)?⁹⁹

For the normal population there is no risk of infection, neither in the public nor in the private sphere, that could be reduced by wearing face masks.

that could be reduced by the use of face masks (or other measures).

could be reduced.

4 Can the risk of infection be reduced by observing distance regulations, especially for children? especially in children?

There is no evidence that compliance with distance regulations can reduce the risk of infection.

reduce the risk of infection. This applies to people of all ages, including children and adolescents.

children and adolescents.

The expert has added the following literature list to her expert opinion:

Expert opinion - Literature

1 Robert Koch Institute (RKI). Mouth-to-nose covering in public spaces as a further component to reduce transmission of COVID-19. *Epid Bull* 2020; 19: 3-5.

Cheng KK, Lam TH, Leung CC. Wearing face masks in the community during the COVID-19 pandemic: altruism and solidarity. *Lancet* 2020; 395: DOI: 10.1016/S0140-6736(20)30918-1

3 Deutsches Ärzteblatt. Masks: 'Low added value' according to RKI only if used correctly,

28.04.2020. <https://www.aerzteblatt.de/nachrichten/112349/Masken-Geringer-Mehrwertlaut-RKI-nur-bei-richtigem-Umgang>

4 Ganyani T et al. Estimating the generation interval for coronavirus disease (COVID-19)

based on symptom onset data, March 2020. *Eurosurveillance* 2020; 25: 1-8;

<https://doi.org/10.2807/1560-7917.ES.2020.25.17.2000257>

5 Li R et al. Substantial undocumented infection facilitates the rapid dissemination of novel coronavirus (SARS-CoV-2). *Science* 2020; 368: 489-493;

<https://doi.org/10.1126/science.abb3221>

6 Robert Koch Institute (RKI). Consideration of the duration of quarantine and isolation for COVID-19. *Epid Bull* 2020; 39; 3-11; <https://doi.org/10.25646/7140>

7. he et al. Temporal dynamics in viral shedding and transmissibility of COVID-19. *nature.*

Medicine 2020; 26: 672-675; <https://doi.org/10.1038/s41591-020-0869-5>

8. Slifka MK and Lao L. Is presymptomatic spread a major contributor to COVID-19

transmission? *Nature Medicine* 2020; 26: 1531-1533; [https://doi.org/10.1038/s41591-](https://doi.org/10.1038/s41591-020-1046-6)

[020-1046-6](https://doi.org/10.1038/s41591-020-1046-6)

9 Du Z et al. Serial interval of COVID-19 among publicly reported confirmed cases.

Emerging Infectious Diseases 2020; 26: 1341-1343;

<https://doi.org/10.3201/eid2606.200357>

10 Wei WE et al: Presymptomatic transmission of SARS-CoV-2 - Singapore, January 23-

Morbidity and Mortality Weekly Report 2020; 69: 411-415;

<https://www.cdc.gov/mmwr/volumes/69/wr/mm6914e1.htm#>

11 Buitrago-Garcia D et al. Occurrence and transmission potential of asymptomatic and presymptomatic SARS-CoV-2 infections: A living systematic review and meta-analysis.

PLOS Medicine 2020; <https://doi.org/10.1371/journal.pmed.1003346>

12 Furukawa NW et al. Evidence supporting transmission of severe acute respiratory syndrome coronavirus 2

syndrome coronavirus 2 while presymptomatic or asymptomatic. *Em Infect Dis* 2020; 26:

e1-e6; <https://doi.org/10.3201/eid2607.201595100>

13 Kampf, Günter: Corona measures - benefits, risks and consequences. 2021. tredition, Hamburg (p. 120)

14. World Health Organization (WHO). Asymptomatic spread of coronavirus is 'very rare',

WHO says. <https://www.cnn.com/2020/06/08/asymptomatic-coronavirus-patients-arentspreading-new-infections-who-says.html>

15 World Health Organization (WHO). WHO walks back comments on asymptomatic coronavirus spread, says much is still unknown. <https://www.cnn.com/2020/06/09/whoscrambles-to-clarify-comments-on-asymptomatic-coronavirus-spread-much-is-stillunknown.html>

16 Rothe et al. Transmission of 2019-n-CoV infection from an asymptomatic contact in Germany. *N Engl J Med* 2020; 382: 970-971 (incl. Supplement); <https://doi.org/10.1056/NEJMc2001468>

17 Kupferschmidt K: Study claiming new coronavirus can be transmitted by people without symptoms was flawed; .
symptoms was flawed; <https://www.sciencemag.org/news/2020/02/paper-nonsymptomatic-patient-transmitting-coronavirus-wrong#>

18. RKI Press Office. RKI statement on accusations of ignoring findings on asymptomatic asymptomatic transmission of 03.07.2020.
<https://www.rki.de/DE/Content/Service/Presse/Zusammenfassung-2020-07-01.html>

19. Böhmer MM et al. Investigation of a COVID-19 outbreak in Germany resulting from a single travel-associated primary case: a case series. *Lancet Infect Dis* 2020; 20: 920-928; [https://doi.org/10.1016/S1473-3099\(20\)30314-5](https://doi.org/10.1016/S1473-3099(20)30314-5)

20. Byambasuren O et al.: Estimating the extent of asymptomatic COVID-19 and its potential for community transmission: Systematic review and meta-analysis. *Official Journal of the Association of Medical Microbiology and Infectious Disease Canada (JAMMI)*; <https://doi.org/10.3138/jammi-2020-0030>

21. Cao S et al. Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China. *Nature Communications* 2020; <https://doi.org/10.1038/s41467-020-19802-w>

22. Madewell ZJ et al. Household transmission of SARS-CoV-2 - A systematic review and meta-analysis. *JAMA Network Open* 2020; 3: e2031756; <https://doi.org/10.1001/jamanetworkopen.2020.31756>

23. Johansson MA et al. SARS-CoV-2 transmission from people without COVID-19 symptoms. *JAMA Network Open* 2021; 4: e2035057; <https://doi.org/10.1001/jamanetworkopen.2020.35057>

24. Qiu X et al. Defining the role of asymptomatic and pre-symptomatic SARS-CoV-2 transmission - a living systematic review. *Clinical Microbiology and Infection* 2021; <https://doi.org/10.1016/j.cmi.2021.01.011>
25. Marks M et al. Transmission of COVID-19 in 282 clusters in Catalonia, Spain: a cohort study. *Lancet Infect Dis* 2021; [https://doi.org/10.1016/S1473-3099\(20\)30985-3](https://doi.org/10.1016/S1473-3099(20)30985-3)
26. Ng OT et al. SARS-CoV-2 seroprevalence and transmission risk factors among high-risk close contacts: a retrospective cohort study. *Lancet Infect Dis* 2020; [https://doi.org/10.1016/S1473-3099\(20\)30833-1](https://doi.org/10.1016/S1473-3099(20)30833-1)
27. Cornelissen L, André E. Understanding the drivers of transmission of SARS-CoV-2. *Lancet Infect Dis* 2021; [https://doi.org/10.1016/S1473-3099\(21\)00005-0](https://doi.org/10.1016/S1473-3099(21)00005-0)
28. World Health Organization (WHO). 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, 2020/5, version 2, 13.01.2021101
29. Beesoon S et al. Universal masking during COVID-19 pandemic: Can textile engineering help public health? Narrative review of the evidence. *Preventive Medicine* 2020; <https://doi.org/10.1016/j.ypmed.2020.106236>
30. Leung NHL, Chu DKW, Shiu EYC et al. Respiratory virus shedding in exhaled breath and efficacy of face masks. *Nature Med* 2020; 1-20; <https://doi.org/10.1038/s41591-020-0843-2>
31. World Health Organization (WHO). Non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza. WHO 2019; <file:///C:/Users/dell6410/Downloads/WHO-Text-2019.pdf>.
32. European Centre for Disease Prevention and Control (ECDC). Using face masks in the community - Reducing COVID-19 transmission from potentially asymptomatic or presymptomatic people through the use of face masks (8 April 2020). <https://www.ecdc.europa.eu/sites/default/files/documents/COVID-19-use-face-maskscommunity.pdf>
33. European Centre for Disease Prevention and Control (ECDC). Using face masks in the community: first update - Effectiveness in reducing transmission of COVID-19 (15.

February 2021). <https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-facemasks-community-first-update.pdf>

34. Centres for Disease Control and Prevention (CDC). Guidance for Wearing Masks - Help Slow the Spread of COVID-19 (FAQ, May 2020: version no longer available).

<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover.html>

35. Centres for Disease Control and Prevention (CDC). Scientific brief: Community use of cloth masks to control the spread of SARS-CoV-2 (20 November 2020).

<https://www.cdc.gov/coronavirus/2019-ncov/more/masking-science-sars-cov2.html#print>

36. Jefferson T et al. Physical interventions to interrupt or reduce the spread of respiratory viruses. Part 1: Face masks, eye protection and person distancing: systematic review and meta-analysis (preprint).

<https://www.medrxiv.org/content/10.1101/2020.03.30.20047217v2>

37. Jefferson T et al. Physical interventions to interrupt or reduce the spread of respiratory viruses. Cochrane Database of Systematic Reviews, Issue 11, Art. No.: CD006207.

<https://doi.org/10.1002/14651858.CD006207.pub5>

38. Ioannidis JPA et al. Forecasting for COVID-19 has failed. *Int J Forecast* 2020;

<https://doi.org/10.1016/j.ijforecast.2020.08.004>

39. Rancourt DG. Face masks, lies, damn lies, and public health officials: 'A growing body of evidence'. Working Report, Research Gate; <https://10.13140/RG.2.2.25042.58569>

40. Brainard J, Jones N, Lake I et al. Community use of face masks and similar barriers to prevent respiratory illness such as COVID-19: a rapid scoping review. *Euro Surveill* 2020;

25: <https://doi.org/10.2807/1560-7917.ES.2020.25.49.2000725>

41. World Health Organization (WHO). Advice on the use of masks in the context of COVID19 (5 June 2020) [https://www.who.int/publications-detail/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novelcoronavirus-\(2019-ncov\)-outbreak](https://www.who.int/publications-detail/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novelcoronavirus-(2019-ncov)-outbreak).

42. World Health Organization (WHO). Masks in the context of COVID-19 (Interim Guidance).

(1 December 2020). [https://www.who.int/publications/i/item/advice-on-the-use-of-masksin-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-thenovel-coronavirus-\(2019-ncov\)-outbreak](https://www.who.int/publications/i/item/advice-on-the-use-of-masksin-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-thenovel-coronavirus-(2019-ncov)-outbreak)

43. Chu DK, Akl EA, Duda S et al. Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic

review and meta-analysis. *Lancet*, 2020; [https://doi.org/10.1016/S0140-6736\(20\)31142-9102](https://doi.org/10.1016/S0140-6736(20)31142-9102)

44. Lau JTF et al. Probable secondary infections in households of SARS patients in Hong Kong. *Emerging Infectious Diseases* 2004; 10: 235-243;
45. Wu J et al. Risk factors for SARS among persons without known contact with SARS patients, Beijing, China. *Emerging Infectious Diseases* 2004; 10: 210-216;
<https://doi.org/10.3201/eid1002.030730>
46. Tuan PA et al. SARS transmission in Vietnam outside of the health-care setting. *Epidemiology and Infection* 2007; 135: 392-401;
47. Ioannidis JPA. Infection fatality rate of COVID-19 inferred from seroprevalence data;
https://www.who.int/bulletin/online_first/BLT.20.265892.pdf
48. World Health Organization (WHO). Advice on the use of masks for children in the community in the context of COVID-19. Annex to the Advice on the use of masks in the context of COVID-19.
the context of COVID-19 (21 August 2020); https://www.who.int/publications/i/item/WHO2019-nCoV-IPC_Masks-Children-2020.1
49. German Society of Pneumology (DGP). Statement of the DGP on the impact of oral-nasal masks on self-protection and the protection of others in the case of infections in the population. *Pneumology*, 2020; <https://doi.org/10.1055/a-1175-8578>
50. Mitze T, Kosfeld R, Rode J et al. Face masks considerably reduce COVID-19 cases in Germany: a synthetic control method approach. IZA Institute of Labour Economics, IZA DP No. 13319, June 2020
51. Mitze T, Kosfeld R, Rode J et al. Face masks considerably reduce COVID-19 cases in Germany: a synthetic control method approach. CESifo Working Papers No. 8479, August 2020.
52. Mitze T, Kosfeld R, Rode J et al. Face masks considerably reduce COVID-19 cases in Germany. *PNAS* 2020; <https://doi.org/10.1073/pnas.2015954117>
53. Buchholz U, Buda S, Prahm K. Abrupt decline in respiratory disease rates in the respiratory diseases in the German population. *Epid Bull* 2020; 16: 7-9;
https://edoc.rki.de/bitstream/handle/176904/6601.2/16_2020_2.Artikel.pdf?sequence=3&isAllowed=y;
54. an der Heiden M, Hamouda O. Estimating the current evolution of the SARS-CoV-2 epidemic in Germany - Nowcasting. *Epid Bull* 2020; 17: 10-16;
https://edoc.rki.de/bitstream/handle/176904/6650.4/17_2020_2.Artikel.pdf?sequence=4&isAllowed=y

sAllowed=y

55. <https://ourworldindata.org/coronavirus-data-explorer>
56. <https://rationalground.com/mask-charts/>
57. <https://rationalground.com/more-mask-charts/>
58. <https://corona-transition.org/maskenpflicht-brachte-in-oesterreich-keinerlei-messbarennutzen>
59. Zhang R, Li Y, Zhang AL et al. Identifying airborne transmission as the dominant route for the spread of COVID-19. www.pnas.org/cgi/doi/10.1073/pnas.2009637117
60. <https://reason.com/2020/06/22/prominent-researchers-say-a-widely-cited-study-onwearing-masks-is-badly-flawed/>
61. Kampf G. Protective effect of mandatory face masks in the public - relevant variables with likely impact on outcome were not considered; www.pnas.org/cgi/doi/10.1073/pnas.2012415117
62. Hou YJ et al. SARS-CoV-2 reverse genetics reveals a variable infection gradient in the respiratory tract. *Cell* 2020; 182: 1-18; <https://doi.org/10.1016/j.cell.2020.05.042103>
63. Eikenberry SE, Mancuso M, Iboi E et al. To mask or not to mask: modelling the potential for face mask use by the general public to curtail the COVID-19 epidemic. *Infect Dis Modelling* 2020; 9: 293-308
64. Sunstein CR. *Laws of fear - Beyond the precautionary principle*. Suhrkamp Verlag, Frankfurt am Main, 2007
65. EU Commission. *Applicability of the Precautionary Principle*. Brussels, 02.02.2000; <https://eurlex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:52000DC0001&from=DE>
66. Chan JFW, Yuan S, Zhang AJ et al. Surgical mask partition reduces the risk of noncontact transmission in a golden Syrian hamster model for coronavirus disease 2019. (COVID-19). *Clin Infect Dis* 2020 May 30; <https://doi.org/10.1093/cid/ciaa644>
67. van der Sande M, Teunis P, Sabel R Professional and home-made face masks reduce exposure to respiratory infections among the general population. *PLoS One* 2008; 3: e2618
68. Davies A, Thompson K-A, Giri K, Kafatos G, Walker J, Bennett A Testing the efficacy of homemade masks: would they protect in an influenza pandemic? *Disaster Med Public Health Prep* 2013; 7: 413-418
69. Esposito, S. et al.: Universal use of face masks for success against COVID-19: evidence and implications for prevention policies.

and implications for prevention policies. Letter to the editor. *European Respiratory Journal*, 2020;
<https://doi.org/10.1183/13993003.01260-2020>

70. Stutt ROJH et al: A modelling framework to assess the likely effectiveness of facemasks in combination with 'lock-down' in managing the COVID-19 pandemic. *Proc R Soc A* 2020; 476 <https://doi.org/101098/rspa/2020.0376>

71. Worby CL, Chang H-H. Face mask use in the general population and optimal resource allocation during the COVID-19 pandemic. *Nature Communications* 2020;
<https://doi.org/10.1038/s41467-020-17922-x>

72. Howard J et al.: Face masks against COVID-19: an evidence review. *PNAS* 2021; 118:
<https://doi.org/10.1073/pnas.2014564118>

73. Zamir M et al: Nonpharmaceutical interventions for optimal control of COVID-19. *Computer Methods and Programs in Biomedicine* 2020; 196.
<https://doi.org/10.1016/j.cmpb.2020.105642>

74. Prather KA et al. Reducing transmission of SARS-CoV-2 - Masks and testing are necessary to combat asymptomatic spread in aerosols and droplets. *Science* 2020; 368: 1422-1424; <https://doi.org/10.1126/science.abc6197>

75. Matuschek C et al. Face masks: benefits and risks during the COVID-19 crisis. *Eur J Med Res* 2020; 25: 32; <https://doi.org/10.1186/s40001-020-00430-5>

76. Wong SH et al: COVID-19 and public interest in face mask use (Correspondence). *American Journal of Respiratory and Critical Care Medicine* 2020; 202: 453-454.
<https://doi.org/10.1164/rccm.202004-1188LE>

77. Chernozhukov V et al.: Causal impact of masks, policies, behavior on early covid-19 pandemic in the U.S. *Journal of Econometrics*, 2020;
<https://doi.org/10.1016/j.jeconom.2020.09.003>

78. Lyu W, Wehby GL: Community use of face masks and COVID-19: Evidence from a natural experiment of state mandates in the US. *Health Affairs* 2020; 39.
<https://doi.org/10.1377/hlthaff.2020.00818>

79. Leffler CT et al: Association of country-wide coronavirus mortality with demographics, testing, lockdowns, and public wearing of masks. *American Journal of Tropical Medicine and Hygiene*, 2020; <https://doi.org/10.4269/ajtmh.20-1015104>

80. Aravindakshan A et al.: Mask-wearing during the COVID-19 pandemic (preprint).

<https://doi.org/10.1101/2020.09.11.20192971>

81. Matzinger P, Skinner J. Strong impact of closing schools, closing bars and wearing masks during the COVID-19 pandemic: results from a simple and revealing analysis

(Preprint). <https://doi.org/10.1101/2020.09.26.20202457>

82. Pozo-Martin et al. Rapid review of the effectiveness of non-pharmaceutical interventions in controlling COVID-19.

in the control of the COVID-19 pandemic.

https://www.rki.de/SiteGlobals/Forms/Suche/serviceSucheForm.html?nn=2375194&resourceId=2390936&input_=2375194&pageLocale=en&searchEngineQueryString=pozomartin+et+al&submit.x=0&submit.y=0 and

https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Projekte_RKI/RapidReview-NPIs.pdf?__blob=publicationFile

83. Pozo-Martin et al. Impact of infection control measures on the.

growth of the COVID-19 epidemic: Member countries of the Organisation for Economic Co-operation and

Cooperation and Development (OECD), January - July 2020.

https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Projekte_RKI/impactcontrol-measures-oecd-summary.pdf?__blob=publicationFile and

https://www.rki.de/SiteGlobals/Forms/Suche/serviceSucheForm.html?nn=2375194&resourceId=2390936&input_=2375194&pageLocale=de&searchEngineQueryString=pozomartin+et+al&submit.x=0&submit.y=0

84. Karaivanov A et al.: Face Masks, Public Policies and Slowing the Spread of COVID-19:

Evidence from Canada (Preprint); <https://doi.org/10.1101/2020.09.24.20201178>

85. Cypionka T et al. Masks and face coverings for the lay public: a narrative update. *Ann*

Intern Med <https://doi.org/10.7326/M20-6625>

86. Agarwal N et al. Facemasks for prevention of viral respiratory infections in community settings: A systematic review and meta-analysis. *Indian Journal of Public Health* 2020;

https://doi.org/10.4103/ijph.IJPH_470_20

87. Xiao J et al. Nonpharmaceutical measures for pandemic influenza in nonhealthcare settings - personal protective and environmental measures. *Emerging Infectious*

Diseases 2020; 26: 967-975; <https://doi.org/10.3201/eid2605.190994>

88. Chou R et al. Masks for prevention of respiratory virus infections, including SARS-CoV-2, in health care and community settings - a living rapid review. *Annals of Internal Medicine*

2020; <https://doi.org/10.7326/M20-3213>

89. Chou R et al. Masks for prevention of respiratory virus infections, including SARS-CoV-2, in health care and community settings - update alert. *Annals of Internal Medicine* 2020; <https://doi.org/10.7326/L20-0948>

90. Chou R et al. Masks for prevention of respiratory virus infections, including SARS-CoV-2, in health care and community settings - update alert 2. *Annals of Internal Medicine* 2020; <https://doi.org/10.7326/L20-1067>

91. Chou R et al. Masks for prevention of respiratory virus infections, including SARS-CoV-2, in health care and community settings - update alert 3. *Annals of Internal Medicine* 2020; <https://doi.org/10.7326/L20-1292>

92. Chou R et al. Masks for prevention of respiratory virus infections, including SARS-CoV-2, in health care and community settings - update alert 4. *Annals of Internal Medicine* 2020; <https://doi.org/10.7326/L20-1429>

93. Chou R et al. Masks for prevention of respiratory virus infections, including SARS-CoV-2, in health care and community settings - update alert 5. *Annals of Internal Medicine* 2021; <https://doi.org/10.7326/L21-0116105>

94. Dugré N et al. Masks for prevention of viral respiratory infections among health care workers and the public - PEER umbrella.

workers and the public - PEER umbrella systematic review. *Canadian Family Physician* 2020; 66: 509-517

95. Brauner JM et al: The effectiveness of eight nonpharmaceutical interventions against COVID-19 in 41 countries (preprint); <https://doi.org/10.1101/2020.05.28.20116129>

96. Brauner JM et al: Inferring the effectiveness of government interventions against COVID19 in 41 countries. *Science* 2020; <https://doi.org/10.1126/science.abd9338>

97. Bundgaard H et al. Effectiveness of adding a mask recommendation to other public health measures to prevent

health measures to prevent SARS-CoV-2 infection in Danish mask wearers. *Annals of Internal Medicine* 2020; <https://doi.org/10.7326/M20-6817>

98. Deutsche Bahn (DB), German Aerospace Center (DLR). Air quality in (LUQAS) - Investigations on the dispersion probability of aerosols in the of aerosols in the passenger compartment of rail vehicles.

<https://www.dlr.de/content/de/downloads/2020/kurzfassung-abschlussbericht-luqas.pdf>

99. Saunders-Hastings P et al. Effectiveness of personal protective measures in reducing pandemic influenza transmission: A systematic review and meta-analysis. *Epidemics* 2017; 20: 1- 20; <http://dx.doi.org/10.1016/j.epidem.2017.04.003>
100. Barz H. Masks in everyday school life - tolls for the 'new normality'. Guest article from 06.09.2020; <https://www.cicero.de/kultur/corona-masken-schule-evidenz-studien>
101. DGPI, bvkj, DGKJ, GPP and SGKJ. Statement on the use of masks in children to prevent infection with SARS-CoV-2 (as of 12.11.2020). <https://dgpi.de/covid19-masken-stand-10-11-2020/>
102. Veit M. 'Open letter' of 17.11.2020 to DGPI, bvkj, DGKJ, GPP and SGKJ on. statement on the use of masks in children to prevent infection with SARS-CoV-2 (as of 12.11.2020). E-mail as PDF file.
103. Veit M. Hauptsache Maske !?. *Deutsche Apotheker Zeitung* online. <https://www.deutsche-apotheker-zeitung.de/daz-az/2020/daz-33-2020/hauptsachemaske>
104. Schwarz S et al. Corona children studies "Co-Ki": First results of a Germany-wide registry on mouth and nose covering (mask) in children. Preprint. <https://doi.org/10.21203/rs.3.rs-124394/v1>
105. AWMF. S3 guideline: Measures for the prevention and control of SARS-CoV-2-transmission in schools (Living guideline); AWMR register number: 027-076, version. 1, 01.02.2021
106. Fikenzer S et al. Effects of surgical and FFP2/N95 face masks on cardiopulmonary exercise capacity. *Clinical research in Cardiology* 2020; <https://doi.org/10.1007/s00392-020-01704-y>
107. Prousa D. Study on psychological and psychovegetative complaints due to the current oral-nasal protection regulations in Germany (as of June/July 2020). Preprint. <http://dx.doi.org/10.23668/psycharchives.3135>
108. Burgess A, Horii M. Risk, ritual and health responsabilisation: Japan's 'safety blanket' of surgical face mask-wearing. *Sociology of Health & Illness* 2012; 34: 1184-1198; <https://doi.org/10.1111/j.1467-9566.2012.01466.x>
109. <https://orf.at/stories/3174732/>
110. <https://www.bundesregierung.de/breg-de/themen/coronavirus/die-aha-regeln-imneuen-alltag-1758514>

111. Federal Institute for Drugs and Medical Devices (BfArM). Instructions of the BfArM on the use of mouth-nose coverings, medical face masks and 106 particle filtering half masks (FFP masks).
particle-filtering half masks (FFP masks).

<https://www.bfarm.de/SharedDocs/Risikoinformationen/Medizinprodukte/DE/schutzmasken.html>

112. Alonso WJ, Nascimento FC, Shapiro J et al. Facing ubiquitous viruses: when handwashing is not enough (Correspondence).

handwashing is not enough (Correspondence). Clin Infect Dis 2013; 56: 617

113. Gwaltney M, Moskalsky PB, Hendley JO. Hand-to-hand transmission of rhinovirus colds. Ann Int Med 1978; 88: 463-467.

114. Hall CB, Douglas RG Jr, Geiman JM. Possible transmission by fomites of respiratory syncytial virus. J Infect Dis 1980; 141: 98-102

115. Hall CB. Nosocomial respiratory syncytial virus infections: The 'cold war' has not ended. Clin Infect Dis 2000; 31: 590-596

116. World Health Organization (WHO). Transmission of SARS-CoV-2: implications for infection prevention precautions (05.07.2020);

<https://www.who.int/news-room/commentaries/detail/transmission-of-sars-cov-2-implications-for-infection-prevention-precautions>

117. European Centre for Disease Prevention and Control (ECDC). Transmission of COVID-19. <https://www.ecdc.europa.eu/en/covid-19/latest-evidence/transmission>

118. Centres for Disease Control and Prevention (CDC). SARS-CoV-2 and potential airborne transmission. <https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-briefsars-cov-2.html#print>

119. Robert Koch Institute (RKI). Epidemiological profile of SARS-CoV-2 and COVID-19 (update 25.01.2021).

https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Steckbrief.html;jsessionid=9239C340793F6DB445372E5159462370.internet121?nn=13490888#doc13776792bodyText2

120 Thomas RJ. Particle size and pathogenicity in the respiratory tract. Virulence 2013; 4: 847-858; <https://dx.doi.org/10.4161/viru.27172>

121. Xie X et al. How far droplets can move in indoor environments - revisiting the Wells evaporation-falling curve. Indoor Air 2007; 17:211-225; <https://doi.org/10.1111/j.1600->

0668.2007.00469.x

122. de Gabory L et al. The influenza virus, SARS-CoV-2, and the airways: clarification for the otolaryngologist. *European Annals of Otorhinolaryngology, Head and Neck diseases*. 2020; 137: 291-296; <https://doi.org/10.1016/j.anorl.2020.05.015>

123 Tellier R. Aerosol transmission of influenza A virus: a review of new studies. *J R Soc Interface* 2009; 6: S783-790; <https://doi.org/10.1098/rsif.2009.0302.focus>

124. Scheuch G. Breathing is enough: for the spread of influenza virus and SARS-CoV-2 by breathing only. *Journal of Aerosol Medicine and Pulmonary Drug Delivery* 2020; 33: 230-234; <https://doi.org/10.1089/jamp.2020.1616>

125 Seto WH. Airborne transmission and precautions: facts and myths. *Journal of Hospital Infection* 2015; 89: 225-228; <https://doi.org/10.1016/j.jhin.2014.11.005>

126 Tellier R et al. Recognition of aerosol transmission of infectious agents: a commentary. *BMC Infectious Diseases* 2019; 19: 101-108; <https://doi.org/10.1186/s12879-019-3707-y>

127 Gralton J et al. The role of particle size in aerosolized pathogen transmission. A review. *J Hosp Infect* 2011; 62: 1-13; <https://doi.org/10.1016/j.inf.2010.11.010>

128. tang JW. The effect of environmental parameters on the survival of airborne infectious agents. *J R Soc Interface* 2009; 6: S737-746; <https://doi.org/10.1098/rsif.2009.0227.focus107>

129 Stadnytskyi V et al. The airborne lifetime of small speech droplets and their potential importance in SARS-CoV-2 transmission.

importance in SARS-CoV-2 transmission. *PNAS* 2020; 117: 11875-11877; <https://doi.org/10.1073/pnas.2006874117>

130 Popa A et al. *Science Translational Medicine* (2020); <https://doi.org/10.1126/scitranslmed.abe2555>

131 Klompas M et al. Airborne transmission of SARS-CoV-2: Theoretical considerations and available evidence.

and available evidence. *Journal of the American Medical Association (JAMA)*. 2020;324(5): 441-442; <https://doi.org/10.1001/jama.2020.12458>

132 Günther T et al.: Investigation of a superspreading event preceding the largest meat processing plant-related SARS-CoV-2.

processing plant-related SARS-Coronavirus-2 outbreak in Germany;

<https://ssrn.com/abstract=3654517>

133 Lu J et al: COVID-19 outbreak associated with air conditioning in restaurant, Guengzhou, China, 2020. *Emerging Infectious Diseases* 2020; 26: 1628-1631;

<https://doi.org/10.3201/eid2607.200764>

134 Miller SL et al.: Transmission of SARS-CoV-2 by inhalation of respiratory aerosol in the Skagit Valley chorale superspreading event. *Indoor Air* 2020;

<https://doi.org/10.1111/ina.12751>

135 Hamner L et al. High SARS-CoV-2 Attack Rate Following Exposure at a Choir Practice - Skagit County, Washington, March 2020. *Morbidity and Mortality Weekly Report* 2020; 69: 606-610; <https://www.cdc.gov/mmwr/volumes/69/wr/mm6919e6.htm>

136 Ho K-F, Lin L-Y, Wenig S-P, Chuang K-J: Medical mask versus cotton mask for preventing respiratory droplet transmission in micro environments. *Science of the Total Environment* 2020;

<https://www.sciencedirect.com/science/article/pii/S0048969720330278>

137 Asadi S et al. Efficacy of face masks and face coverings in controlling outward aerosol particle emission from expiratory activities. *Nature Research* 2020;

<https://doi.org/10.1038/s41598-020-72798-7>

138 Ueki H et al. Effectiveness of face masks in preventing airborne transmission of SARS-CoV-2. *Clinical Science and Epidemiology* 2020;

<https://doi.org/10.1128/mSphere.00637-20>

Gandhi M, Rutherford GW. Facial masking for Covid-19 - potential for 'variolaion' as we await a vaccine. *NEJM* 2020; 383: e101; <https://doi.org/10.1056/NEJMp2026913>

140 Fangerau H, Labisch A. Plague and Corona - Pandemics in history, present and future. and future. Herder Freiburg - Basel - Vienna 2020, p. 70.

Seyringer K. EU authority spurs discussion on FFP2 mask, 04.02.2021;

<https://www.tips.at/nachrichten/linz/land-leute/526490-eu-behoerde-facht-diskussion-umffp2-maske-an>

142 Meers P et al. *Infection control in healthcare*. 2nd edition, 1997, Stanley Thornes Publishers Ltd, Cheltenham

143 Murken AH: 'From hospital for the poor to large hospital - the history of the hospital from the 18th century to the present day'.

Hospital from the 18th Century to the Present', DuMont Buchverlag Cologne, 1988.

144. society for virology (GfV). Statement of the Ad-hoc-Commission SARS-CoV2 of the Society for Virology: SARS-CoV-2-Prevention Measures at the Start of School

after the summer holidays, 06.08.2020; <https://www.g-f-w.org/node/1326>

145 Christian Drosten. NDR podcast no. 40, 12.05.2020;

<https://www.ndr.de/nachrichten/info/Coronavirus-Update-Die-Podcast-Folgen-alsSkript,podcastcoronavirus102.html108>

146. Christian Drosten. NDR Podcast No. 54 from 01.09.2020;

<https://www.ndr.de/nachrichten/info/Coronavirus-Update-Die-Podcast-Folgen-alsSkript,podcastcoronavirus102.html>

147. Bavarian State Dental Association (BLZK). Info Oral Health of the Bavarian

Landeszahnärztekammer, 30 November 2020. brochure 'Bad breath?'

https://www.blzk.de/blzk/site.nsf/id/li_im_mundgeruch_maske.html?OpenDocument&Click=

k=

148. <https://www.thepioneer.de/originals/steingarts-morning-briefing/podcasts/ansteckungim-aussenbereich-nahezu-ausgeschlossen>

149 Horii M. Why do the Japanese wear masks? Electronic journal of contemporary

japanese studies, 2014; <https://www.japanesestudies.org.uk/ejcs/vol14/iss2/horii.html>

150. <https://www.japandigest.de/aktuelles/kolumne/mundschutz-in-japan/>

IX. Expert opinion Prof. Dr. Christof Kuhbandner

Prof. Dr. Christof Kuhbandner is Professor of Psychology, Chair of the Department of Educational Psychology at the University of Regensburg and an expert in the field of scientific methods and diagnostics.

The expert has provided his expert opinion, which is inserted here in full, as follows:

In the following, I, as Professor of Psychology, Chair of the Department of

Educational Psychology at the University of Regensburg and an expert in the field of scientific

methods and diagnostics, I would like to present my professional assessment of the

questions raised. I will deal with each of the questions

and describe the state of the art, with reference to the underlying scientific sources.

scientific sources.

1) Can wearing different types of face masks reduce the risk of infection with the coronavirus SARS?

with the SARS-CoV-2 coronavirus (significantly)? A distinction should be made between

children in particular and adults in general and between asymptomatic

asymptomatic, pre-symptomatic and symptomatic people.

and symptomatic people.

In order to answer this question, a rating scheme is first used to classify the quality of evidence from studies with different methodological approaches.

Subsequently, the recommendations of the Robert Koch Institute (RKI) on measures in the school sector, the recommendations in the Sociological Report of the German Federal Ministry of Education and Research (BMBF) are discussed.

the recommendations in the S3 guideline "Measures for the prevention and control of SARS-CoV-2".

SARS-CoV-2 transmission in schools" and the WHO recommendations on mask-wearing, especially for children and adults.

wearing masks, especially in children, and the scientific studies on which these recommendations are based.

scientific studies on which these recommendations are based. Next, the state of the science with regard to

the state of the art with regard to studies of high quality from an evidence-based

from an evidence-based perspective. In particular, the special features of mask-wearing in children

mask-wearing by children. Based on this, the extent to which the risk of infection with

the extent to which the risk of infection can be reduced by wearing masks in schools. 109

Finally, the current increase in the number of reported positive SARS CoV-2

positive SARS-CoV-2 test results from children and the relevance of the virus variant.

B.1.1.7. is discussed.

Evaluation scheme for ranking the quality of evidence from studies

Various methodological approaches can be found in research on the effect of masks.

methodological approaches can be found in research. Many studies are so-called observational studies

observational studies in which, for example, people are asked whether or not they wear masks in everyday life and the

masks in everyday life, and the incidence of infection is compared. The methodological

problem is that you cannot conclude from such studies that the mask has a causal effect, because

mask, because people who wear masks can behave differently in terms of hygiene.

otherwise behave differently. For example, it is very likely that mask-wearing people also wash their hands more often.

washing their hands more frequently, so that an observed effect could be due to more frequent

effect may be due to more frequent hand washing instead of the mask.

Furthermore, there are studies in which the filter effect of the mask is examined in the laboratory.

The problem with this type of study is that it is not possible to deduce the virus from such laboratory findings to the spread of the virus in real life. The reason is, is that in such studies only one route of transmission is tested experimentally. In real life, however, there are other transmission pathways on which the wearing of a mask may have a negative effect on, so that in total masks may even have negative even have a negative effect on the spread of the virus, although a positive effect on the transmission via the air stream can be experimentally demonstrated. For example studies show that masks reduce the viral load in the exhaled air, but that more viruses more viruses accumulate on the outside of the mask [1]. This means that a transmission via the air is reduced by means of a mask, but the transmission via transmission via touching the mask with the hands. From the from the investigation of a single route of transmission in the laboratory to the from the perspective of application research is a well-known misconception, because in practice In practice, it is the interaction of all transmission routes that counts.

Finally, there are studies in which attempts are being made, on the basis of modelling of the spread of the virus in the population to estimate the effect of mandatory mask to estimate the effect. However, the results of modelling studies depend fundamentally on the parameters built into the model.

parameters built into the model. For example, many modelling studies ignore the fact that the spread of the virus is strongly influenced by seasonal effects, which would then be which can then be falsely attributed to an effect of prescribed measures [2].

Furthermore, some parameters cannot be estimated from empirical data, but must be determined with certain theoretical assumptions. For example time between infection and reporting a test result to the health department varies substantially from person to person.

health authorities varies substantially from person to person, which is not adequately reflected not adequately reflected in several modelling studies [3].

In order to investigate the effect of mask-wearing in a really scientifically sound way, studies are actually

studies are needed in which people are randomly assigned to a group with or without a mask and the

with or without masks and the infection incidence in both groups is observed over a longer period of time.

observed in both groups over a longer period of time (so-called randomised controlled trials).

This can be regarded as the gold standard of efficacy research.

Recommendations of the RKI on measures in the school sector¹¹⁰

On 12 October, the RKI published a recommendation on prevention measures in schools [4].

published a recommendation [4]. There, the wearing of everyday masks is recommended, if a minimum distance of 1.5 m cannot be maintained. Depending on the incidence

and grade level, it is recommended that masks be worn not only on school grounds but also in the classroom.

but also in class - for primary schools from a 7-day incidence in the population of

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's recommendations do not refer to any studies on the effectiveness of mask-wearing. The paper only states - without referring to a single supporting empirical study - that the study (p. 3):

"The recognised infection control measures are also effective in childhood and adolescence, at least effective, at least for older children, and are an important building block in the in coping with the pandemic".

Furthermore, it is explicitly pointed out that in these recommendations possible damage caused to children by wearing masks was completely disregarded. Thus the RKI explicitly writes in the corresponding paper (p. 4):

"Psychosocial and other aspects such as the avoidance of stigmatisation are not part of this recommendation.

stigmatisation are not part of this recommendation; the focus is on infection prevention."

From the perspective of evidence-based medicine, where it is important to assess both the benefits and the costs of an intervention against the background of the evidence, this is not the case.

costs of a measure against the background of existing empirical studies, this recommendation is studies, this paper by the RKI on the recommendations of prevention measures in

prevention measures in schools must be regarded as questionable: The claimed benefit of

The claimed benefit of children wearing masks is not supported by empirical studies.

were even explicitly ignored in the development of 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 the SARS-CoV-2 transmission in schools" was published by the Scientific Medical Societies [5].

societies [5]. The recommendations for action formulated in the guideline were

by a representative group of experts from the scientific medical

societies - in charge were the German Society for Epidemiology, the German

German Society for Public Health, the German Society for Paediatrics and

and the German Society for Paediatric Infectious Diseases - as well as those involved in school

and decision-makers involved in school life. With regard to

masks, the recommendation (p. 5) is as follows:2.1 Evidence-based recommendation

Recommendation

2.2 Evidence-based recommendation

Proper wearing of masks by schoolchildren, teachers and other school personnel should be implemented in schools.

should be implemented in schools.

Quality of Evidence: Low ⊕⊕⊙⊙

Grade of recommendation: Strong recommendation A

Consensus strength: strong consensus (100%); yes votes 24, no votes 0,

Abstentions 1

Literature: Chu et al. (2020); Krishnaratne et al. (2021); Li et al. (2020)111

2.2 Evidence-based recommendation

If the incidence of infection is high, a medical mouth-nose protector should be used.

should be used.

Quality of evidence: Low ⊕⊕⊙⊙

Grade of recommendation: Strong recommendation A

Consensus strength: 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 added by the author of the expert report):

Evidence base

The evidence on the effects of the intervention on SARS-CoV-2 transmission was evaluated using a cochlear implant.

transmission was systematically reviewed in a Cochrane Rapid Review [1].

The evidence obtained is largely based on modelling studies with quality deficiencies. The trustworthiness of this evidence is evidence is very low or low.

Indirect evidence on the transmission of SARS-CoV-2 with the use of masks in the general population has low confidence.

Health outcomes beyond COVID-19 have not been systematically reviewed and are and are based on indirect evidence, individual studies and/or expert consensus. expert consensus.

Evidence on other criteria (acceptability, health equity, social and environmental impacts, financial and economic impacts, feasibility) was not reviewed, i.e. no systematic search and evaluation of scientific and evaluation of scientific studies. All assessments of these criteria are based on expert consensus. A

The restriction of fundamental rights by the measure was taken into account, also with regard to the proportionality of the measure.

the proportionality of the measure. A legal examination was not carried out.

As the highlights show, the evidence base on which the recommendations on the wearing of masks in children were based is consistently low to very low.

wearing masks in children has been consistently low to very low, a systematic systematic search and evaluation of scientific studies has not taken place.

taken place. Nevertheless, the following claims are made with regard to the benefits

the following claims are made about the benefits - without providing any concrete empirical claims made (p. 6):

"Wearing masks reduces transmission of SARS-CoV-2.

Wearing masks in schools reduces the frequency of infection as part of a package of measures".

It should also be critically noted that the studies cited under "Literature" are also

Chu et al. (2020), Krishnaratne et al. (2021) and Li et al. (2020) - are only meta-analyses of observational data.

are exclusively meta-analyses of observational studies. Thus Li et al.

explicitly in the conclusion in the abstract:112

"Robust randomized trials are needed in the future to better provide evidence for these interventions."

Likewise, Chu et al. write in the interpretation in the abstract:

"Robust randomised trials are needed to better inform the evidence for these interventions."

In addition, the studies analysed in the meta-analyses are mostly hospital-based studies.

studies analysed in the meta-analyses are mostly hospital studies, which, with regard to the

These studies cannot simply be transferred to the area of schools with regard to the occurrence of infections.

For example, only one of the six studies included in the meta-analysis by Li et al.

only one of the six studies included in the meta-analysis by Li et al. was not in a hospital setting, but in the general population.

and in this study, interestingly, there was no significant effect on non-hospital

no significant effect of mask-wearing for people outside of hospitals.

In fact, there are now relatively extensive observational studies of the

These are not yet included in the meta-analyses mentioned, but point in a similar direction. For example

recently published in the Lancet [6], in which 282 infection clusters in households were investigated.

infection clusters in households were investigated with regard to factors which influenced the

influenced the incidence of infection. One factor was whether or not masks were worn.

not. There was no significant difference in the incidence of infection between the groups "never wore a mask" and "always wore a mask".

there was no significant difference in the incidence of infection, 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 justified with convincing scientific evidence.

scientific evidence, as should be the case with high-quality S3 guidelines.

should be the case.

It is particularly remarkable that possible harms are almost completely ignored.

As can be seen above in the cited section from the S3 guideline on the evidence base,

the health consequences of mask-wearing beyond COVID-19 were not systematically reviewed. With regard to the assessment of the possible harm of mask-wearing the guideline - although the evidence was not systematically reviewed (p. 6).

reviewed (p. 6):

"There are few adverse health effects associated with mask-wearing. There is no evidence of possible harm from wearing a mask".

Overall, the S3 guideline does not meet the actual expectations of such a guideline in terms of scientific quality.

of such a guideline in terms of scientific quality. The claimed benefit

is not substantiated with high quality scientific evidence, but is based on studies that are studies that provide only very low to low evidence and are questioned by more recent studies.

studies are also questioned. With regard to harm, it is claimed that there would be

there is no evidence for possible harm, although the studies have not been systematically been systematically reviewed. As will be described in more detail in a moment

a look at the official WHO recommendation, where the 113 possible harms are listed, at least in part, with corresponding references.

potential harms are listed, at least in part, with corresponding references.

Especially with regard to harm, the S3 guideline almost borders on misleading the users of such products.

misleading the users of such guidelines.

WHO recommendations on the wearing of masks

The WHO general recommendations on mask use were last updated on 1 December 2020 [7].

December 2020 [7]. On the one hand, it explicitly differentiates between settings inside and

and outside of hospitals. On the other hand, it states with regard to

settings outside hospitals (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 evidence, the use of masks is recommended in cases of high viral spread

is recommended when a distance of 1 m cannot be maintained. However

explicitly referred to the numerous possible harms, with reference to corresponding scientific

scientific evidence, which should be taken into account when deciding on the wearing of masks (p. 10).

(p. 10; the references given refer to the numbering in the WHO recommendation).

WHO recommendation):

The potential disadvantages of mask use by healthy people in the general public include:

headache and/or breathing difficulties, depending on 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 21 August 2020, the WHO also published a recommendation on mask-wearing specifically for children [8].

specifically for children [8]. There, too, explicit reference is made to the lack of empirical evidence. It states (p. 2):

"Evidence on the benefits and harms of children wearing masks to mitigate transmission of COVID-19 and other coronaviruses is limited. "114

Studies are also cited which indicate that masks are less effective in children than in adults.

effective in children than in adults. Thus it is said (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 as to whether children should wear masks, it is then explicitly pointed out that the possible

that the potential harm should be given priority. Thus

the Main Conclusions (p. 2) state:

"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 negatively impact development and learning outcomes.

Surprisingly, however, the wearing of masks is recommended for children from the age of but only if (among other things) there is a higher risk of virus spread in the population and a higher risk of infection.

population and a higher risk of infection in the corresponding age group and possible and possible negative influences on learning and psychosocial development are weighed up. development are weighed.

In summary, the WHO recommendations explicitly point to the lack of high-quality scientific evidence on the efficacy of carrying the virus.

evidence on the efficacy of mask-wearing in general and in relation to children in particular.

and especially in relation to children. At the same time, many of the possible

and it is explicitly recommended to consider the possible physical, psychological and social psychological and social harms for children and to prioritise them if necessary.

Randomised controlled trials on the effect of the mask on virus spread

As mentioned at the beginning, for a high-quality scientific investigation of the effect of masks on the spread of the virus, randomised controlled studies are required.

of the effect of masks on the spread of the virus requires randomised controlled

studies are needed. Since such studies are very costly, they were not available until relatively recently.

recently, such studies were not available for the SARS-CoV-2 virus. However, there are several such

studies on the already known respiratory viruses. There the situation is relatively clear: in two different meta-analyses from 2020 on the existing randomised 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)."¹¹⁵

Policy Review of the American Centers 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 RKI Vice President Lars Schaade, at a press conference on 28 February 2020 that the RKI explicitly does not recommend wearing masks in everyday life.

masks in everyday life. Verbatim, he clarified when asked [11]:

"This has been studied several times: There is simply no scientific

There is simply no scientific evidence that this [wearing masks] makes any sense.

At the beginning of the SARS-CoV-2 pandemic, there was no scientific evidence from randomised controlled trials to support the use of masks.

randomised controlled trials that the spread of respiratory viruses by means of masks was a respiratory viruses by means of masks in a relevant way. This has now also been confirmed in the first major randomised controlled trial on the effect of mask-wearing on SARS-CoV-2 infections. In a Danish study [12], 4,862 people were either randomly assigned to either a group that wore high-quality surgical masks (filtering rate masks (filter rate 98%) when leaving home for one month, or to a group that was not to group who were not to wear masks for the same period. At the time of the study, masks were not compulsory in Denmark and the wearing of masks was uncommon.

The result was that there was no significant difference ($p = 0.18$) in the infection rate between the mask group and the non-mask group.

between the mask group (infection rate: 1.8%) and the control group (infection rate: 2.1%) was observed. When only those people were left in the mask group, who actually wore the mask as prescribed, then the effect of mask wearing almost completely disappeared (infection rate mask group: 2.0% versus control group: 2.1%). (infection rate control group: 2.1%, $p = 0.82$). The first large randomised controlled study on the effect of mask-wearing on SARS-CoV-2 infections thus confirms the lack of effect of mask-wearing on SARS-CoV-2 infections observed in previous studies on other respiratory viruses. It should be noted that in this study, the effect of mask-wearing on the effect of mask-wearing on self-protection. With regard to external protection - i.e. the extent to which masks prevent an infected person from infecting other people. there have been no randomised controlled trials.

At the end of November, an update of the aforementioned Cochrane Review was published [13], which includes the newly added studies. The result is unchanged:

"The pooled results of randomised 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."

Thus, there is still no evidence from randomised controlled trials that masks could prevent the spread of infection. In fact, with regard to the wearing of 116 cotton masks, the only randomised controlled trial [14] that exists to date shows that controlled trial [14] shows that wearing cotton masks not only does not reduce the risk of infection, but that it not only does not reduce the risk of infection, but actually increases it significantly. In the study, the effect of 1,607 hospital workers, one third of whom wore cotton masks and one third wore operating one-third wore cotton masks, one-third wore surgical masks, and the remaining one-third were asked to

behave as they usually do (in this condition, almost all people also wore either medical masks or cotton masks). The authors summarise 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 arm. Cloth masks also had significantly higher rates of ILI compared with the control arm."

The risk of infection was found to be significantly higher in the cotton mask group. In the group with the medical mask, the risk of infection was reduced compared to the control condition.

reduced. However, this should not be interpreted as an indication that medical masks actually had an effect. In the control group, the people did not wear masks, but either cotton masks or medical masks.

Therefore, the risk of infection in the control group is exactly in the middle between the cotton mask group and the medical mask group.

between the cotton mask group and the medical mask group.

Interestingly, there are two other studies by the same researchers with a very similar design. In these studies, medical masks were compared with a real control condition without a mask. There was no difference in infection risk between the groups. The authors use these results to interpret the findings from the study on the cotton masks and write:

"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."

The authors thus conclude that the findings are probably to be interpreted in such a way that also medical masks do not reduce the spread of virus, but that cotton masks increase the risk of increase the risk of infection. In concrete terms, the main conclusion derived from the study is as follows

main conclusion in the abstract:

"The results caution against the use of cloth masks. "117

Interesting, especially with regard to the question of children wearing masks is the authors' explanation for the increased risk 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 modelling studies have quantified the contamination levels of masks. Selfcontamination 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 pathogen retention. These effects may be associated with cloth masks. "

The authors therefore assume that cotton masks soak through more quickly and viruses can remain in the mask.

viruses can remain in the mask and that this can increase the risk of infection if risk of infection if mishandled. Interestingly, the problems mentioned are problems mentioned - long wearing time, higher moisture penetration, long term use of the same mask

without adequate cleaning and problematic handling - are exactly the same problems problems that are typically observed when students wear masks in the classroom. typically observed when students wear masks in class.

The factor of correct handling of the masks when worn

It should be noted that correct handling of masks in general is a key factor in is crucial for masks to have any effect at all. Thus it says

WHO recommendation on the correct handling of masks [7] states that

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 after discarding a mask.

Do not re-use single-use mask. 118

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 clearly shows, the correct wearing of masks places high demands on the person wearing the mask.

demands on the person wearing the mask. Considering that

students are required to wear masks in class for up to 10 hours a day (school bus).

hours per day (school bus, school grounds, morning and afternoon lessons), correct

afternoon lessons), it is almost impossible to implement correct handling at schools. In addition

In addition, for younger pupils, correct handling of masks is cognitively demanding.

which are not given to younger children due to their development. Since

the prefrontal cortex is not fully developed until around the beginning of adolescence [15].

fully developed until around the beginning of adolescence [15], children's behaviour is strongly controlled by automated

behavioural tendencies, which can only be regulated to a limited extent by the child itself.

can only be regulated to a limited extent. Thus, requirements such as not touching the mask can hardly be implemented by children.

implemented. There is thus a danger that when children wear masks, the increased infection caused by

risk of infection due to incorrect handling outweighs the low to non-existent benefit of the controlled trials outweighs the small to non-existent benefit.

From the perspective of evidence-based medicine, it should be critically noted in particular,

that there are no randomised controlled trials on the effect of wearing masks in schools on the spread of the

randomised controlled trials on the effect of wearing masks in schools on the spread of the virus. In view of the situation described above, it is

questionable to what extent it can be justifiable at all to impose a comprehensive masking masks without any scientifically verifiable proof of benefit. The

This is all the more the case as the long-term wearing of masks is associated with possible harm physical, psychological and social levels - beyond a possible increase in the spread of spread of the virus (see below).

The extent of the reduction in the risk of infection by means of mask-wearing at schools

It is important to note that the effect of a measure on the spread of viruses in the population does not depend

population does not depend solely on the effectiveness of a measure. The effect of a depends on the number of infections that can be prevented in the setting in which the measure is

can be prevented in the setting in which the measure is used. If, for example, there are

If, for example, there are hardly any infections in a particular setting, even a highly effective measure effective measure can hardly influence the incidence of infections in the population because there are hardly any

because there are hardly any infections that can be prevented by the measure.

can be prevented.

This point is particularly relevant if a measure is associated with potential side effects.

side effects are associated with a measure. This can be illustrated by the so-called Number Needed to Treat - i.e. the number of people who have to be treated with a measure in order for a single

to be treated in order to prevent a single case of illness. If

for example, a large number of people have to be treated with a drug and suffer from potential side-effects in order to bring about an improvement in just one person, the use of the drug is questionable.¹¹⁹

In relation to the issue of mask-wearing in schools, this point is particularly relevant because because practically all available data indicate that infections in schools are comparatively rare. occur comparatively rarely in schools. This is the case simply because extensive meta-analyses indicate that children under 12 years of age in particular are less likely to be infected and less likely to pass on the virus than adults [16,17].

In addition, the measure of keeping children with symptoms at home can already the number of infected children in schools is significantly reduced. As meta-analyses show that on the one hand, asymptotically infected persons, i.e. persons who - people who have tested positive for SARS-CoV-2 but who do not develop any symptoms but do not develop any symptoms of the disease - hardly ever infect other people. A meta-analysis of studies on infections among people living together in the same household [17] showed that the probability of infection among asymptomatic

household [17] showed that the probability of contracting the disease from an asymptomatic person (secondary infestation rate) is only 0.7 per cent, whereby the statistical analysis showed that the value does not differ significantly from that of an asymptomatic person.

showed that the value was not significantly different from zero. A comparable finding is found in another recently published large meta-analysis of contact tracing studies [18].

contact tracing 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.

Thus, asymptotically infected children do not pose a relevant risk of infection.

In the case of infected children with symptoms, it is the case that an infection occurs a maximum of two days before the onset of symptoms.

before the onset of symptoms [19]. If children with symptoms there is only a two-day window of opportunity for children who develop symptoms to infect others. can infect other people, which significantly reduces the risk of infection. reduced.

In fact, numerous data confirm that there are hardly any infected children or infections at schools.

infections in schools. Of particular interest with regard to the wearing of masks are the current figures from Austria.

the current figures from Austria, where no masks are worn at primary schools and at the same time and at the same time, rapid tests are carried out three times a week throughout the country.

This makes it possible to estimate the number of infected pupils relatively well. In the week of 22-28 February (the most recent data set available), only 0.08 per cent of the

only 0.08 per cent of the rapid tests were positive [20]. Assuming that the number of and false-negative results are more or less equal, the probability that a pupil

the probability that a pupil would develop an infection within a week would be

would be only 0.08 per cent. The probability that an infected pupil would be infected during contact without wearing a mask at school is also very small,

is also very small and, according to extensive contact tracing studies, is in the order of only about of only about 0.5 per cent [21,22].

Based on these figures, a calculation example can be used to illustrate how large the risk reduction is. example to illustrate the extent of the risk reduction that can be achieved by wearing masks.

can be achieved. The risk of an infection occurring in a class of 25 children in the course of a week is therefore

is 0.08 per cent times 25 (the probability of one infected child in a class) times

infected child in a class) times 25 (number of contacts including the teacher) times 0.5

per cent (probability of infection per contact) = 0.25 per cent.¹²⁰

This figure would correspond to the risk of infection that can potentially be reduced with measures in schools.

measures in schools. The extent of the reduction depends on the

effectiveness of a measure. If one interprets the non-significant effects from the randomised controlled

randomised controlled trials as null effects, no risk reduction could be achieved with mask-wearing in no risk reduction could be achieved with mask-wearing in schools.

If one assumes the non-significant effect sizes in the aforementioned current Cochrane Review review (see above), according to which the probability of infection when wearing medical masks

medical masks is reduced by a maximum of about 10 per cent, the risk of infection would be

the risk of infection at the level of a school class from 0.25 per cent to 0.225 per cent.

which would correspond to an absolute risk difference of 0.025%.

Extrapolated to the Number Needed to Treat, the pupils in 4,000 primary school classes would have to wear a mask for a week to prevent a single infection. This is an extremely small effect size and would mean that just under 100,000 primary school pupils would have to suffer the possible side effects of the mask.

the possible side effects of wearing a mask to prevent a single infection per week. one infection per week.

Assuming that masks would reduce the probability of infection in the order of 80 per cent (result of the meta-analysis by Chu et al. 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 reduced from 0.25 from 0.25 per cent to 0.05 per cent, which would correspond to an absolute risk difference of 0.2 per cent.

would correspond. Extrapolated to the Number Needed to Treat, this would still require the pupils in 500 primary school classes would still have to wear a mask for a week, and thus and thus almost 12,500 primary school pupils would have to suffer the possible side-effects to prevent a single infection per week.

In order to evaluate such a ratio, an example from the area of drug approval is helpful. drug approval is helpful. Here, it would be difficult to imagine a positive assessment of a drug 100,000 (reduction of the probability of infection by masks by 10 percent) or 12,500 by 10 per cent) or 12,500 (reduction of the probability of infection by masks by 80 per cent) would have to be treated and suffer from side effects in order to achieve a positive a positive effect on a single person.

In summary, it can be concluded that the achievable extent of the reduction of the the risk of infection by wearing masks in schools is very low, because even without masks infections occur very rarely in schools even without masks. It is intuitively obvious that an absolute risk reduction of 0.025 per cent (reduction of the probability of probability of infection by 10 per cent) and also with an absolute risk reduction of 0.2 per cent. reduction of 0.2 per cent (reduction of the probability of infection by 80 per cent through masks by 80 per cent), a pandemic cannot be combated in a relevant way.

In addition, this small benefit is accompanied by numerous possible side effects in terms of physical, psychological and mental health.

physical, psychological and social well-being of children,

from which many children would have to suffer to prevent a single infection (see below).

(see below).

The currently observed increase in reported infections among children¹²¹

Finally, the increase in the number of reported infections among children observed in the previous

the increase in the number of reported positive SARS-CoV2 test results in children observed in the previous calendar weeks and the relevance of the new virus variant B.1.1.7.

should be addressed. The RKI and the media have interpreted this increase to mean that the number of

that the number of infections among children is rising sharply, which has something to do with the new virus variant

B.1.1.7 could have something to do with it. Both are used as an argument for the need for more stringent

tightened measures would be necessary in schools.

However, the RKI is overlooking a serious aspect here: In the previous

In the previous calendar weeks, the number of Corona tests (PCR tests) carried out on children quadrupled (see the figures published by the RKI on the number of tests carried out).

tests carried out: [24]). However, an expansion of the tests is not feasible in view of the existing infected but not yet detected, an increase in the number of infections found automatically leads to a number of infections found, without the incidence of infection having to have changed.

have changed. The increase in the number of cases among children suspected by the RKI could therefore only be due to the fact that the number of tests among children has quadrupled and the number of unreported cases has thus been increasingly uncovered.

If we look at the proportion of positive test results received, however, we find that that there was no increase in the number of children aged 5-14 years in the previous calendar weeks. calendar weeks. Instead, the proportion of positive test results has been decreasing for several weeks.

Contrary to what is conveyed by the RKI and disseminated in the media, there is therefore - in relation to the proportion of

of positive test results - instead of an increase, there is a decrease.

There is actually only one single case when an increase in the number of detected

infections with a simultaneous increase in the number of tests performed indicates a real

increase in the number of infections. This would only be the case if the increase in the number of tests was

number of tests is driven by the fact that more and more people are observed with corona-specific

symptoms, which are then targeted with tests. However, this is not the case with the

This is most likely not the case with the current corona testing of children.

This is indicated by the fact that over 90 per cent of the tests carried out on children are negative.

children are negative. The question of which children to test therefore appears to be largely largely independent of whether children have corona-specific symptoms or not.

In fact, for weeks there has been very strong advocacy for the blanket testing of children at schools and day-care centres regardless of symptoms. Due to the

the increasing number of mass tests regardless of symptoms, the number of unreported cases infected but not yet detected, which causes the number of cases to rise.

test-related rise in the number of cases. At the same time, the number of PCR tests independent of symptoms

regardless of symptoms. According to RKI calculations [25], in mass testing with

tests regardless of symptoms, the probability of actually being infected when receiving a positive result is actually infected, at an incidence of 50 (test specificity 80%,

test sensitivity 98%) is only two percent. This would mean that for every two genuinely positive positive rapid test results, there would be 98 false-positive rapid test results.

all of which would have to be retested with a PCR test.

In addition, there is currently a strong increase in respiratory illnesses caused by rhinoviruses and the due to rhinoviruses and the coronavirus hCoV in particular. According to the current 122

influenza weekly report of the RKI [26], the number of sentinel samples examined in the course of flu the number of rhinovirus-related and hCoV-related respiratory illnesses has increased in the last four years.

respiratory illnesses more than tripled within the last four weeks. The graph published in the same

The graph published in the same weekly report on the age dependency of the virus spreads shows that the rhinovirus in particular

shows that the rhinovirus in particular is spreading among children and adolescents.

According to RKI guidelines [27], the presence of acute respiratory symptoms of any

symptoms of any severity, the current increase in rhinovirus and hCoV-related respiratory

hCoV-related respiratory illnesses means that more and more people are being tested for SARSCoV-2, even though the majority of respiratory illnesses are caused by a different virus.

virus. Again, since PCR test results are still available weeks and sometimes even

months after a SARS-CoV-2 infection [19], this leads to rhinovirus and hCoV-related increase in the number of SARS-CoV-2 tests, the number of unreported cases of past but as yet undetected infections is being infections are increasingly being uncovered.

Taken together, this means that from a diagnostic perspective: It is extremely

It is extremely unlikely that the increase in the number of tests is driven by the increase in corona-specific symptoms in children. Instead, the increase in the number of

test number is most likely due to the advertised mass testing of children and the increasing children and the increasing number of rhinovirus and hCoV-related respiratory respiratory diseases among children. Both of these factors are leading to an increasing the number of children infected with SARS-CoV-2 who have not yet been detected. which leads to an increase in the number of infections due to the number of tests.

Interestingly, the results from the sentinel samples of the

flu surveillance sentinel samples, which are not distorted by the increase in testing

the increase in the number of tests in the population confirm that the new coronavirus SARS-CoV-2 is not

spread than in previous weeks. As the virus detections on the sentinel samples show,

the number of SARS-CoV-2 infections detected in the sentinel samples has been at a low

the 4th calendar week, a "third wave" is practically not discernible here.

is practically not discernible.

The relevance of the virus variant B.1.1.7

In the argumentation for measures in schools, reference is often made to the allegedly higher level of infection among children.

the allegedly higher risk of infection among children with the new B.1.1.7 mutation.

However, recent comprehensive studies have not been able to confirm this fear. Thus

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 Paediatric Infectious Diseases and the

German Society for Hospital Hygiene in a recent statement [30]:"

Initial media reports of an increased risk of infection or transmission compared to adults

infectiousness or transmissibility for children have not been confirmed. "123

Here it is still important to point out a common statistical misintuition. Statements such as "the new variant is 50 per cent more contagious" intuitively sound like a lot. In reality depends on how high the probability of infection is for the new the probability of infection with the old virus variant is: the percentage value says yes, the percentage of the old probability of infection that the new probability of infection is higher. probability of infection is higher. If the old probability of infection is small, then the new probability of infection is still small with a 50% increase. still small.

An illustrative example of this, which is particularly relevant to the risk of infection from children

According to the extensive contact tracing studies in schools mentioned above, the

According to the extensive contact tracing studies in schools mentioned above, the probability of an infected

infected child infecting a contact at school (without masks at the schools) is only about

about 0.5 per cent. With an increase of 50 per cent, the

probability of infection would still only be 0.75 per cent. Extrapolated to 100

contacts, this would mean that despite a 50 per cent increase in the

probability of infection, less than a single other person would become infected.

would be infected. Even with a 50% increase in the probability of infection, the

probability of infection, the risk of infection at schools is still very low.

so that a tightening of the measures cannot be justified from a scientific perspective.

scientific perspective.

Summary evaluation

In summary, it can be stated that there is no high-quality scientific evidence to date that the risk of evidence that wearing face masks can significantly reduce the risk of infection.

can be significantly reduced. The recommendations of the RKI and the S3 guideline of the

are based on observational studies, laboratory tests on the filter effect and modelling studies.

filter effect and modelling studies, which provide only low and very low evidence,

because, due to the underlying methodology, no really valid conclusions can be drawn from such studies about the effect of masks.

conclusions about the effect of masks in everyday life and at schools can be drawn from such studies.

In addition, the results of the individual studies are heterogeneous, and more recent

more recent observational studies also provide contradictory findings.

The randomised controlled trials on the effect of mask-wearing that have existed so far do not indicate any efficacy of mask-wearing.

of mask-wearing do not indicate any efficacy of masks, the observed effects are consistently small and meta

effects are consistently small and meta-analytically not significant. On the contrary, the only

only large randomised controlled trial on the use of cotton masks indicates that

suggests that cotton masks may actually increase the risk of infection. A role

handling of the mask, which can have a negative effect on the risk of infection when

can have a negative effect on the risk of infection. This point is particularly interesting for the

interesting for schools, because handling problems in the school setting and

and especially with younger pupils are hardly avoidable.

In addition, the achievable extent of the reduction in the risk of infection through

the risk of infection by wearing masks in schools is very small, because even without masks

infections occur very rarely in schools. Accordingly, the absolute reduction in risk is so

that it cannot be used to combat a pandemic in any relevant way. In addition 124

benefit, there are numerous possible side effects in terms of physical, psychological and social health.

physical, psychological and social well-being of children (see below).

below), from which numerous children would have to suffer to prevent a single infection.

prevent a single infection.

The current alleged increase in the number of infections in children is very

probability that the number of tests carried out on children has risen sharply in the preceding

in the preceding weeks. Since the risk of infection at schools is

is very small, even a possible increase in the rate of infection with the new

B.1.1.7 in the order of magnitude suspected in studies, it is not to be expected that the virus

spread of the virus in schools is likely to increase significantly. 2.

2. what physical, psychological and pedagogical damage can be caused by the

can be caused by the wearing of masks, especially in children?

In order to answer this question, we will first of all provide an overview of the already mentioned

the above-mentioned list of the harms of wearing masks from the official WHO recommendation and, in addition

and, as a supplement, the overviews from two specialist publications on the harm of

of mask-wearing are presented. Subsequently, the results of an online register on the physical and psychological

the physical and psychological side-effects of mask-wearing in children, which were which were recently published. This is followed by a more detailed description of physical and psychological damage, particularly with regard to the particularities of children. Finally, questionable plausibility arguments are plausibility arguments that are often cited.

Overview studies on the harms of mask-wearing

As already stated in the elaboration of question 1, the WHO recommendations on mask-wearing, updated on 1 December 2020, do not mention the harm of wearing masks.

December 2020, the WHO's updated recommendations on mask-wearing [7]

numerous possible harms are mentioned with reference to corresponding empirical evidence.

These are presented again in the following list, and the corresponding empirical evidence is listed in the bibliography.

The corresponding empirical evidence is linked in the bibliography at the end (see WHO recommendation,

S. 10):

headache and/or breathing difficulties, depending on 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] 125

In January 2021, the peer-reviewed journal Medical Hypothesis published a comprehensive article on the state of the science on the harms of mask wearing on the physical and the physical and psychological harms of mask-wearing and the resulting health consequences [40]. health consequences [40]. As the following overview table from the (see Table 1), there are additional indications of further - in particular psychological - damage. psychological damage, which have 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 disease
Exacerbation of existing
conditions and diseases
Accelerated aging process
Health deterioration
Premature mortality

In August 2020, the British Medical Journal published an article on the possible psychological, biological and immunological risks.,

biological and immunological risks, especially for children and schoolchildren, of wearing masks for long periods of time [41]. In summary, it states (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, fuelling 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 skinproblems 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 behavioural problems and a 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].

tract infections and mortality [56-59]."

These overview articles already show how numerous the possible harms of mask-wearing are. of mask-wearing are. In particular, there is a lack of some other possible harms, such as such as the risk of discrimination against children who are medically unable to wear masks. children who cannot wear masks for medical reasons, or developmental impairments. On the children are more susceptible to many of the harm concerns due to their developmental immaturity. are more susceptible to many of the side effects listed.

Results of a registry on side effects of mask-wearing in children

Clear and impressive evidence of the range and magnitude of the side effects of mask-wearing of the side effects of mask-wearing in children are the results of the world's first first register worldwide, in which - comparable to the collection of side effects of of side effects of medicines by the Paul-Ehrlich-Institut - parents, doctors, educators and others parents, doctors, educators and others can enter their observations on the side effects of wearing a children and adolescents. On the one hand, a checklist is used to

possible symptoms (see the following table from the article), on the other hand

On the other hand, further symptoms can be entered in a free text field.

The first results were recently published in the journal *Monatsschrift Kinderheilkunde* [60].

[60]. Within one week after the start of the register, 20,353 people had already made entries.

The group of parents alone entered data on 25,930 children.

In the article, the results from the parents' entries are reported. The reported

average time spent wearing the mask was 270 minutes per day. Overall, the

68 per cent of respondents reported that children complained of adverse effects from wearing

complain. For example, 13,811 of the children suffered from headaches, 12,824 from difficulties in

concentration difficulties, 9,460 sleepiness, 7,700 shortness of breath, 6,848 dizziness, 5,365

dizziness, 5,365 fainting spells and 4,292 nausea. The following

table from the article shows the frequencies for all symptoms on the symptom checklist (see table 3 in the article):

Symptoms

Total

n (%)

Age 0 to 6

n (%)

7 to 12 years

n (%)

Age 13 to 17

n (%)

Headache 13,811

(53,3)

960

(24,0)

7863

(54,6)

4988

(66,4)

Concentration difficulties

n

12.824

(49,5)

961

(24,0)

7313

(50,8)

4550

(60,5)

Indisposition 10,907

(42,1)

1040

(26,0)

6369

(44,2)

3498

(46,5)

Learning impairment 9845

(38,0)

621

(15,5)

5604

(38,9)

3620

(48,2)

Drowsiness/fatigue 9460

(36,5)

729

(18,2)

5163

(35,8)

3568

(47,5)127

Tightness under the mask 9232

(35,6)

968

(24,2)

5427

(37,7)

2837

(37,7)

Feeling of breathlessness 7700

(29,7)

677

(16,9)

4440

(30,8)

2583

(34,4)

Vertigo 6848

(26,4)

427

(10,7)

3814

(26,5)

2607

(34,7)

Dry neck 5883

(22,7)

516

(12,9)

3313

(23,0)

2054

(27,3)

Lack of strength 5365

(20,7)

410

(10,2)

2881

(20,0)

2074

(27,6)

Disinclination to move, disinclination 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 of weakness 3820

(14,7)

300

(7,5)

2020

(14,0)

1500

(20,0)

Abdominal 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)

Tightness in the chest 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, heart palpitations

Heart stitches

1459

(5,6)

118

(2,9)

766

(5,3)

575

(7,6)

Noise in the ears 1179

(4,5)

107

(2,7)

632

(4,4)

440

(5,9)

Short-term

Impairment of consciousness

fainting spells

565

(2,2)

39

(1,0)

274

(1,9)

252

(3,4)

Vomiting 480

(1,9)

40

(1,0)

296

(2,1)

144

(1,9)

In the free text field, further health problems were indicated:

269 entries on worsened skin, especially increased pimples, rashes and allergic
around the mouth and even fungal infections in and around the mouth.
and around the mouth

151 entries on nosebleeds

122 entries on reluctance to go to school, up to and including fear of school/refusal to go to school

64 Entries on increased sweating¹²⁸

52 Entries on pressure sores and wounds behind the ears

46 Entries on sore or cracked and sometimes bloody lips

31 Entries on increased frequency and severity of migraine attacks

23 entries on impaired vision

13 entries on aphthae

As the authors note, this means that within a single week more children and adolescents with mask-related

with mask-related physical complaints than the total number of children and adolescents with mask-related

children and adolescents with positive SARS-CoV-2 test results.

test results had been reported.

In addition to the physical side-effects, numerous psychological side-effects were also

side effects were also reported, which are listed in the following table (see table

4 in the article):

Psychological

Side effects

Total

n (%)

Age 0 to 6

n (%)

7 to 12 years

n (%)

Age 13 to 17

n (%)

The child is more often irritable
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
go to school/kindergarten
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 developed new fears
developed

4762

(25,3)

713

(27,4)

2935

(27,8)

1114

(19,7)

The child sleeps more than
than usual

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 greater
urge to move than usual

1615

(8,6)

253

(9,7)

1124

(10,6)

238

(4,2)

In the free text, the fears that occurred were specified even further:

In addition to a general fear of the future, the fears of suffocating even with a mask and of the death of

and of the death of relatives due to Corona were the most common.

represented.

In addition, there is the fear of being stigmatised by both wearing and not wearing a mask.

wearing or not wearing a mask in the social environment.

Many parents also report nightmares and anxiety disorders related to masked people whose masks are worn.

people whose facial expressions and identities are not recognisable to the children.¹²⁹

recognisable to the children.¹²⁹

On the one hand, it should be noted that the entries could not be comprehensively validated.

validated. Thus, the authors write about the limitations of the study:

"By its very nature, an open-access registry can never cross-validate all entries by doctors.

validate all entries. The registry entries increase daily in the multi-digit range, and

additional validity checks are being carried out in order to obtain more reliable data on the health

data on the health situation of children in Germany with regard to the wearing of

wearing mouth-nose protection."

As an argument for the credibility of the data, the authors state:

"With few exceptions, the data sets in the free-text entries testify to a very

differentiated approach and overall provide a balanced picture with plausible

overall picture with a plausible spectrum of symptoms and a well comprehensible description of the

description of the impairments observed in children in connection with the mask.

observed in children. The response to hundreds of incoming e-mails by the

initiators with answers to questions about the existence of the registry, specification

participants, detailed case histories and suggestions for further research.

and suggestions for further research, are a further indication of the high relevance of the topic and the

the high relevance of the topic and for the honesty with which many participants have dedicated question."

Furthermore, the authors note that biased reporting with respect to the

particularly severely affected children or children who are fundamentally critical of the critical of protective measures cannot be ruled out.

can be ruled out.

Overall, this study on the world's first registry for possible

side-effects of mask-wearing in children shows very impressively that there is a very large range of physical and psychological side effects. The central

conclusion of the authors is:

"The frequency of use and the range of symptoms point to the importance of the and call for representative surveys, randomised controlled trials with different mask types and randomised controlled trials with different types of masks and a risk-benefit assessment of the mask requirement in the vulnerable group of children."

The complaints described when children wear masks for a long time are also confirmed by other are also confirmed by further studies on other groups of people who also have to wear long

who also have to wear masks for a long time. In the meantime, there have been several studies on the complaints of

people who work in the health sector and who also have to wear masks for long periods of time.

It should be noted here that, unlike in the school sector, in addition to masks

protective equipment must be worn in addition to masks (e.g. protective goggles, protective suits),

protective suits). In a recently published preprint meta-analysis of existing studies with a total of

studies with a total of 11,746 participants on the physical side effects was the

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 a wide range of side effects can be associated with the use of masks.

a wide range of side effects can be associated with mask use. In the following, some of the side effects

some of the side effects that have not yet been mentioned or that are not

which have not yet been mentioned or which are associated with special features in relation to children.

Physiological side effects

Studies on adults show that wearing masks can have effects on the physiological level, especially under physical strain.

physiological level, especially during physical exertion. After just a few

a few minutes, some studies show a slightly higher CO₂ concentration in the blood, faster heartbeat blood, a faster heartbeat and faster breathing [62,63]. Wearing surgical masks for masks for hours, there is also a drop in oxygen saturation in the blood [64].

It is important to note that there are also studies in which such effects are not observed [65].

were not observed [65]. On the other hand, it is important to note that the values of the

values when wearing masks in relation to the average values across the subjects studied

the subjects studied are in the order of magnitude that, according to the current guidelines

clinical relevance according to current guidelines.

However, it should be noted that in the case of undiagnosed pre-existing conditions, there are nevertheless

side effects such as panic, seizures and impaired consciousness [66].

can occur [66]. In this respect, an important methodological aspect in the

interpretation of studies on possible side effects of masks: Alone

from the observation that there is no statistically significant difference in mean

physiological values between the masked and non-masked conditions, it cannot be

cannot be used to conclude the non-existence of side effects.

The first problem is that in the case of small samples, existing differences in mean values

only become statistically significant if the differences are very large. In medicine

even small effects can be quite relevant. The second problem is that

even with non-significant effects at the group level, extreme values can occur

extreme values can occur, which are strongly detrimental to the persons concerned.

for the persons concerned.

A negative example of this is a study by a group of researchers led by Michael Campos [67].

Campos [67], which was widely disseminated in the media and allegedly shows that even people with even people with lung disease would not show any physiological effects from wearing masks.

However, on the one hand, the sample studied is very small - in this study only

only 15 healthy people or people with lung disease were tested in this study - so that statistically only extremely large effects can be detected.

extremely large effects can be detected with this study. On the other hand, despite the lack of significant effect at the group level, extreme values occurred in individual persons. Thus 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."

Two of the patients with COPD did show more fundamental side effects, but only at the mean level. side effects, but at the mean level there was no effect on average across all patients.

no effect across all patients. If, for example, this were to become the rule for the approval of medicines

approval, rarer side effects would no longer have to be taken into account - which is questionable. which is questionable.

In summary, a mini review published in February 2021 on the existing studies [68]:131

"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 hypoxaemia 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."

With regard to the potential physiological harm of mask-wearing in children, a fundamental fundamental problem is that there are hardly any studies on the effects in children.

This is particularly problematic because the effects described could be more pronounced in children effects described could be stronger in children, because oxygen consumption is higher and the the breathing reserve is lower, and the percentage of the dead space volume of the of the total respiratory volume is greater in children and the flow resistance of the

mask can have a greater effect due to the weaker respiratory musculature.

In the aforementioned mini-review, a comprehensive literature search uncovered one study was found in which the physiological consequences of five minutes of wearing N95 masks for five minutes in 7-14 year old children, once during reading and once during light physical activity [69]. It showed that the CO₂-concentration (end-tidal carboxylic dioxide and fractional inspired carbon dioxide) increased by up to 34 per cent in both cases (light physical exercise), although the values still did not reach clinical relevance.

The problem, however, is that in the course of compulsory mask wearing in classrooms, children do not wear masks for only

five minutes, but up to ten hours a day, five days a week.

There are no studies on such long wearing times. This is particularly problematic because particularly problematic because the government's prescription of mandatory measures for millions of children, it is absolutely necessary from a medical ethics medical ethics, it is imperative to examine possible risks before prescribing the measure. and to exclude them on the basis of evidence, or at least to quantify the risk.

Oral diseases - the so-called "mask mouth

Wearing masks can be associated with a number of oral diseases, such as.

caries, bad breath, gingivitis and inflammation of the mouth region - here the technical term

The technical term "mask mouth" was coined [70].

Deformation of the auricle

Children before puberty have an undeveloped ear cartilage with less resistance to deformation.

against deformation. Prolonged pressure from the elastic loops of the mask can affect the correct growth and angulation of the outer ear and increase the angle of the outer auricle [71].

increase the angle of the outer ear [71].

Accumulation of viruses and bacteria on the mask

Viruses, bacteria and fungi can accumulate on masks, which can be repeatedly inhaled and cause disease.

inhaled and can cause illness, as studies on the use of surgical masks have shown [71].

studies on the wearing of surgical masks [72]. Whereas exhaled droplets and aerosols are

are normally released into the ambient air when exhaled and dry quickly, they remain in the air when worn.

dry quickly, they remain in the mask when masks are worn, with the effect that bacteria and fungi can grow in the constantly

bacteria and fungi can multiply in the constantly moist environment of the mask, be inhaled again and

be inhaled and contaminate the body.¹³²

Possible toxins contained in masks

Problematic side effects can also occur if masks that are worn contain toxins.

contain toxins. In an article in the Frankfurter Rundschau, the results of a study by the private Hamburg Environmental Institute (HUI) [73]. There considerable quantities of pollutants in the masks currently in use.

including volatile organic hydrocarbons and formaldehyde. In addition

also showed that when worn for several hours and used repeatedly - as is the case in schools - microplastic

in schools - microplastics are inhaled. The HUI chairman, Professor

Michael Braungart, is quoted as saying:

"In trials we have found up to 2000 fibres per day, some of which enter the lungs with the air we breathe".

into the lungs with the air we breathe".

A recent article by the German Allergy and Asthma Association (DAAB) states [74]:

"In the course of the Corona pandemic, the DAAB has received several enquiries about odours on protective masks. Particularly at the beginning of the pandemic, there were certainly also products on the market that contained harmful substances. But even now

But even now this can still be the case in isolated cases, as the magazine WISO has now checked.

Harmful substances in masks can get directly into the lungs through breathing".

Since the certification of medical masks only takes into account the filtering performance and the germ load, but not necessarily the presence of toxic components (see DIN EN 14.1).

toxic components (see DIN EN 14683, 5.2.7 Summary of performance requirements).

performance requirements), this could indeed be a problem for some medical masks.

masks. If it were true that medical masks could contain problematic

ingredients, children would be exposed to a health risk when wearing medical masks.

children would be exposed to a health risk. Since the masks are compulsory in class, on

school grounds and on the school bus, a period of wear is reached when such risks are particularly high.

is reached when such risks would be particularly high.

Psychological side effects

As already described on the basis of the entries in the register described above on the side effects side effects of mask-wearing in children described above, there are psychological masks in schools can be expected to have far-reaching negative effects on the development and development and maturation of children. In a recent on the side-effects of mask-wearing on emotional experience and social communication and social communication, the neuroscientist Manfred Spitzer points to the three following problems [75]:

Restriction of non-verbal communication

Wearing masks extremely restricts non-verbal communication, which is communication, which is one of the most important channels for the development of a for the development of a sustainable social relationship. Furthermore, facial facial expression is one of the central signals through which we communicate our own emotional state and reveal the emotional state of the other person. emotional state of the other person, which is one of the fundamental building blocks of emotional and social competence. Children in particular still have to learn to reliably interpret these signals in the faces of others.

Negative distortion of emotional experience¹³³

In addition, there is another negative effect: according to studies, fear and sadness are more likely to be

eyes and joy is more likely to be read from the mouth. Furthermore, without the signal from the mouth region, emotional facial expressions are misinterpreted. A facial expression that is actually

expression is often misinterpreted as a sceptical expression, a surprised expression

a surprised facial expression is often misinterpreted as anger or sadness.

sadness. Wearing masks could therefore make it less likely to see positive and positive emotions in the faces of others and more negative ones.

Impairment of empathy

Furthermore, empathy - feeling the emotional state of others - is impaired by wearing masks.

is impaired by wearing masks. Studies show that when people

unconsciously take on the facial expression of the other person and feel the

the inner state of the other person, which is prevented by wearing a mask.
prevented.

In summary, Manfred Spitzer writes in his overview paper:

"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. Emotional 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 psychological side effects of wearing a face mask are also mentioned in the Bavarian law on education, health and safety.

also mentioned in the Bavarian law on education, upbringing and care of children in kindergartens, other day care facilities and in day care (BayKiBiG).

is taken up. Although this law deals with kindergarten children, the corresponding contents can also be transferred to primary school age.

can also be transferred to primary school age. There, in Part 3 on Article [76] on safeguarding the best interests of the child:

Article 9a: Prohibition of face covering

Employees in child day-care facilities may not cover their faces during visiting hours, unless face during visiting hours, unless there are reasons for not doing so. Sentence 1 applies accordingly to day care workers.

On the official website of the Bavarian State Ministry for Family Affairs, Labour and Social Affairs provides a more detailed interpretation. There, the various pedagogical justifications for the ban on covering the face [77]:

Excerpt from the legal justification for Art. 9a BayKiBiG:

The aim of day care facilities for children and day care for children is, among other things, to impart the ability to cooperate and communicate, as well as to encourage the children to learn the skills of cooperation and communication.

communication skills and to enable children to integrate.

Particularly in the area of very young children, it is essential for a child's development that

development, it is essential that good pedagogical work is done. This would be severely jeopardised if the child were to be confronted with a carer or other person working in the day care centre who or other person working in the day care centre who does not show his or her face.

However, facial expressions are important in order to learn about and understand the different ways of expressing oneself.

and to be able to understand them. Furthermore, a veiled 134

face prevents communication and interaction between the child and the educator.

and thus impairs the development of bonding and relationships, which is essential for the

and relationship building that is indispensable for children's education and upbringing. After all, it is precisely the personal and intimate

contact between child and staff is enormously important for early childhood education.

It is therefore necessary that employees in child day care facilities are present during visiting times during visiting hours and at events organised by the facility (between chin and forehead).

forehead) during visiting hours and at events organised by the institution. (...) The prohibition does not apply if there are reasons for not doing so.

reasons stand in the way. Care-related reasons would be, for example, a disguise in a role play or at a carnival.

role play or at a carnival party.

In view of the fact that the aforementioned negative effects of mask-wearing on the

development of children are considered so important in the BayKiBiG that a ban on wearing

that a ban on wearing masks is prescribed by law, it is all the more surprising that none of the

none of the side effects mentioned in the current regulation of a

masks in the primary school - and also not among the educators in the

types of children - is being taken into account.

In addition, there are a number of other possible psychological side effects:

Restriction of speech transmission

Wearing masks is also associated with negative effects on speech transmission [78].

speech transmission [78]. On the one hand, higher frequencies are attenuated, and on the other hand, the visual signal from the lips is completely obstructed.

signal from the lips is completely obstructed, which impairs verbal communication

and is associated with the risk of misunderstandings. This has a particularly detrimental effect

language learning, so that foreign language acquisition and, in particular, children with a

children with a migration background are particularly affected.

Risk of discrimination

Finally, there are negative side effects on a psychological level for children who are not allowed to wear a mask for medical reasons. There is a danger that discriminated against and excluded from the social class - justified by hygiene arguments. excluded from their social class, with negative consequences for their psychological and and social well-being. I know of cases where children who cannot wear a mask for medical mask for medical reasons have to wear yellow armbands for the whole school day. the whole school day. In another case, a corner of the classroom and playground is taped off where children can

where children who cannot wear masks for medical reasons have to stay, for medical reasons. The risk of discrimination is also evidenced by the fact that in the above the above-mentioned register on the side effects of mask-wearing on children. fear of being stigmatised both by wearing and not wearing a mask in the social environment. wearing a mask in the social environment.

The danger of such discrimination is reinforced by questionable statements by experts in the media. experts in the media. For example, the youth psychiatrist Dr. Biskup-Meyer said in an SZ interview on the compulsory wearing of masks in primary school [79]:

"If the teachers wear a mask and the pupils are made to believe that this is just necessary, that this is just necessary, then primary school children are certainly the ones who most willing to comply. This also means that there is unity in the class because everyone wears a mask. "135

If a need to wear a mask is strongly communicated to children by teachers and if social dynamics create peer pressure, there is an even greater risk that some children will that some children will be discriminated against.

In addition, children who are not allowed to wear masks for medical reasons may find themselves in a psychological situation, are put in a psychological situation that cannot be resolved positively for the child.

No matter how the child behaves, there are negative consequences: If the child does not If the child does not wear a mask, it will be socially excluded; if the child wears the mask, physical suffering will occur.

Such a situation can be associated with very negative psychological consequences, up to the development of mental disorders.

even the development of psychological disorders.

The triggering and maintenance of developmentally psychologically inappropriate fears

In relation to Corona measures at primary schools, there is the additional problem that with measures such as wearing masks or keeping a distance from others, the children are children that there is a great danger from others for themselves as well as from themselves for others.

and that they themselves are a great danger to others. This can be accompanied by fears and feelings of guilt, which a child

which a child cannot deal with due to its developmental immaturity. If

this is the case, anxiety disorders develop which impair the child's development.

development.

Prolonged anxiety has a problematic effect on various levels of the psyche.

psyche. For example, thoughts begin to revolve around the fearful event, so that the child can no longer concentrate on other things.

so that the child can no longer concentrate on other things. On the level of

motivation, the avoidance-related behavioural system is chronically activated, which leads to the

the child no longer strives for the things he or she wants to achieve, but instead sees the world

the world through the lens of possible threatening events that he or she would like to

which he or she wants to avoid. The consequence is that the child increasingly stops in its development and withdraws.

development and becomes increasingly withdrawn. In extreme cases this can go so far that

depression develops. This can lead to "biological scars" on the level of brain development.

"biological scars" on the level of brain development, which results in a lifelong increased vulnerability to physical and psychosocial stress.

physical and psychosocial stress situations [80].

In addition, there is another important point: the fears that can be triggered by the Corona measures in schools do not relate to an aspect

which has little meaning for us humans. In the case of a fear of snakes, for example, it is

snakes, for example, does not necessarily have to be severely debilitating, because snakes are not

snakes are not a relevant part of our human life. The fears that

triggered by the Corona measures at schools, on the other hand, concern

one of the most central aspects of human life: contact with other people.

people. Human beings are genuinely social creatures; the need for closeness and good social relations is a basic human need.

social relationships is a basic human need, just like eating, drinking or sleeping [81].

sleep [81].

The measures taken at schools, such as wearing masks and keeping a distance, therefore basic social needs of children are violated. If this is compounded by the fact that children develop a fear of the other person, there is a danger that psychological disorders in the acquired in the social sphere and that the social health of children - and thus their mental development as a whole - will be permanently impaired.

In fact, there is now a great deal of empirical evidence that mental health problems in children are on the rise.

important to note here at the outset that these are not 136 causally related to the masquerade. causally attributable to the wearing of masks, but are a product of the problematic of the overall problematic situation.

The so-called COPSY study of the University Medical Centre Hamburg-Eppendorf [82], that at the time of the school closures in spring 2020, 71 per cent of the children and adolescents felt burdened by the contact restrictions. For 39 percent of the children and adolescents felt that the relationship with friends had deteriorated due to the the relationship with friends worsened due to the restricted personal contacts, which was a burden on almost all respondents. The proportion of

The proportion of children and adolescents with a reduced health-related quality of life increased from 15 to 40 percent.

from 15 to 40 per cent, and the risk of mental health problems from about 18 to 30 per cent.

Recent studies also point to the dramatic situation. The child and youth psychologist and youth psychologist Prof. Dr. Julian Schmitz from the Institute of Psychology at the University of Leipzig summarised his current findings in a recent interview as follows.

[83]:

"We do not currently see an increase in only one group of disorders, but rather a but a strong increase in mental stress from the entire spectrum, such as depression such as depression, anxiety, obsessive-compulsive disorders and behavioural disorders. At the same time

On the one hand, children and adolescents who are already suffering from a mental with a mental disorder and whose situation has often worsened considerably.

worsened. On the other hand, we also see that many children who were

were mentally healthy before the crisis, have now become mentally ill during this time - especially the

lockdowns - have become mentally ill. (...) Our research data show

clearly that the majority of mental disorders do not disappear on their own.

but that these disorders often take a chronic course and that further disorders are

and over time other disorders are added. So we cannot assume

that after the end of the pandemic the situation of children, young people and adults with mental

children, adolescents and adults with mental illnesses will simply

relaxed by itself.

The Austrian psychology professor Manuel Schabus summarises the results of his recent

current surveys in an interview thus [84]:

"FOCUS Online: Mr. Schabus, how do you assess the effects of the

months of lockdown, especially on children and young people?

They will suffer a lot from this lost year - maybe it will even be a lost year and a half or two years.

year and a half or two years - they will suffer a lot. We see this in the data of our

surveys. The main fear of 6- to 18-year-olds is that their lives will never be the same again.

as it was before the pandemic and the lockdowns. They assume that

their future will be negatively affected in the long term. For example: three quarters of the

children and young people surveyed believe that Corona will not be "over" until 2022 or 2023.

be "over" until 2023. We have to assume that the youth in their

psychological development will have a big problem with the issue of fear.

Psychotherapists tell me that the children have very diffuse fears, not

just about Corona. There are fears coming from all corners that they respond to because

they are conditioned to be afraid and to live under this pressure.

under that pressure. We have to assume that this then also leads to more

psychosomatic excesses and physical illnesses. If

stress, the immune system naturally suffers, and every infection and illness

and every infection and illness has an easier time of it. It is not 137

not be ruled out that in the coming years there will even be an increase

cancer will increase in the years to come, as this connection is scientifically well

known scientifically."

Questionable plausibility arguments

As an argument for the alleged harmlessness of wearing masks, there is a

A number of plausibility arguments can be found, which do not stand up to closer scrutiny.

A first argument that is often heard is the comparison with operating theatre doctors, who also wear masks for hours during operations.

who wear masks for hours on end during operations, without any alleged

any adverse effects. On the one hand, physiological side effects

side effects have been proven, such as a drop in oxygen saturation in the blood [63].

[63]. On the other hand, wearing masks in the classroom is not comparable to wearing masks in operating theatres.

wearing masks in operating theatres. Operating theatres are equipped with

high-powered ventilation systems that maintain positive pressure and increase

and increase the oxygen content of the room air [85]. In addition, the masks are changed

masks are changed immediately, which is not possible in the classroom due to the limited number of masks per child.

masks per child. Furthermore, operating theatre physicians are highly

highly trained in the hygienic use of masks, so that infections caused by the

germs on the mask via the hands are minimised, which is not possible with

This is impossible for primary school pupils due to their developmental psychological maturity.

Another questionable argument comes from the spokesperson of the Professional Association of Paediatricians and Adolescents (BVKJ), Dr Jakob Maske. He made the following statement to the Deutsche PresseAgentur (quoted by Die Welt [86]):

"Even small children could wear a mouthguard. 'That's not a problem at all',

explains the expert. Suppose a child really did not breathe enough

oxygen or breathe in too much CO₂, then he or she would get tired and feel

feel tired, the doctor says. In this case, the child would "take the mask off

on its own".

In view of the fact that there are no empirical studies on this, this statement is a mere hypothesis.

this statement is a mere hypothesis. When strict rules are imposed by social authorities

social authorities and there is social pressure in the class, it is not to be expected from a

psychological perspective, it is not to be expected that smaller children, in particular, will

take off their masks of their own accord in such a case.

A third questionable argument is that children themselves would not make a catastrophe of wearing a mask and would quickly

would not make a disaster of wearing a mask and would quickly get used to it. From the

children would not make a disaster of wearing masks, to conclude that children would

that children do not mind is highly negligent. Even if a

Even if a child is abused, it does not necessarily turn it into a catastrophe, because a child still

a child still lacks the rational standards of evaluation. To conclude from this that

that would be okay, would be absurd. That is precisely why our children are not yet of age, and

adults are needed to evaluate situations for children. In addition, the

side effects of the mask are not noticeable for a long time, because children simply become quieter and thus less

become quieter and therefore less noticeable. What is needed here is a very good eye

on the part of teachers and parents.

Summary evaluation¹³⁸

In summary, there is ample evidence of the range of possible harms on the

physical, psychological and social damage that can be associated with the prolonged

mask-wearing in children. On the one hand, these are substantiated by

studies on the various side effects, especially in relation to adults.

adults, and by the existing register on the side effects of mask wearing by children.

wearing masks by children. Furthermore, from a psychological perspective, there is

fears that a longer period of compulsory wearing of masks in schools could have very

development of children could be associated with a prolonged compulsory wearing of masks in schools.

development, which cannot be clearly proven at present, but which, according to various

psychological theories, it is highly probable that this will occur.

It is particularly problematic that, despite the numerous side effects to be feared, there has not been a single randomised controlled study.

there is not a single randomised controlled trial in which the side effects of the long-lasting

side effects of prolonged mask-wearing in children.

Before compulsory measures are even prescribed for millions of children,

it would be imperative from a medical ethics perspective to examine possible risks before prescribing the

risks before prescribing the measure and to exclude them on the basis of evidence, or at least to

quantify the risk and weigh it against the benefit. It is also problematic problematic is that, in view of the existing evidence for numerous potential side effects, these are not mentioned in the recommendations of the RKI or in the S3-guideline. guideline nor in the corresponding government statements.

3.

3. is there any risk of infection at all that can be reduced by wearing face masks? (or other measures)?

This question has already been answered in the course of answering question 1 (cf. Section "The extent of the reduction of the risk of infection by means of wearing masks at schools" on p. 10 ff).

4 Can the risk of infection be reduced by observing distance regulations? especially among children?

A recently published study is relevant to this question [87]. There, on the basis of a very large sample (537,336 pupils and 99,390 school staff) and a large period of time a large period of time (24 September to 27 January) to investigate the extent to which it makes a difference whether schools were required to have a three-foot or six-foot clearance.

The results show that the size of the distance did not make a difference to either student or teacher infections.

infections, nor did it make a difference to teacher infections. Accordingly, at least no effect of further increasing the distance, at least from a distance of 90 cm. It should be noted

It should be noted that from secondary school onwards, masks were compulsory at all the schools studied.

At primary level, the wearing of masks was compulsory in 70 per cent of the cases. Also

The results of this extensive study also confirm once again that infections among school school staff than among the students, which is further convincing evidence that the further convincing evidence that pupils are at a lower risk of infection.¹³⁹

risk of infection.¹³⁹

5 Children may even provide a "protective function" against the spread of SARS-C SARS-CoV-2 coronavirus, in the sense that they are more likely to slow down the spread of the spread of the virus and protect against severe covid-19 disease?

In order to answer this question, extensive studies are first presented which

show that the risk of contracting severe COVID-19 is lower when adults have a lot of contact with children.

have a lot of contact with children. This is followed by a discussion of recent findings that show, that children - contrary to initial assumptions - have a lower viral load, which reduces the risk of which, according to recent findings, can reduce the risk of infection and the resulting severity of the disease. Finally, the findings from sick leaves are critically examined.

that occupational groups involved in the upbringing and care of children are the most frequently children were the most likely to be on sick leave due to COVID-19.

This is often used as an argument that children pose a particular risk.

The lower risk of contracting severe COVID-19 from close contact with children. disease.

In one of the most comprehensive studies to date on the factors influencing the risk of of developing severe COVID-19 disease, all the corona cases in Scotland were analysed.

cases that have occurred in Scotland [88]. This showed that teachers (no

(no mask-wearing of pupils up to the age of about 15 years) had a 64 per cent reduced risk of developing severe

a 64 per cent reduced risk of severe COVID-19 compared to other professions (rate ratio of 0.36, see (rate ratio of 0.36, 95% CI 0.19 to 0.69). The study also showed that the risk of

of severe COVID-19 in adults was reduced by 28 per cent if children lived in the same

children lived in the same household (rate ratio of 0.72, 95% CI 0.63 to 0.82). This effect of

children was seen even when adults were in a high-risk group (e.g. cancer, severe cancer, severe asthma and other severe chronic respiratory diseases

respiratory diseases, hypertension, immunosuppression, etc.). Comparable findings

Sweden, where the risk of severe illness for teachers was 57 per cent higher than for other occupational groups.

was reduced by 57 per cent compared to other occupational groups (relative risk of 0.43, 95% CI, 0.28 to 0.68) [89].

The authors of the study suggest that this may be due to the fact that the contact with children increases pre-existing immune protection due to cross-reactions with other coronaviruses.

Coronaviruses. 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 it can now be considered that the viral load in children is lower than in adults.

adults. Initially, based on a study by a team of researchers led by Christian Drosten, the Christian Drosten's team, it was assumed that children had the same viral load as adults and that adults and that children posed a similar danger. However

study contained what is actually a very classic and fundamental methodological 140

as, for example, the renowned statistician David Spiegelhalter of the University of Cambridge has shown [90].

of Cambridge has pointed out [90].

Due to the small sample size in childhood and the division into numerous age age groups in adulthood and the subsequent correction for multiple testing, the power of the the power of the study - that is, the likelihood of finding an existing difference between the child and adult groups - is so low that the study is practically that the study could not in principle have statistically proven any differences.

in principle. To conclude the null hypothesis in the case of a non-significant effect is methodologically absolutely inadmissible in the case of low power. This is actually a matter of basic statistical knowledge (the so-called "second kind of error", see e.g. [91]).

As David Spiegelhalter interestingly demonstrates, the study by the research team of Christian Drosten's research team actually shows - if it had been evaluated correctly - that the the viral load is lower in children. Descriptively expressed, in the study the

0-10 year old children is only 27 percent of the viral load of adults over 20 years of age.

years (this is the actual comparison group, the artificial division in the

in the article into 10-year increments is not appropriate in view of the actual

research question - viral load in children versus adults - is difficult to understand, because

such a division only substantially reduces the power). In fact, this is supported by a

recently published preprint study with much larger samples (2654 children and adolescents) than in the

adolescents) than in the study of the research team around Christian Drosten (117 children and adolescents) [92].

adolescents) [92].

As recent studies show [93], the risk of infection decreases with the viral load of the person from whom the infection originates.

the risk of severe COVID-19 disease decreases. Thus the

lower viral load in children could have a protective function against the

from developing a more severe COVID-19 disease. However, it should be noted that

the direct scientific evidence that the lower viral load has the positive effect of frequent

the positive effect of frequent contact with children on the lower severity of the disease has not yet been

has not yet been established.

Frequent COVID-19 diagnoses in occupational groups involved in childcare

Finally, it is important to note a misleading portrayal in the media.

At the end of 2020, the Wissenschaftliches Institut der AOK (Scientific Institute of the AOK) published the results

analysis [94] of which occupational groups were most frequently diagnosed with "COVID-19" from March to October.

with the diagnosis "COVID-19". Surprisingly, in first place were

occupational groups involved in the education and care of children. In the

media concluded that educators were the most likely to be diagnosed with COVID-19.

most likely to contract COVID-19.

A closer look at the study, however, reveals that this is a misleading portrayal.

With regard to the diagnosis "COVID-19", there are two different diagnosis codes [95]:

One is a diagnosis confirmed by a positive PCR test (diagnosis code

U07.1!) and once a mere suspected diagnosis without confirmation by a positive

PCR test (diagnosis code U07.2!). Since persons with a mere suspected diagnosis do not have a 141

positive SARS-CoV-2 test result, it is very likely that such cases are in fact only a harmless case.

cases are in fact just a harmless cold.

It is a common practice in day-care centres for teachers to always immediately contact

symptoms of a cold and then have to take sick leave until they receive the test results.

and then have to go on sick leave until they receive the test results. On the sick note, the suspected diagnosis

diagnosis U07.2! is noted on the sick note. If the test result then shows that in reality there is no

SARS-CoV-2 infection is not actually present, the initial suspected diagnosis of

U07.1! is actually a false COVID-19 diagnosis.

The problem with the AOK's analysis is that it does not distinguish whether it is a "COVID-19 diagnosis" on a sick note is possibly only a mere suspected diagnosis.

only a suspected diagnosis. Thus, it could be that people working with children are simply more likely to be tested for a suspected diagnosis (diagnosis U07.2!), but are in fact not but in reality do not get COVID-19 more often (U07.1!).

This is indeed confirmed by a more detailed analysis of the AOK data, which was recently published [96].

recently [96]. According to this data, professions in child rearing and child care are in the lower in terms of the total number of "COVID-19" diagnoses received. However

However, 48.0 per cent of the cases are merely suspected diagnoses. Occupations in geriatric care or health care and nursing are in first place in terms of the total number of "COVID-19" diagnoses received.

COVID-19" diagnoses are only in second and third place. However, only 31.8 and 28.9 of the 31.8 and 28.9 per cent, respectively, are merely suspected diagnoses. With regard to actually confirmed

COVID-19 diseases, on the other hand, the occupational groups in geriatric care (22.9 percent (22.9 per cent more cases) or health care and nursing (25.7 per cent more cases).

occupational groups in child education and child care. In reality

In reality, educators are much less likely to contract COVID-19 than workers in elder care, health care and nursing,

health care and nursing.

Summary assessment

In summary, there is indeed strong evidence from very large scientific studies that frequent scientific studies that frequent contact with children may indeed have a protective protective function against the development of severe COVID-19 disease.

disease. In particular, an extensive study now shows that children do indeed have a lower viral load than adults.

lower viral load than adults, which could be one of the explanations for this protective function.

6 What is the methodological level and, if applicable, what are the methodological shortcomings of existing studies on the occurrence of infections?

existing studies on the incidence of infections in schools and on the efficacy of

of measures such as wearing masks and keeping a distance in schools?

This question has already been answered in the course of answering question 1 (see section "Evaluation scheme").

section "Evaluation scheme to classify the quality of evidence from studies" on p. 1

ff). 142

Literature

- [1] <https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-019-4109-x>
- [2] <https://www.medrxiv.org/content/10.1101/2020.12.06.20244780v2>
- [3] https://advance.sagepub.com/articles/preprint/Comment_on_Dehting_et_al_Science_15_May_2020_eabb9789_Inferred_change_points_in_the_spread_of_COVID19_reveals_the_effectiveness_of_interventions_/12362645
- [4] https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/PraeventionSchulen.html
- [5] <https://www.bmbf.de/de/die-s3-leitlinie-als-handlungsempfehlung-fuer-schulen13722.html>
- [6] [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30985-3/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30985-3/fulltext)
- [7] <https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-2019-ncov-outbreak>
- [8] https://www.who.int/publications/i/item/WHO-2019-nCoV-IPC_Masks-Children-2020.1
- [9] <https://www.medrxiv.org/content/10.1101/2020.03.30.20047217v2>
- [10] https://wwwnc.cdc.gov/eid/article/26/5/19-0994_article
- [11] <https://reuters.screenocean.com/record/1461268>
- [12] <https://www.acpjournals.org/doi/10.7326/m20-6817>
- [13] https://www.cochrane.org/CD006207/ARI_do-physical-measures-such-hand-washing-or-wearing-masks-stop-or-slow-down-spread-respiratory-viruses
- [14] <https://bmjopen.bmj.com/content/5/4/e006577>
- [15] [https://www.cell.com/fulltext/S0896-6273\(01\)00583-9](https://www.cell.com/fulltext/S0896-6273(01)00583-9)
- [16] <https://jamanetwork.com/journals/jamapediatrics/fullarticle/2771181>
- [17] <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774102>
- [18] <https://pubmed.ncbi.nlm.nih.gov/33484843/>
- [19] [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00425-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00425-6/fulltext)
- [20] <https://www.bmbwf.gv.at/Themen/Forschung/Aktuelles/BeAntiGenT.html>
- [21] [https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642\(20\)30251-0/fulltext](https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(20)30251-0/fulltext)

- [22] <https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2020.26.1.2002011?crawler=true>
- [23] [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31142-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31142-9/fulltext)
- [24] http://ars.rki.de/Docs/SARS_CoV2/Wochenberichte/20210323_wochenbericht.pdf
- [25] https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Infografik_Antigentest_PDF.pdf?__blob=publicationFile
- [26] https://influenza.rki.de/Wochenberichte/2020_2021/2021-12.pdf
- [27] https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Massnahmen_Verdachtsfall_Infographic_DINA3.pdf?__blob=publicationFile
- [28] <https://www.medrxiv.org/content/10.1101/2021.01.13.21249721v1>
- [29] <https://virological.org/t/tracking-sars-cov-2-voc-202012-01-lineage-b-1-1-7-dissemination-in-portugal-insights-from-nationwide-rt-pcr-spike-gene-drop-out-data/600>
- [30] <https://dgpi.de/stellungnahme-dgpi-dgkh-kinder-in-der-covid-19-pandemie-2020-02-05/>
- [31] <https://pubmed.ncbi.nlm.nih.gov/33619199/>
- [32] <https://journals.co.za/doi/10.10520/EJC-c3ca4ee66>
- [33] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7273023/143>
- [34] <https://onlinelibrary.wiley.com/doi/10.1111/ced.14376>
- [35] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7448728/>
- [36] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7546964/>
- [37] <https://www.medrxiv.org/content/10.1101/2020.05.23.20111302v2>
- [38] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5964546/>
- [39] <https://link.springer.com/article/10.1007/s10163-020-01123-1>
- [40] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7680614/#b0130>
- [41] <https://www.bmj.com/content/370/bmj.m3021/rr-6>
- [42] <https://pubmed.ncbi.nlm.nih.gov/32232837/>
- [43] <https://www.springermedizin.de/effects-of-wearing-n95-and-surgical-facemasks-onheart-ratether/8473730>
- [44] https://www.nieuwsblad.be/cnt/dmf20200904_95874991
- [45] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3437281/>
- [46] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3959229/>
- [47] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6043392/>

- [48] <https://pubmed.ncbi.nlm.nih.gov/26680569/>
- [49] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4555996/>
- [50] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3235257/>
- [51] <https://www.sciencedirect.com/science/article/pii/S0306453018312137>
- [52] <https://pubmed.ncbi.nlm.nih.gov/21883162/>
- [53] <https://pubmed.ncbi.nlm.nih.gov/31174162/>
- [54] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5289034/>
- [55] <https://www.nytimes.com/2020/08/24/well/family/young-adults-mental-healthpandemic.html>
- [56] <https://academic.oup.com/aje/article/184/3/199/2195463>
- [57] <https://pubmed.ncbi.nlm.nih.gov/32045472/>
- [58] <https://academic.oup.com/aje/article/168/5/481/92689>
- [59] <https://pubmed.ncbi.nlm.nih.gov/32340216/>
- [60] <https://link.springer.com/article/10.1007/s00112-021-01133-9>
- [61] <https://www.medrxiv.org/content/10.1101/2021.02.03.21251056v1>
- [62] <https://www.aerzteblatt.de/archiv/215610/Einfluss-gaengiger-Gesichtsmasken-aufphysiologische-Parameter-und-Belastungsempfinden-unter-arbeitstypischerkoerperlicher-Anstrengung>
- [63] <https://link.springer.com/article/10.1007/s00392-020-01704-y>
- [64] <https://pubmed.ncbi.nlm.nih.gov/18500410/>
- [65] <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0247414>
- [66] <https://www.aerzteblatt.de/nachrichten/112344/Nicht-fuer-jeden-ist-das-Tragen-einerMaske-unbedenklich>
- [67] <https://www.atsjournals.org/doi/abs/10.1513/AnnalsATS.202007-812RL>
- [68] <https://onlinelibrary.wiley.com/doi/full/10.1111/apa.15784>
- [69] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6908682/>
- [70] <https://in.dental-tribune.com/news/mask-mouth-a-novel-threat-to-oral-health-in-the-covidera/>
- [71] <https://link.springer.com/article/10.1007/s00266-020-01833-9>
- [72] <https://www.sciencedirect.com/science/article/pii/S2214031X18300809144>
- [73] <https://www.fr.de/politik/corona-maske-ffp2-mikroplastik-muell-meer-gesundheit90190572.html>
- [74] <https://www.daab.de/blog/2021/01/corona-pandemie-schadstoffe-in-schutzmasken/>
- [75] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7417296/>

- [76] <https://www.gesetze-bayern.de/Content/Document/BayKiBiG>
- [77] <https://www.tagespflege.bayern.de/gesetz/verbot-gesichtsverhuellung/index.php>
- [78] <https://pubmed.ncbi.nlm.nih.gov/28054912/>
- [79] <https://sz.de/1.5097188>
- [80] <https://pubmed.ncbi.nlm.nih.gov/11392867/>
- [81] https://www.researchgate.net/publication/275566849_Die_Entwicklung_psychischer_Sicherheit_in_Bindungen_-_Ergebnisse_und_Folgerungen_fur_die_Therapie
- [82] <https://www.aerzteblatt.de/archiv/216647/Psychische-Gesundheit-und-Lebensqualitaetvon-Kindern-und-Jugendlichen-waehrend-der-COVID-19-Pandemie-Ergebnisse-derCOPSY-Studie>
- [83] <https://www.jugendhilfeportal.de/fokus/gesundheit/artikel/psychische-belastungenhaben-deutlich-zugenommen/>
- [84] https://www.focus.de/corona-virus/massive-probleme-fuer-kinder-und-jugendliche-dasschlimmste-kommt-erst-noch-psychologe-warnt-vor-jahrelangen-lockdownfolgen_id_13092846.html
- [85] <https://www.management-krankenhaus.de/news/belueftung-von-op-reinraeumen>
- [86] <https://www.welt.de/wissenschaft/article217116574/Coronavirus-AngeblicheTodesfaelle-Ist-die-Maske-gefaehrlich-fuer-Kinder.html>
- [87] <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab230/6167856>
- [88] <https://www.medrxiv.org/content/10.1101/2021.03.02.21252734v1.full>
- [89] <https://www.nejm.org/doi/full/10.1056/NEJMc2026670>
- [90] <https://d-spiegel.medium.com/is-sars-cov-2-viral-load-lower-in-young-children-thanadults-8b4116d28353>
- [91] <https://support.minitab.com/en-us/minitab-express/1/help-and-how-to/basicstatistics/inference/supporting-topics/basics/type-i-and-type-ii-error/>
- [92] <https://www.medrxiv.org/content/10.1101/2021.01.15.21249691v2>
- [93] [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30985-3/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30985-3/fulltext)
- [94] <https://www.wido.de/news-events/aktuelles/2020/krankschreibungen-wegen-covid-19/>
- [95] <https://www.dimdi.de/dynamic/de/klassifikationen/icd/icd-10-gm/kodierfragen/>
- [96] <https://www.wido.de/news-events/aktuelles/2021/krankschreibungen-aufgrund-voncovid-19/>

X. Expert opinion Prof. Dr. rer. biol. hum. Ulrike Kämmerer

Prof. Dr. rer. biol. hum. Ulrike Kämmerer represents at the University Hospital Würzburg,

Women's Hospital, specialising in human biology, immunology and cell biology.145

The expert has provided her expert opinion on molecular biology, which is inserted here in full, as follows

inserted in full here, as follows:

On the evidentiary question "What is the significance for the detectability of an infection with the SARS-CoV-2 coronavirus infection are provided by the RT-qPCR test and the rapid tests currently used?

rapid tests".

1. nucleic acid detection by RT-qPCR test

Reverse transcriptase-quantitative polymerase chain reaction (RT-qPCR) tests are used as a diagnostic tool for active infection with SARS-CoV-2 for numerous reasons.

for a number of reasons.

1.1 Explanation of terms/basics

In a polymerase chain reaction (PCR), the enzyme polymerase is used to produce a short (usually 100-1000 bases) piece of deoxyribonucleic acid.

deoxyribonucleic acid (DNA) is amplified. The piece of DNA to be amplified is

The piece of DNA to be amplified is narrowed down with the help of two very short single-stranded DNA segments, the "primers".

These primers usually consist of a defined sequence of 18-25 nucleic acid bases (the nucleic acid bases (the primer sequence), which specifically match the regions on the DNA that contain the

which flank the section to be amplified. To ensure the specificity of the PCR

specificity of the PCR, these primers must explicitly match only this flanking region and no

and not to any other region of a DNA. With the help of large gene databases and

corresponding software programmes (e.g. Primer-Blast

<https://www.ncbi.nlm.nih.gov/tools/primer-blast/>), these primers can be designed in a highly

can be designed in a highly specific way. Specialised companies then use the primer sequences sent in to

the molecular chains from the primer sequences sent in and delivered to the PCR laboratory or the

manufacturer of PCR kits. These primers then have to be tested with valid positive and negative

and negative controls under various experimental conditions and optimised for use.

optimised in use. This ensures that the primer pair used exclusively

DNA is detected and amplified with the primer pair used, and that no other similar

similar DNA segments.

Once the primers have been found and are specific, the DNA to be amplified can be

DNA to be amplified can be mixed with the primer pair, various auxiliary chemicals and the enzyme enzyme polymerase and the chain reaction can be started.

PCR procedure: This runs in cyclic repetitions of the following individual steps

1:

1. the mixture is boiled up at over 90°C (denatured). This causes the DNA strands, which are usually present as a double strand, into single strands in order to the subsequent attachment of the primers. 2.

2 During the subsequent cooling down to the so-called "annealing temperature", the primers can attach to their

primers can attach themselves to their matching regions on the separated DNA strands. The

The binding of the primers, the annealing, only takes place in a narrowly limited temperature range, the so-called melting temperature. This depends primarily on the base composition of the primers and therefore their

primers and therefore their sequence will ideally always be chosen so that both primers have the same melting temperature.

primers have the same melting temperature of approx. 60°C. The attached primers

form the starting point for the polymerase. 3.

3 This polymerase, starting from the primers, completes the single-stranded DNA that is

the single-stranded DNA that is present as a result of the heating into a matching double strand (elongation).

usually at about 72°C. 146

Due to the position of the two primers on the flanking sides of the sought DNA section, the elongation reactions on the single strands are in opposite directions, since the polymerase only works in one direction.

polymerase only works in one direction. At the end of this step, the original double-stranded two identical double-stranded DNA molecules have been created from the original double-stranded DNA.

which are separated by boiling and then, with the help of primer addition and the polymerase and the polymerase into 4 identical DNA molecules, and so on. Each PCR cycle consisting of boiling, annealing and elongation causes a doubling of the DNA section sought, so that the amplification takes place in the logarithm of 2 and thus very quickly produces an extremely high number of copies of the original DNA molecule.

an extremely high number of copies of the original starting material is available.

Thus, after 10 PCR cycles, $2^{10} = 1,024$ DNA copies are obtained from one DNA strand.

20 cycles more than 1 million (1,048,576) and 30 cycles more than 1 billion (1,073,741).

(1,073,741,824) copies.

In the quantitative PCR (qPCR) technique, which is currently mainly used worldwide for the genomic RNA of SARS-CoV-2, uses a third short piece of DNA, similar to the

short piece of DNA, similar to the two primers, which can bind appropriately in the middle of the DNA section sought, the "probe". Unlike the two primers, this

probe is still connected to two molecules, a fluorescent dye at one end and another molecule (quencher) at the other.

another molecule (quencher), which can prevent the fluorescence from being emitted, as long as both

fluorescence as long as both are on the sample at the same time (i.e. in the immediate vicinity of each other).

sample. During the elongation step, the polymerase now degrades this probe. This separates the the quencher is separated and the fluorescence molecule can now emit its colour signal.

This colour signal is detected and measured in the PCR device (thermocycler).

measured. With each PCR cycle, more and more fluorescence signals are generated according to the increasing number of copies.

fluorescence signals are released, the probe "glows" more and more. And the

curve of the colour signal intensity rises with each cycle. At a certain value, the curve

the curve then exceeds 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 rises (lower CT), the more initial copies of the sought

DNA was present in the PCR set. Since neither the primers nor the enzyme

enzyme always work 100% specifically, a fraction of non-specific DNA is also copied in each

unspecific DNA is also copied. And the more cycles the PCR runs through, the greater the risk that these

that even these few non-specific reactions will exceed the threshold value.

threshold value. Therefore, from a CT value of 40 onwards, it is most likely that a false positive signal is

positive signal due to non-specific starting materials. A

reliable PCR should therefore not require more than 30-35 cycles to generate a clear "positive" signal.

positive" signal; in the case of active infections with the desired viruses, a sufficient number of sufficient number of cycles is 25-30 (see also point 3.2.).

The reverse transcriptase reaction (RT) is required if the starting nucleic acid to be amplified is not available as DNA.

nucleic acid to be amplified is not present as DNA but as ribonucleic acid (RNA), as is the case with SARS-CoV-2.

as is the case with SARS-CoV-2 as an RNA virus. Since only DNA can be amplified in PCR, RNA must be converted into DNA. This is done with the help of the enzyme "reverse transcriptase", which creates a complementary copying strand of DNA from RNA. This DNA, which then serves as the starting material for the PCR.

In order to be able to evaluate the reliability of a result obtained by RT-qPCR or even just PCR, the results are

evaluated. Results obtained by RT-qPCR or PCR alone, diluted correct target genes (e.g. RNA from the sought virus) and very similar, but not sought target genes (e.g. closely related viruses) to evaluate the sensitivity and specificity of the test system used.

The sensitivity indicates how sensitively the test can detect even the smallest amounts of the target gene, while the specificity describes how reliably the test excludes the possibility that other, closely related genes may also lead to a positive result (false positive). The higher the specificity, the more reliable it is to exclude the possibility that the PCR system itself can produce false positive results.

However, false positive events caused by laboratory contamination with target genes are still possible. Laboratory contamination with target genes, contamination of test chemicals and contamination directly during sample collection. These contamination-related false positive results can be eliminated by rigorous quality assurance and standard operating procedures (SOPs), the use of specially trained personnel as well as permanent external control in the form of interlaboratory comparisons.

1.2 Basic information on diagnostic significance

The inventor of the PCR test, Nobel Prize winner Kary Mullis, who died in August 2019, repeatedly pointed out that his test alone is suitable for detecting a molecule that is otherwise invisible to the human eye (deoxyribonucleic acid, DNA) or a fragment of DNA through amplification. Not, however, to make a statement as to whether what has been made visible is dangerous or

makes you ill.

In particular, a PCR test - even if it is carried out correctly - cannot give any whether a person is infected with an active pathogen or not.

This is because the test cannot distinguish between "dead" matter*, such as a harmless genome fragment as a remnant of the body's own immune system's fight against a immune system's fight against a cold or flu (such genome fragments are still found many months after the immune system has "taken care" of the problem), and "living" matter, i.e. a "fresh" virus capable of reproducing.

For example, PCR is also used in forensics to identify residues from hair remains or other trace materials by means of PCR.

DNA from hair residues or other trace materials by means of PCR in such a way that the the genetic origin of the perpetrator(s) can be identified ("genetic fingerprint").

Even if the PCR, including all preparatory steps (PCR design and establishment of the (PCR design and establishment, sample collection, preparation and PCR performance) everything is done

is done "correctly" and the test is positive, i.e.: detects a genome sequence which is also 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 has been infected with a replicating SARS-CoV-2 virus.

infected with a replicating SARS-CoV-2 and therefore infectious = dangerous to others.

dangerous to others.

Rather, for the determination of an active infection with SARS-CoV-2, further, and specifically methods such as the isolation of viruses that are capable of replicating (gold standard).

viruses (gold standard).

1.3 Factors influencing the reliability of the PCR test

In fact, however, the results of a PCR test depend on a number of parameters that, on the one hand which, on the one hand, cause considerable uncertainty and, on the other hand, can be deliberately manipulated in such a way that many or few (apparently) positive results are obtained.

are obtained.

1.3.1 Number of independent target genes ("targets")¹⁴⁸

In the protocol originally published by the WHO on 13.01.2020 "Diagnostic detection of Wuhan coronavirus 2019 by real-time PCR" ().

(<https://www.who.int/docs/default-source/coronaviruse/wuhan-virus-assayv1991527e5122341d99287a1b17c111902.pdf>), the sequence of PCR detections of three independent

three independent partial genes of the virus later renamed SARS-CoV-2.

The sequence referred to the E gene, the RdRp gene and then the N gene. Already on

17.01.2020, a change was made by the WHO with the protocol "Diagnostic detection

of 2019-nCoV by real time PCR" (https://www.who.int/docs/defaultsource/coronaviruse/protocol-v2-1.pdf?sfvrsn=a9ef618c_2) in which the N-gene was removed as a detection

was removed and only 2 targets were recommended instead of the original 3 targets.

were recommended. On 02.03.2020, a new updated test protocol of 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-laboratory2020.4-eng.pdf?sequence=1&isAllowed=y>), it was 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 switched to analysing only 1 target on a large scale,

whereupon many laboratories specialised only in the E-gene introduced as the first target as a valid

as the valid PCR, as explicitly described by the Augsburg laboratory on 03.04.

available in the internet cache: https://www.oder-spree-piraten.de/wpcontent/uploads/2020/05/Ge%C3%A4ndertes-Befundlayout-der-SARS-CoV2-PCRErgebnisse-_Labor-Augsburg-MVZ-GmbH.pdf

The outstanding significance of the number of independent target genes analysed by PCR results from the following calculation

target genes analysed by PCR results from the following calculation:

The three target genes originally specified in the WHO protocol for the detection of SARS-CoV-2 are

targets E, RdRp and N-gene were rapidly used in many laboratory and commercial test systems.

test systems. An interlaboratory comparison by the Instand e.V. Institute

(<https://coronaausschuss.de/wp-content/uploads/2020/07/Instand-Ringversuch-Virusgenom-NachweisSARS-CoV-2.pdf>) showed a mean specificity of for these genes:

Target gene

of the

SARSCoV-2

genome

Number

reviewed

tests

Specificity

only

Cell culture

(without

virus RNA)

Specificity

with

related

Coronavirus

(HCoV 229E)

% Mean

Specificity

absolute

Mean

error rate

(1-abs.

Spec.)

E-gene 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, even if there were no genuinely infected person due to the mean error rate:

For an E-only genetic test: $100,000 \times 0.0269 = 2690$ false

positive

With E and RdRp test in sequence: $100,000 \times (0.0269 \times 0.0577) = 155$ false

positive

For all three genes (E, RdRp, N): $100,000 \times (0.0269 \times 0.0577 \times 0.0692) = 10$ false

positive

This means that the WHO's requirement to successively reduce the number of target genes to be tested from

of SARS-CoV-2 to be tested from 3 to 1, resulted in an increase in the number of false positives 149 in the above example from 10 with 3 genes to almost 3000 with only the E gene per 100,000.

E gene per 100,000 tests carried out. If the 100,000 tests carried out

100,000 citizens of a town or district within 7 days, the result would be

the question of the target genes used alone would result in the following

with regard to the "7-day incidence", there would be a difference of 10 versus 155 versus 2690

and, depending on this, the severity of the restrictions on citizens' liberty taken.

Evaluation: The calculation example also shows how, by "playing by the rules" in terms of

targets to be detected for the laboratories, the daily case numbers can be manipulated.

can be manipulated. Given the immense impact on political decisions,

which are determined by the absolute numbers of positive tests and the "7-day incidence" derived from them, the WHO's (and also the RKI's) stipulation to reduce the number of

target genes was clearly suitable for artificially inflating the "pandemic" by a factor of

by a factor of 300.

This is an evidence-free approach that, on the one hand, imposes enormous personal

quarantine/isolation that the falsely "positively tested" persons must suffer.

quarantine/isolation that the falsely "tested positive" persons have to suffer, and on the other hand the

the enormous social and economic restrictions and damages.

and damage.

If the correct target number of three or even better (as e.g. in

Thailand) up to 6 genes had been used for PCR analysis, the rate of positive tests and thus the

positive tests and thus the "7-day incidence" would have been reduced almost completely to zero.

1.3.2 Number of cycles performed (CT value)

In addition to the number of target genes detected, especially in the case of only one or a maximum of

2 genes, the number of cycles of amplification in the qPCR up to the evaluation "positive" and the resulting

"positive" and the resulting CT value represent a decisive adjustment screw. The

value of a sample in a qPCR, the higher the initial amount of DNA in the sample.

of DNA in the sample. This correlates under standardised conditions with (in the case of

the initial amount of viruses, the so-called viral load, which is ideally expressed as the "number of viral copies" per ml of sample.

viral copies" per ml of sample. This viral load also correlates in the correlates in the case of SARS-CoV-2 with the cultivability of infectious viruses in cell culture, as already

Drosten was already published in March 2020. (Figure 1e in Wölfel et al., <https://doi.org/10.1038/s41586-020-2196-x>) Here, a minimum quantity of 10⁶ RNA copies/ml was required in order to be able to grow viruses from the sample accordingly, whereas

RT-qPCR from the original protocol (Corman V et al., 10.2807/1560-7917.ES.2020.25.3.2000045) already detects viruses at approx. 4 copies per sample (5µl corresponding to

10³ copies/ml), i.e. already a factor of 1000 earlier than in a sample with actual than in a sample with an actual infectious virus load.

Even commercial PCR test systems, so-called kits, sometimes have detection limits of less than detection limits of less than 10 copies/reaction, such as kits from the company TIB Molbiol (https://www.roche-as.es/lm_pdf/MDx_53-0777_96_Wuhan-Rgene_V200204_09155376001%20%282%29.pdf).

A technical distinction must be made here between a "colonisation" of the pharynx with a few individual

with a few viruses that do not cause an infection and a real "infection".

"infection". The latter is accompanied by viruses that are able to multiply, which then a) lead to a symptomatic

symptomatic illness and b) infectivity, i.e. the ability to infect other people.

infecting other people.

Christian Drosten already mentioned this aspect in 2014 in an interview in Wirtschaftswoche (<https://www.wiwo.de/technologie/forschung/virologe-drosten-im-gespraech-2014-die-whokann-nur-empfehlungen-aussprechen/9903228-2.html>) in connection with MERS 150.

"Yes, but the method (note: PCR is meant) is so sensitive,

that it can detect a single hereditary molecule of this virus. If such a pathogen

a nurse's nasal mucosa for just one day (note: PCR is so sensitive that it can detect a single nasal mucosa for a day (note: this would be the "colonisation" mentioned above) without her

or notices anything else about it, then she is suddenly a case of Mers. Where

where previously terminally ill people were reported, now suddenly mild cases and people who are

who are actually perfectly healthy are now included in the reporting statistics." [...] "Because what is initially

of interest are the real cases (note: these are the 'infected'). Whether symptomless

or mildly infected hospital workers are really virus carriers, I think is questionable. Even more questionable is whether they can pass the virus on to others."

The latter is a crucial statement also in relation to the very closely related to MERS closely related SARS-CoV-2 viruses. But it is precisely this point of virus transmission (and thus driving the pandemic) is the justification for the intervening measures like 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, which can be read at the link (<https://doi.org/10.1093/cid/ciaa638>), came to the conclusion as early as May

2020 came to the conclusion that above a CT value of 24, no reproducible virus was found.

virus was found above a CT value of 24 - this means that the attempt to test positive from positive test at a higher CT value, to cultivate viruses that are capable of reproducing.

viruses from smear samples that only tested positive at a higher CT value failed. According to this study, above a CT value of 24, the amount of detectable viral

the amount of detectable viral genetic material is so small that the positive test can no longer be interpreted as an active infection.

could no longer be interpreted in the sense of an active infection. A large study by Jaffar

et al. (Doi 10.1093/cid/ciaa1491) set the limit for the cultivability of SARS-CoV-2 from patient samples at a CT value of

patient sample material at a CT value of 30 .

In his NDR podcast of 16.02.2021, C. Drosten explicitly stated that an increase

of the CT from 25-27 over the limit of 28 means that persons from whom these smears were obtained with the higher CT are no longer infectious. "and again

there is again a Ct shift from 25 to 27 approximately, 27, 28. And that is

And that is a range where, in our estimation, the infectivity has really come to an end. If you patient sample and you would ask whether the patient is still infectious, I would say

I would say: No, this is no longer an infectious area. You can

correlate" page 4 (top right column in:

<https://www.ndr.de/nachrichten/info/coronaskript270.pdf>)

Unanimous scientific opinion (including that of Dr. Fauci of the US CDC, but also

a number of scientists 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 that are only detected from a cycle of 35 onwards, have no scientific (i.e.: not evidence-based) basis. The RT-qPCR

RT-qPCR test for the detection of SARS-CoV-2, which was propagated worldwide with the help of the WHO, was (and it

(and following it, all other tests based on it as a blueprint) was set to 45 cycles without a without defining a CT value for "positive".

Also as early as May 2020, the National Centre for Infectious Disease in Singapore issued issued a position paper

(<https://www.ncid.sg/Documents/Period%20of%20Infectivity%20Position%20Statementv2.pdf>), which points out that¹⁵¹

1. it is important that the detection of viral RNA by PCR does not imply either infectivity, nor a replicable virus ("it is important to note that viral RNA detection by PCR does not equate to infectiousness or viable virus").

2. the cycle threshold value (CT) of the PCR, as a surrogate marker for viral RNA content viral RNA content from a CT of 30, but not the presence of replicating viruses. viral RNA, but no longer the presence of replicable viruses, and the affected persons 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 multicentre cohort of 73 COVID-19 patients, when the Ct value was 30 or higher (i.e. when viral load is low), no viable virus (based on being able to culture the virus) has been found."

The RKI also explains on its homepage as of 11.08.2020

(https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Vorl_Testung_nCoV.html#doc13490982bodyText4) "Initial results from diagnostics at the RKI show that the

loss of cultivability in cell culture was accompanied by an RNA quantity of <250 copies/5 µL RNA determined by real-time PCR (note: is RTqPCR). This RNA concentration corresponded to a Ct value >30 in the test system used."

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 another recent study from Frankfurt (<https://www.mdpi.com/2077-0383/10/2/328>) showed that out of 64 RT-qPCR positive patient samples (one gene tested), only 33 (=52%) could be cultured for virus. These infectious samples were already positive up to a mean CT value of 26 (Supplementary Figure 1) whereas no virus could be cultured from the samples with a higher CT.

In the Instand e.V. ring trial (http://www.finddx.org/covid-19/pipeline/?section=molecularassays#diag_tab), see also next point, the enormous range of CT values even with highly standardised samples between the different laboratories and also with regard to the different target genes becomes apparent.

also with regard to the different target genes. Here, for example, the CT varies for the same defined diluted sample of SARS-CoV-2 (sample number 340061) for the WHO-recommended genes varies between 15-40 (E gene), 20-40.7 (N gene) and 19.5-42.8 (RdRp gene).

This impressively demonstrates an extreme lack of test standardisation within the involved (and certified) laboratories.

Against this background, it is disconcerting that RT-qPCR is still considered the "gold standard" by the RKI.

"standard" without defining the exact validations and external certification conditions (and without certification conditions (and without these being fully monitored by the authorities). apparently fully monitored by the authorities).

Assessment:

In general, RT-qPCR cannot detect intact, interrogatable (infectious) viruses, not even the complete intact virus.

viruses, not even the complete intact virus genome, but only nucleic acid of the nucleic acid of the sought section. It is generally possible, in the case of well-adjusted and and correctly performed PCR tests by validation with a parallel virus

It is generally possible to define a threshold value (CT) above which a positive PCR signal no longer correlates with viruses that can be interrogated. This has been well practised in the routine in the monitoring of blood products for years.

This stringent validation then allows - as long as the test system is NOT changed - a surrogate marker for

an estimation of the viral load and thus the possible infectivity of the tested sample.

infectivity of the tested sample, but never definitive detection. As soon as a component on the PCR test system (be it chemicals, plastic goods, enzymes, protocol procedures or 152 machines) is changed in one of the steps used, the system must be recalibrated.

must be recalibrated.

From all the information published so far (see above), it can be assumed, that any CT value above 35 is no longer associated with the cultivability of infectious viruses and is therefore the absolute threshold for the decision "positive", also independent of the test system used. The CT range 25-35 is possibly still valid as a "positive" valid as "positive in the sense of infectiousness" if, as described above, it is adequate validation in the laboratory carrying out the test.

CT ≤ 25 : positive

CT 26-35 : only positive if compared with a virus culture.

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 on its own, without information about the matching with the specific number of virus genomes (viral load) and the correlation with a cultivability of corresponding virus. However, the CT value is worthless as an evaluation criterion for a positive PCR detection.

1.3.3 Adequate controls

In order to correctly assess the sensitivity and specificity of RT-qPCR, it is necessary to adequate samples must be included in each reaction run. This starts at the with "blank swabs" at the test site to exclude contamination at the sample collection extraction controls to ensure the correct isolation of reproducible RNA with all the of reproducible RNA with all subsequent processing steps, i.e. an artificially artificially produced defined RNA, which is carried along in all steps of the sample preparation preparation up to PCR and for which PCR is then carried out with the help of suitable primers. the PCR is also carried out. This rules out the possibility that inhibitory substances or inhibiting substances or errors during sample processing prevent the amplification of RNA. amplification.

Furthermore, in each correct test series, a series of external (i.e. in parallel with patient samples) negative

samples) and a positive control, ideally consisting of an inactivated defined SNA.

ideally consisting of an inactivated defined strain of SARS-CoV-2 virus. This would be a task of the RKI (with the assistance of other, suitable public institutions such as the

such as the Bernhard Nocht Institute or the Friedrich-Löffler Institute), in the available (safety level 4) to isolate a sufficient number of SARS-CoV-2 viruses from patient samples.

viruses from patient samples, to cultivate defined strains from them as controls, to inactivate them and distribute defined numbers of viruses as controls to the testing local regulatory authorities as controls to the testing laboratories. However, after this service is still not offered even after more than a year of the "pandemic".

pandemic, the positive control usually consists of a synthetic RNA, which only encodes the target genes of the test system. This positive control can also be used to determine the

lower detection limit of the PCR can be determined. This is set by some commercial kits with 20 or fewer viral genomes per sample and thus already indicates (see point 1.3.2.) already indicates a viral quantity in the smear that is lower by a factor of 10⁵ below the

infectious dose, i.e. has no diagnostic/prognostic value. An

overview of the currently used commercial kits with their performance data can be found at

can be found at http://www.finddx.org/covid-19/pipeline/?section=molecular-assays#diag_tab. 153

Interlaboratory tests:

Correctly performed controls also include the participation of the test

laboratories in so-called "interlaboratory comparisons" (see also 1.3.1.). In these

an anonymised panel of test samples is made available by an external provider.

provided by an external provider. In the case of virus detection, these contain negative samples and samples with

closely related viruses (inactivated) to check the specificity (these samples must not give a positive signal) and

positive signal) and positive samples with different dilutions of the virus of

virus (inactivated) to check the sensitivity (from which number of viruses does the PCR turn positive, with which CT value).

In the case of SARS-CoV-2, the first round robin test "Virus genome detection - SARSCoV-2 (340)" was carried out by the association "INSTAND e.V." and was ready in April 2020.

According to the report, 488 laboratories participated, 463 of which reported results. The

results can be found in the published commentary (Zeichhardt M: Kommentar zum Extra

EQA scheme group 340 virus genome detection SARS-CoV-2", available at:

<https://corona-ausschuss.de/wp-content/uploads/2020/07/Instand-Ringversuch-VirusgenomNachweis-SARS-CoV-2.pdf>) and show two deviations from the usual EQA procedure.

procedure, which already indicate laboratory problems with RT-qPCR for the detection of SARS-CoV-2.

for the detection of SARS-CoV-2: Thus, on page 4 of the publication it states:

"Important information on the evaluation: Only 4 of the 7 samples that were examined in this extra ring test

will be considered for obtaining a certificate of successful participation".

participation". The footnote on page 10 of the commentary states: "In the

Interim Evaluation of 17 April 2020, all participants in the Extra INSTAND

EQA scheme (340) virus genome detection of SARS-CoV-2 April 2020.

sample characteristics of samples 340059, 340060 and 340064 ahead of schedule. The

results of these 3 samples will not be considered for the granting of a certificate [...]."

The reason for this exclusion of certain samples is set out on page 4 of the commentary

"While the extra ring trial was still running, INSTAND e.V. received urgent requests from Germany and

urgent requests from within and outside Germany to test the properties of the samples before the end of the extended deadline, i.e. before 28 April 2020.

April 2020, to uncover the properties of the samples to be tested, so that

laboratories can improve their test method in the short term in the event of any incorrect measurements."

(page 4 above in the INSTAND e.V. report))

This procedure is very unusual for a real interlaboratory comparison and thus does not constitute an independent external verification procedure of the participating laboratories.

Despite the samples already detected and the reduced scope of the test, there was a

of laboratories there were mix-ups of samples - as is stated on page 18 of the

commentary: "For sample 340064 (SARS-CoV-2 positive diluted 1 : 100 000), the reduced success rate of only

reduced success rate of only 93.2 % is mainly due to incorrect result assignments

(mix-ups) with 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 [...]."

A large number of laboratories therefore incorrectly confused sample 340064 (slightly diluted SARSCoV-2) with sample 340065 (negative for SARS-coV-2 and positive for the closely related

HCoV 229E virus).

Apart from the shocking fact that even under highly standardised procedures in a ring standardised procedures in an interlaboratory comparison, a considerable number of samples were samples were mixed up (which raises the question of the corresponding quota of sample mix-ups and thus incorrectly assigned swab samples under mass test conditions), it is striking that all reported mix-ups concerned only these two samples, but not the samples, but not the sample with the final number 61 (very highly diluted S (very highly diluted SARS-CoV-2) and 62 (negative). The detailed results of a second round robin test from June/July 2020 (<https://www.instand-ev.de/System/rvfiles/Zusammenfassung%20der%20Probeneigenschaften%20und%20Sollwerte%20Virologie154%20June%20July%202020200911a.pdf>) are still not publicly available.

viewable.

1.3.4 Exclusion of contamination of reagents and "problems in the course of action".

The best PCR design can still lead to false positive results if either the underlying reagents / kits are contaminated with positive samples, or, much more likely, contamination occurs in the laboratory workflow. Since the PCR is an extremely sensitive method (exponential reaction) that can detect only a few molecules of a DNA.

molecules of DNA, laboratory contamination by PCR end products is a major

PCR end products is a major problem in clinical diagnostics (described, for example, as early as 2004 in Aslanuadeh J et al.,

<http://www.annclinlabsci.org/content/34/4/389.full.pdf+html>: "A typical PCR generates as many as 10^9

copies of target sequence and if aerosolized, even the smallest aerosol will contain as many as 10^6

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 presupposes that the diagnostic laboratories

diagnostic laboratories that work with PCR must take the utmost care in

testing - highly skilled staff, contamination-proof environment,

permanent independent control.

Already in the above-mentioned round-robin test 340 in April, a problem with false positive positive results, which was commented on as follows (page 20 below): "In addition, in some cases the in some cases, the tests with the SARS-CoV-2-negative control samples 340060, 340062 and 340065 indicate specificity problems, which are independent of the of the swaps of samples 340064 and 340065. It must be clarified whether these false positive results are due to a specificity problem of the tests used or to a carry-over of carry-over of SARS-CoV-2 during the test procedure or due to mix-ups with other with other samples in this round robin test in the laboratories concerned.

" (Seite 21 unten in <https://www.instand-ev.de/System/rv-files/340%20DE%20SARSCoV-2%20Genom%20April%202020%2020200502j.pdf>). For the mix-up in this

See details in point 3.3. end of paragraph.

If, against this background, one further sees how, for example, according to a BBC report, in major in large test laboratories in England is openly and extremely contamination-prone with untrained staff ().

(<https://www.youtube.com/watch?v=Uk1VK1reNtE>), it comes as no surprise,

that even in Germany (where such reports have not been filmed so far) there are occasional reports of

reports of "false positive cases" due to laboratory contamination are occasionally found in the media.

(e.g. MVZ Augsburg - link at the end of the section). Even under controlled

laboratory conditions, contamination due to PCR steps cannot be ruled out with certainty.

such a highly sensitive method. The problem of false positive

positive PCR results in SARS-CoV-2 diagnostics due to laboratory

laboratory procedures and already in the first publication of RT-qPCR (Corman et al., DOI:

10.2807/1560-7917.ES.2020.25.3.2000045): "In four individual test reactions,

weak initial reactivity was seen but they were negative upon retesting with the same assay".

[.....] ".... most probably to handling issues...."

Even if the handling procedure in the laboratory functions optimally and is extremely monitored to laboratory contamination, an unexpected source of false positive results may be the contamination of the

of false positive results in the contamination of the materials/chemicals used.

from the manufacturer. For example, the swab materials used to take the samples may already be contaminated ex works - as in the case of the "Phantom of Heilbronn", in which

the cotton swabs used to collect DNA traces at the crime scenes were contaminated with the DNA of a

were contaminated with the DNA of a packaging employee of the manufacturing plant, thus hindering forensic

forensics with false traces for years 155

(<https://www.faz.net/aktuell/gesellschaft/kriminalitaet/dna-ermittlungspanne-das-phantomvon-heilbronn-ist-widerlegt-1925411.html>).

Similarly, in the case of SARS-CoV-2 diagnostics, as early as June 2020, a

contamination problem due to PCR primers containing positive controls ex works (Wernike et al.

were published (Wernike et al., DOI: 10.1111/tbed.13684). Here it was noticed that even pure

water samples with several independent primer batches resulted in a clearly positive SARSCoV-2 detection in RT-qPCR: "However, there were also primers/sample sets that displayed very low-level contaminations.

that displayed very low-level contaminations, which were detected only during thorough internal validation."

Also, some false-positive results of SARS-CoV-2 RT reported in the daily press in summer 2020

of the SARS-CoV-2 RT-qPCR test reported in the daily press in summer 2020 were attributed to material problems (e.g.

<https://www.br.de/nachrichten/bayern/probleme-in-augsburger-labor-bringen-falschetestergebnisse,SEh5Qq4>)

Assessment:

Even with an ideal RT-qPCR design and good laboratory practice with adequate validation

problems in the daily workflow as well as from outside via samples that are already

contaminated samples can significantly influence the quality of the results of RT-qPCR and lead to false positive

and lead to false positive results.

1.3.5 Commercial PCR test kits: Approval for diagnostics?

Very early on, commercial PCR test systems, the "PCR kits" were used in the

used in routine laboratories for diagnostics, although a large number of them were declared for "RUO" ("research

use only").

Particularly noteworthy here is the first and therefore most concise test manufacturer, the

Berlin company TIB Molbiol, whose owner (Olfert Landt) was already listed as an author on the WHO protocol recommendations alongside Christian Drosten. The kits, which

which are based on the WHO recommendations, are used by Roche on their large-scale

Roche on their large-scale automatic machines "Cobas" and therefore probably make up the used for routine diagnostics in Germany.

Exact figures cannot be determined, but according to TIB Molbiol, by 2020 it will have according to its own information, TIB Molbiol has already delivered more than 60 million tests worldwide (<https://www.tibmolbiol.de/de/covid-19>), although they are still classified as "Not tested for use in diagnostic procedures".

procedures" (e.g. header in https://www.roche-as.es/lm_pdf/MDx_53-0777_96_Wuhan-Rgene_V200204_09155376001%20%282%29.pdf). The corresponding

package inserts with the protocol details and kit descriptions of the company TIB Molbiol were astonishingly

were, astonishingly, already available according to meta data of the originally available PDFs (can be provided electronically) already on 15.01.2020 (!!!) completely with ROCHE

SAP number are still available unchanged (even though with

metadata analysis 06.02.2020) parallel to other test kits, which in the meantime have a have been approved for in vitro diagnostics.

1.4 Relationship between positive nucleic acid detection in RT-qPCR and infectivity

Only those who are actually infected can pass on the virus and are at risk of contracting the disease. disease and are therefore to be used to determine the course of an infection rate and a wave of disease

"PCR detection is the standard test for diagnosing viral infections such as SARS-CoV-2.

SARS-CoV-2. The test detects individual pathogen genes, but not intact pathogens.

intact pathogens." And: "There is a possibility that the test will remain positive beyond the duration of the infection 156

positive beyond the duration of the infection because there is still 'viral debris' in the nose or throat." A reliable

infectiousness is only possible with complex tests in which the laboratory examines laboratory to determine whether the material from the swabs can kill living cells."

This was written by the Dt. Ärzteblatt on 01.02.2021

(<https://www.aerzteblatt.de/nachrichten/120745>).

"The PCR test detects gene segments of SARS-CoV-2; it says nothing about, whether they are viruses that are capable of infection or virus residues after a infection. This would require pathogen culture." Was in a 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 13.07.20 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 the presence of infectious virus or that 2019-nCoV is the causative agent for clinical symptoms".

presence of infectious virus or that 2019-nCoV is the causative agent for clinical symptoms".

2019-nCoV is the causative agent of clinical symptoms."

That a pure mRNA detection of SARS-CoV-2 does not necessarily correlate with a disease

correlate with disease and should not be used as the sole criterion for the assessment of disease

but only as a tool to confirm a clinical diagnosis, is also clearly stated in the

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" of 13.01.2021 (published on 20.01.2021 at

<https://www.who.int/news/item/20-01-2021-who-information-notice-for-ivd-users-2020-05>)

If the test results do not match the clinical picture, a new sample should be taken and tested,

a new sample should be collected and retested using the same or a different NAT technology." - 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."

Further: "Most PCR assays are indicated as an aid to diagnosis, so healthcare providers must

health care providers need to consider each result in combination with the time of

the sample collection time, sample type, assay specifics, clinical observations, patient history, confirmed

patient history, confirmed status of all contacts, and epidemiological

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 a recent 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 view, the current

PCR test is therefore not the appropriate gold standard for the evaluation of a SARS-CoV-2-

public health test" In the original: "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 is still positive even if the tested person is no longer positive.

positive, because the RNA continues to be present in the body for weeks and months after the

the immune system, the RNA can persist in the body for weeks and months without the person being

person is still infectious. "As soon as the replication of SARS-CoV-2 by the 157

immune system is brought under control, the levels detectable by PCR in the respiratory

RNA levels in respiratory secretions drop to very low levels, at which it is much less

much less likely to infect others. The remaining

RNA copies may take weeks, and occasionally months, to disappear, during which time the

during which 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 the detection of an infection with the SARS-CoV-2 coronavirus infection. 1.

1. against the background of the problems outlined in point 1.3, RT-qPCR is not an appropriate suitable, reliable (and approved) diagnostic tool for the detection of infectious infectious (replication-capable) SARS-CoV-2 viruses. 2.

2. furthermore, the pure RT-qPCR test result is only a laboratory value, which in view of the aspect outlined in point 1.4. does not allow any statement about the presence of infectious infectious viruses and can only be used in conjunction with a clinical symptom diagnosis of symptoms (ascertained by health care providers, in Germany medical practitioner).

Summary: For testing asymptomatic people on the basis of a nasopharyngeal swab, as is done uncritically in large numbers and predominantly by non-medical staff, the use of a nasopharyngeal swab is not permitted.

non-medical personnel WITHOUT (decisive here: contrary to the WHO requirement!) anamnesis and symptom

and symptom collection from those tested, the RT-qPCR used is not suitable,

2. the antigen detection by means of the

2 Antigen detection by rapid test

2.1 Explanation of terms/basics of the rapid test

The "rapid tests" currently used for the diagnosis of SARS-CoV-2 are based on the principle of an antigen test according to the "lateral flow" test procedure. Hereby a protein component (protein) of the virus.

An antigen is a three-dimensional structure of proteins and other organic organic materials which can be recognised and bound by antibodies (immunoglobulins). and bound by antibodies (immunoglobulins).

In the case of viral antigens, these are usually individual protein components (proteins) from the virus structure.

(proteins) from the virus structure. These can be either complete structural proteins such as the the "spike" protein on the surface of the virus (S-protein, which are the "stalked buttons" in the in the viral markings) or the envelope protein (E protein) or the protein from which the nuclear or the protein that makes up the nuclear envelope (nucleocapsid = N-protein). Fragments of these complete

of these complete structural proteins are often sufficient to be bound by antibodies.

be bound by antibodies. These are the so-called epitopes, which also represent the actual antibody binding site on the

antibody binding site on the intact structural protein. Each structural protein usually has a epitopes, so that different antibodies can bind to different epitopes of the same protein at the same time.

epitopes of the same protein at the same time.

In the case of SARS-CoV-2, the most important antigens (the above-mentioned, S-, E- and N-proteins) are

are those that trigger an immune response in the body when infected with the virus.

As a result, the body forms antibodies that specifically recognise these antigens,

then bind to them (antigen-antibody reaction) to neutralise the viruses and make them destructible for immune cells.

and make them destructible for immune cells. 158

This antigen-antibody reaction can be used in the laboratory to search for antigens with synthetically produced antibodies.

antibodies to search for antigens in any sample.

The basic principle of so-called antigen tests in the laboratory (these aim to detect antigens by antibodies, in contrast to RTPCR, which detects nucleic acids.

nucleic acids) is that two matching antibodies are produced in vitro, which two different epitopes of the antigen sought, a so-called "antibody pair".

"antibody pair". Both antibodies have to be selected in such a way that they exclusively recognise the epitope on the antigen of interest, but not other structures on similar antigens.

antigens, but cannot recognise and bind other structures on similar antigens. They must therefore be highly specific in order to be

be used in diagnostics. This high specificity of diagnostic antibodies

antibodies is ensured by comparing them with many very similar epitopes.

epitopes. In this process, all antibodies that bind unwanted epitopes are discarded,

until only one ideal pair of antibodies remains, which fulfils the requirements: very high specificity specificity, high binding property (sensitivity) and no mutual interference.

influence each other.

The antigen test is then based on this pair of antibodies, in which the sought-after

antigen is bound by both antibodies at the same time and spreads between them like the sandwich rolls (hence "sandwich test").

For the lateral flow rapid antigen tests currently used in broad-spectrum testing of the population to detect SARS-CoV-2 antigens, this sandwich test system is now used.

sandwich test system is now used.

The first of the two specific antibodies is bound to a carrier material in such a way that its antigen-binding properties are

that its antigen binding site points freely upwards. This is the later region in the

rapid test, where a colour change gives the signal "positive". The second antibody is

coupled with a detection system, which is later responsible for the colour reaction,

and is located as a depot directly next to the site in the rapid test at which the sample is dropped.

is dripped on.

Test procedure: If the swab sample now contains the antigen sought, in this case the sought protein of SARS-CoV-2, it combines with the first specific protein after dropping into the test field of the

detection cassette with the first specific antibody from the depot. Via

the mixture of antigen with the bound first antibody and excess unbound antibody

and excess unbound antibodies from the depot migrate towards the test field.

towards the test field. Here, the second specific antibody fixed there then binds the antigen with the first antibody already bound to it.

antibody already bound to it. The solution migrates beyond the test field

over another field in which the surplus antibodies are caught (control field).

The detection system of the test begins with a chemical colour reaction wherever the first antibodies are bound.

antibodies are bound, the detection system of the test starts to become visible with a chemical colour reaction. In the control field this causes

and now bound here, which the detection system "brought along".

detection system, thus indicating that the test has, in principle, functioned without

functioned without interference.

In the test field, there is only a colour change if there was actually an antigen in the

antigen was in the sample and was bound via the second antibody fixed there. Since the

antigen has already arrived at the test field with the first antibody and the detection system.

antigen has already arrived at the test field with the first antibody and the detection system.

colour change (usually a violet stripe) at the test region.

Whenever the antigen sought is present in the smear sample, it can bind to the first antibody and

antibody and transport it together with the detection system to the fixed second antibody.

antibody, which then intercepts this antigen-antibody-detection system complex and thus

and thus causes the positive signal at this point.

The colour change on the test field ("positive" signal), which causes the visible stripes in the rapid test, is a chemical reaction.

is a chemical reaction and therefore depends on the reaction conditions such as e.g. 159

pH value or chemicals that come with the sample and is a clear weakness in the reliability of the test.

weakness in the reliability of the test.

This explains the many videos circulating on the internet showing SARS-CoV-2

in apple juice, red wine, beer, etc. using the rapid antigen tests.

2.2 Basic information on the diagnostic value of the rapid antigen test

Like the RT-PCR, rapid antigen tests cannot in principle prove whether the virus antigen belongs to an intact, infectious virus or is a remnant (fragment) of the virus or is a remnant (fragment) of viruses that have been killed by the immune system. killed by the immune system.

Irrespective of this general restriction of the significance with regard to an infectivity, rapid tests are only indicative, not diagnostic. diagnostic significance.

The best-known rapid test before the days of Corona was the rapid pregnancy test, which was based on the same

works on the same principle as the antibody-antigen test. However, here the the pregnancy hormone (HCG) functions as the antigen. If this is present in sufficient quantity in the urine, the test shows "positive" - in this case, presumably pregnant.

in this case. However, the rapid test alone will never be sufficient to prove a pregnancy.

The doctor will use an HCG test in the blood and an ultrasound scan to make the diagnosis. will be used.

The rapid antigen tests for the detection of SARS-CoV-2 components can also only give an indication of possible colonisation.

only give an indication of possible colonisation or infectiousness and are subject to similar limitations similar to those of RT-qPCR.

2.3 Factors influencing the reliability of rapid antigen tests

2.3.1 Pre-test probability

In an infographic, the RKI explains under the heading "Corona rapid test results understanding"

([https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Infografik_Antigentest_PDF.](https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Infografik_Antigentest_PDF.pdf?__blob=publicationFile)

pdf?__blob=publicationFile), the RKI clearly explains how the probability that a test result is correct depends on the so-called pre-test probability.

test result is dependent on the so-called pre-test probability, i.e. on the actual number of genuinely infected persons in the tested population. This aspect of the pre-test probability applies to the rapid antigen tests as well as to the RT-qPCR tests. the RT-qPCR tests.

The calculation example presented by the RKI for the interpretation of the rapid antigen tests is based on a realistic scenario.

scenario based on a sensitivity of the antigen tests of 80% and a specificity of

antigen tests of 80% and a specificity (reliability) of 98%, whereby also here

(https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Vorl_Testung_nCoV.html)

explicitly mentions: "The considerable differences in the performance of the various commercially available tests (e.g.

of the different commercially available tests (reference to:

<https://www.medrxiv.org/content/10.1101/2020.10.01.20203836v1>)."

Assuming 5 persons out of 10,000 tested are really infected with SARS-CoV-2,

there will still be 200 false positive tests and 4 true positive tests. This means,

1 true infected person per 10,000 would be missed, but 200 would test false positive.

and therefore have to be quarantined/isolated until they are tested with an RT-qPCR.

RT-qPCR then gives the "all clear". This would mean in the case of a school test with e.g.

1000 pupils, for example, this would mean that 20 would be told a false "You are Corona positive",

and the school would be blocked as an "outbreak site" until the retesting with RT-qPCR

RT-qPCR gives the all-clear. Such cases have already been reported in the press. 160

- In Altdorf near Nuremberg, for example, 29 of 180 grammar school students tested positive in a rapid antigen test.

upon examination, 28 of them turned out to be negative (Merkur:

<https://www.merkur.de/bayern/nuernberg/nuernberg-corona-bayern-test-fiasko-schnelltestsfehlerhaft-positiv-schule-alt-dorf-gymnasium-zr-90253265.html>)

- In Potsdam, 12 of 36 teachers tested positive in a rapid antigen test and were sent to quarantine.

quarantined. After examination, all test results turned out to be false positive.

positive (<https://www.news4teachers.de/2021/03/sorgen-schnelltests-fuer-chaos-an-schulen-falscher-alarm-legt-grundschule-lahm/>)

- Medscape even headlines: "200 false positives, 8 detected, 2 overlooked - why child and adolescent and adolescent doctors are sceptical about mass rapid tests

(<https://deutsch.medscape.com/artikelansicht/4909842>)

And even if the rate of genuinely infected persons in the tested group were very high, as in the second

as in the second example calculated by the RKI (with 1000 out of 10000 persons tested),

the hit rate of the rapid tests would be poor, and 180 people would get a false positive

would get a false positive result and 200 would get a false negative test. Here the the poor sensitivity of the test.

In the "Hinweisen zur Bewertung der Ergebnisse aus AG-Testen" (note: rapid antigen tests) on the RKI website, the problem of false positive antigen tests is discussed.

antigen tests: "A positive test result using an AG test raises the suspicion of a transmission-relevant infection.

infection with SARS-CoV-2 and must be tested for in order to avoid false-positive results.

positive findings, a follow-up test by PCR is required. In view of the

consequences of incorrect results, there are not only high demands on the sensitivity of antigen tests.

not only the sensitivity of antigen tests, but also the specificity. Thus

prevalence/pretest probability and low test specificity, a high number of false-positive results and

specificity, a high number of false-positive results and a corresponding additional

burden on the ÖGD due to the imposition and, if necessary, withdrawal of measures.

measures."

" https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Vorl_Testung_nCoV.html

2.3.2 Sensitivity (Sensitivity)

The fact that in the antigen test there is no such strong (exponential) amplification of the (exponential) amplification of the output signal as in the RT-qPCR, but only a limited signal amplification by the chemical colour reaction, this type of test is clearly less sensitive than the sensitive than the RNA detection by RT-qPCR used for comparison.

This "underperformance" of the antigen rapid 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)),

However, here the negative test result in the rapid antigen test (here called LTF, lateral flow test) is put into

test) is relativised to: "[...] in all six cases observed, the viral loads were very low ($Ct \geq 29$).

very low ($Ct \geq 29$, which reflects about <1000 RNA copies per mL in the laboratory used).

reflecting) - when 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/>) confirms

that in asymptomatic patients the rapid tests have an unsatisfactorily high inaccuracy and that only in the case of

inaccuracy, and that only in symptomatic individuals are the actual infected individuals actually infected persons are detected. The authors conclude: "Our results show that the test correctly identifies most infectious individuals. Nevertheless, the sensitivity is significantly lower than that of PCR", in the original: "Our results indicate that the test correctly identified most infectious individuals. Nevertheless, the sensitivity is considerably lower than for PCR" ¹⁶¹

This supposed lack of sensitivity is the most frequent point of criticism when discussing the unreliability of antigen testing.

unreliability of the rapid antigen tests. Thus the Pharmazeutische

Zeitung (<https://www.pharmazeutische-zeitung.de/in-der-praxis-deutlich-unzuverlaessigerals-auf-dem-papier-123017/>): "Rapid antigen tests could mostly detect "highly infectious

people with high viral loads", explains Keppler. "However, it is not the case that

infection can be reliably ruled out by a negative result from a rapid test.

could be reliably ruled out." Here, however, the basis is the antigen rapid test compared with RT-qPCR

and criticises the fact that only some of the smear samples that are positive for the RT-qPCR antigen rapid test.

In the Epidemiological Bulletin 3/2021, the RKI reports on a study with rapid tests in a clinic in Stuttgart.

in a clinic in Stuttgart (from page 11 in:

https://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2021/Ausgaben/03_21.pdf;jsessionid=15E8B09E615AECED77C34439BB8052AF.internet051?__blob=publicationFile). Here

Table 1 shows that out of 18 RT-qPCR positive for SARS-CoV-2 RNA

asymptomatic individuals, only 7 also showed a positive signal in the rapid antigen test and

and of symptomatic individuals 36 out of 42. The discussion accordingly states

discussion: "Due to the very limited sensitivity of the antigen test in asymptomatic individuals

asymptomatic individuals, the single test in this population may not indicate infection with

SARS-CoV-2 cannot be adequately excluded. Highly contagious individuals with low Ct values (i.e. high viral load) are detected with sufficient certainty." Here

the data, "At a Ct value of 22 or less, the detection rate of the antigen test was was 100%."

This example shows very clearly that a reliable antigen test, when correctly

for symptomatic individuals with a rapid response in the RT-qPCR

(low CT value) correlates very well, but not for asymptomatic, and only high CT value RT-qPCR positive, individuals. This speaks for the real significance of

of the rapid antigen tests with regard to the detection of a high viral load in

symptomatic persons. However, according to these data, the test is unsuitable for testing asymptomatic persons.

unsuitable for testing asymptomatic individuals, both to identify possibly infected persons

infected persons, as well as to reliably identify healthy persons as negative.

Such a finding was also made in the current Frankfurt study

(<https://www.mdpi.com/2077-0383/10/2/328>), where three rapid antigen tests (AG-RDT, Antigen-RDT

(AG-RDT, Antigen-Rapid Diagnostic Test) were compared with a virus cultivation from the same samples

in cell culture and correlated with RT-qPCR. The authors write in the

Abstract: "In contrast, three Ag-RDTs demonstrated a more significant correlation with cell culture infectivity (61.8.0).

culture infectivity (61.8-82.4%)." Which means that from those samples that were positive in the antigen test, a significantly higher hit rate was also seen in the virus culture than in the positive result than in the case of the clearly more sensitive RT-qPCR "positives".

A recently published study by the CDC also points to the high level of agreement between the antigen test with actual replicable virus in a sample from symptomatic patients ().

patients (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7821766/>). Here a

antigen test was compared with a virus cultured in cell culture and RT-qPCR.

was compared. It shows a high hit rate (positive result) of the antigen test only when

if the samples also contained replicable virus. In this case, 85 of the

of the 147 samples (=58%) that were positive in the rapid antigen test and the RT-PCR (in this case with a

a CT of approx. 22), but only 11 of the 124 samples (= 9%), which contained

samples (= 9%) that were RT-qPCR positive (here with a CT of 33-34) but antigen rapid test negative.

In general, it can be stated from these published data:

- Samples from which viruses can be cultivated in cell culture, i.e. which have a high

(infectious) viral load, are detected with good accuracy by the 162

antigen rapid tests and by RT-PCR with low CT (below 25),

but the vast majority of them come from symptomatic individuals.

- Samples from which no viruses can be grown in cell culture can be identified in evaluated and correctly applied antigen tests.

antigen rapid tests are usually negative (apart from the false positives - see 2.3).

(apart from the false positives - see 2.3.3) and show high CT values in RT-qPCR

(mostly above 33). These samples predominantly come from asymptomatic persons tested

tested individuals and prove that these random "positives" without clinical symptoms

symptoms do not have an infectious viral load.

2.3.3 Reliability (specificity) - exclusion of false positives

Many of the rapid antigen tests used have not yet undergone a regular conformity assessment procedure for CE marking and have so far only received

only a special approval in accordance with § 11 of the Medical Devices Act

(https://www.bfarm.de/DE/Medizinprodukte/Antigentests/_node.html). In addition, these tests are

tests are carried out by untrained, non-medical staff or even as "self-tests".

or even as "self-tests".

Professor Dr. Oliver Keppler, head of the Virology Department, has called for the following comments on the problem of rapid antigen tests.

Oliver Keppler, head of virology at the Max Pettenkofer Institute of the Ludwig Maximilian University in Munich, in an article in the Pharmazeutische Zeitung of 13.01.2021 (DOI:

10.1007/s00430-020-00698-8): "[...] these tests must also be carried out correctly.

be carried out correctly. "This should be in the hands of trained professionals," he says. "Now

there is an idea to recruit large numbers of jobseekers to carry out such tests in

old people's homes and nursing homes. If untrained personnel are used

I am concerned that the reliability of the test results will suffer even more.

suffer"

A recent Cochran review article (<https://www.cochrane.de/de/news/aktualisiertercochrane-review-bewertet-zuverl%C3%A4ssigkeit-von-schnelltests-zum-nachweis-voncovid>) also concludes that rapid antigen tests are significantly more reliable in

are significantly more reliable in symptomatic people than in asymptomatic people.

However, even in symptomatic individuals, the reliability of the best of the rapid tests assessed in this

study is significantly limited, so that the authors describe the following

describe the following scenarios:

1. "In a population of 1000 individuals with symptoms, of whom 50 individuals

actually have COVID-19, these rapid tests can be expected to correctly identify about

40 people will be correctly identified as being infected with COVID-19, and between 6 and 12 cases of COVID-19 will be missed. Between 5 and 9 of the positive positive test results would turn out to be false positives on review.

positive."

2. "In a group of 10,000 people without symptoms, in which 50 people are actually infected with SARS-CoV-2, between 24 and 35 people would be correctly would be correctly identified as virus carriers, and between 15 and 26 cases would be would be missed. One would have to expect that the tests would yield between 125 and 213 positive results, and that between 90 and 189 of these positive of these positive results would actually be false positives.

For the consequences of false positives due to lack of test specificity, see under

2.3.1 "Pre-test probability".

2.5 Conclusion:163

The rapid antigen tests used for mass testing cannot provide any information about infectivity, as they only detect protein components without any connection to an intact without any connection to an intact, reproducible virus.

virus can be detected.

1. in order to allow an estimation of the infectivity of the tested persons, it would be necessary to the respective positive test carried out (similar to RT-qPCR) would have to be individually viruses from the test sample (similar to RT-qPCR), which is not possible under the extremely This is impossible under the extremely variable and unverifiable test conditions. 2.

2. the low specificity of the tests results in a high rate of false positives, which is results, which leads to unnecessary personnel (quarantine) and societal (e.g. school closures, "outbreak

(e.g. schools closed, "outbreak reports") until they turn out to be false alarms.

turn out to be false alarms.

For further details, please refer to the written submissions of the parties involved.

are referred to.

B: Reasons for the decision

I. Admissibility of the suggestion to the Family Court

The application to the Family Court to examine whether there is a risk to the welfare of the child is admissible.

In particular, recourse to the ordinary courts is open and the family courts have subject-matter jurisdiction.

family courts have subject-matter jurisdiction.

According to § 13 GVG, family cases belong before the ordinary courts.

The subject-matter jurisdiction results exclusively from section 23a (1) no. 1 GVG.

According to this, the local courts have jurisdiction over family matters. § Section 23b GVG only concerns the

statutory allocation of family cases within the local court.

Pursuant to section 111 no. 2 FamFG, family matters are also matters of parent and child. The

According to section 151 no. 1 of the Family Proceedings Act (FamFG), child custody includes parental custody. Parental custody also includes the

parental custody also includes the provision of § 1666 of the Civil Code, according to which the family court must

necessary measures if the physical, mental or psychological well-being of the child or his or her

welfare of the child or his or her property is endangered and the parents are unwilling or unable to avert the danger.

are unable or unwilling to avert the danger. In doing so, the family court may, pursuant to section 1666, paragraph 4

BGB (German Civil Code), the family court may also take measures in matters of personal third party.

Nor does § 40 of the Code of Administrative Procedure (VwGO) provide anything to the contrary with regard to legal recourse. Legal recourse to the

administrative courts is not open for proceedings to endanger the welfare of children. For

proceedings concerning a risk to the welfare of a child are expressly assigned by federal law to another court, 164

to another court, namely the family court, section 40, paragraph 1, sentence 1 VwGO in

in conjunction with section 1666 of the Civil Code.

This is also based on constitutional necessities.

Child protection in German law is structured on several tracks. For proceedings before the

For proceedings before the general civil courts or the administrative courts, genuine applications in the legal sense are necessary.

are necessary. Only if such an application has been made can the courts mentioned take action.

become active.

Proceedings under § 1666 of the Civil Code, on the other hand, do not belong to the application proceedings in the sense of

of § 23 FamFG, but are among those under § 24 FamFG that can be initiated ex officio.

of their own motion; at the suggestion of any person or even without such a suggestion if the court considers intervention to be necessary for reasons of the best interests of the child, § 1697a of the Civil Code.

Endangerment of the child is to be affirmed in the case of a present danger to such an extent for the mental, physical

mental, physical or psychological well-being of the child to such an extent that, in the absence of intervention

that, in the event of further development without intervention, considerable harm is can be foreseen with a high degree of certainty (Palandt-Götz, § 1666 marginal no. 8).

According to the current state of science, the wearing of a mouth-nose covering is at least a the current state of science, so that the court had to initiate proceedings in order to proceedings to examine this question.

According to the principle of equal treatment from Article 3 of the Basic Law and the guardianship enshrined in Article 6

of the state community for the family enshrined in Article 6 of the Basic Law, it would be constitutionally unacceptable if some children were able to hope that

that an application will be made for them at a court that appears to be suitable, but not others.

Even children whose parents would in principle be willing and able to file applications that would be and in a position to make appropriate applications, can fall behind if their parents do not do so for fear of disadvantaging their children.

or at least delay doing so out of fear of disadvantages for their children. § Section 1666 BGB applies to all children. In the proceedings themselves, the principle of official investigation applies, § 26 FamFG.

According to the prevailing opinion, the parents are therefore not forced to take the general civil law procedure beforehand (Palandt-Götz, § 1666 marginal no. 41). They are also not compelled to take administrative action against the order on which the order is based and, if necessary

against the ordinance on which the order is based and, if necessary, to seek a judicial review.

Incidentally, this follows from the fact that the administrative procedure pursues a different legal protection objective than the administrative procedure.

legal protection goal is being pursued than with the order sought here against the school the school management and the child's teachers.

Finally, the admissibility requirements for issuing a temporary injunction pursuant to §§ 49 et seq.

order pursuant to § 49 et seq. of the Family Proceedings Act.

In particular, a temporary injunction is admissible because it is asserted here that this is justified according to the provisions governing the legal relationship (§ 1666 BGB) and in view of the school lessons taking place with the obligation to wear a face mask, wearing a face mask, there is an urgent need for immediate action. exists.

II. Merits of the application to the Family Court

1. general points

The suggestion to the Family Court that, in order to avoid a risk to the welfare of the child, it should make a regulation

the operative part, is well-founded in accordance with § 1666 of the Civil Code.

Endangerment of the child is to be affirmed in the case of a present danger to such an extent for the mental, physical

the mental, physical or psychological well-being of the child to such an extent that, in the absence of intervention

that, in the event of further development without intervention, considerable harm is

can be foreseen with a high degree of certainty (Palandt-Götz, § 1666 marginal no. 8).

Such a danger is present here. This is because the children are particularly threatened by the

in particular by the obligation to wear face masks during school hours and to keep their distance from each other and other

and to other persons, not only endangers the children's mental, physical and spiritual well-being, but also

not only endangered, but moreover already presently harmed. At the same time

rights of the children and their parents under the law, the constitution and international conventions.

international conventions are violated. This applies in particular to the right to free

development of the personality and to bodily integrity from Article 2 of the Basic Law

as well as to the right under Article 6 of the Basic Law to upbringing and care by parents

(also with regard to health care measures and "objects" to be carried by children).

"objects" to be carried by children). However, this also applies to further rights of the children, as stated in A IV. by the children's

mother of the children.

The children are physically, psychologically and pedagogically harmed and their rights are

without any benefit for the children themselves or third parties.

The provisions of Land law, as set out in more detail in A II.

school headmasters, teachers and others cannot invoke them. For these regulations are unconstitutional and therefore null and void.¹⁶⁶

The obligation in Article 100(1) of the Basic Law to report a possibly unconstitutional law to the Federal

unconstitutional law to the Federal Constitutional Court or a Land constitutional court, expressly applies only to formal laws of the Federation and of the Länder, but not to substantive laws such as statutory ordinances or the general decree at issue.

According to the established case law of the Federal Constitutional constitution (fundamentally BVerfGE 1, 184 ((195 et seq.)), each court must decide for itself on the AG Weimar, judgement of 11 January 2021 - 6 OWi - 523 Js.

202518/20 -, juris.

How the family court responds to threats to the best interests of the child, for which formal federal or Land laws are invoked to justify, beyond referral to the federal or a Land constitutional court is not relevant to the decision here and therefore requires no further explanation.

and therefore requires no further elaboration.

The provisions of Land law, as explained in more detail in A II (this also applies to them or similar to them), are unconstitutional because they violate the principle of the principle of proportionality rooted in the rule of law, Article 20, 28 of the Basic Law.

According to this principle, also known as the prohibition of excessiveness, measures intended to achieve a legitimate purpose must be

measures intended to achieve a legitimate purpose must be appropriate, necessary and

be appropriate, necessary and proportionate in the narrower sense of the term, i.e. when the advantages and disadvantages they achieve are weighed against each other.

Measures that are not evidence-based, contrary to Section 1(2) IfSG, are already unsuitable, to achieve the fundamentally legitimate purpose of avoiding an overload of the health care system or to reduce

system or to reduce the incidence of infection with the SARS-CoV2 virus. In any case, they are disproportionate in the strict sense of the word, because the considerable

the considerable disadvantages/collateral damage caused is not matched by any discernible benefit for the children

for the children themselves or third parties.

The inappropriateness and disproportionate nature of the prescribed measures is justified below. Nevertheless, it should be pointed out that it is not the parties involved who have unconstitutionality of the encroachments on their rights, but vice versa.

the Free State of Thuringia, which interferes with the rights of the parties through its state rights of the parties involved, would have to prove with the requisite scientific evidence that that the measures it prescribes are suitable to achieve the intended purposes, and that they and that they are proportionate, if necessary. This has not yet been done been done. 167

2. the lack of benefit of wearing masks and observing distance

for the children themselves and third parties

The expert Prof. Dr. med. Ines Kappstein, in her complete report, cf.

In her complete expert opinion, cf. A VIII, she evaluated the entire international scientific data on masks.

masks.

To the conviction of the court, she summarises that an effectiveness of masks for healthy persons in public is not supported by scientific evidence.

scientific evidence. Likewise, 'external protection' and 'unnoticed transmission', with which the RKI justified its 'reassessment', are not proven.

has justified its 'reassessment', are not supported by scientific facts.

Plausibility, mathematical estimations and subjective assessments in opinions cannot replace population-based clinical-epidemiological studies.

epidemiological studies. Experimental studies on the filtering performance of masks and mathematical estimates are not suitable for proving effectiveness in real

in real life. Although international health authorities are in favour of

masks in public places, they also say that there is no scientific evidence to support them.

evidence from scientific studies. On the contrary, all currently available scientific

available scientific evidence suggests that masks have no effect on the incidence of infection.

on the incidence of infection. All publications that are cited as evidence for the efficacy of masks in public spaces

effectiveness of masks in public spaces do not allow this conclusion to be drawn.

This also applies to the so-called Jena Study, as the expert explains in detail in her report.

This is because the Jena study - like the vast majority of other studies, a purely mathematical

purely mathematical estimation or modelling study based on theoretical assumptions.

modelling study without real contact follow-up with authors from the field of

macroeconomics without epidemiological knowledge - remains, as explained in detail by the expert explained in detail, the decisive epidemiological circumstance is not taken into account.

infection levels had already fallen significantly before the introduction of mandatory masks in Jena on 6 April 2020 (about three

weeks later in the whole of Germany) and that by the end of March 2020 there was already no 2020, there were no longer any relevant infections in Jena.

As the expert further explains, in order to be effective in principle, every mask must be worn correctly.

be worn correctly. Masks can become a contamination risk,

if they are touched. However, on the one hand, they are not worn properly by the population and and secondly, they are very often touched with the hands. This is also the case with politicians who are seen on television. The population was not taught

masks, they were not taught how to wash their hands on the way to work or how to or how to disinfect their hands effectively. It was also

why hand hygiene is important and that care must be taken not to touch 168

to avoid touching your eyes, nose and mouth with your hands. The population was left alone with the masks.

The population was left alone with the masks.

Not only is the risk of infection not reduced by wearing the masks, but

the risk of infection is not only not reduced by wearing the masks, but even increased by the incorrect handling of the masks. The expert explains this in

in her expert report as well as the fact that and for what reasons it is "unrealistic".

the reasons why it is "unrealistic" to achieve the appropriate use of masks by the population. achieve.

The transmission of SARS-CoV-2 through 'aerosols', i.e. through the air, is medically implausible and scientifically unproven.

plausible and scientifically unproven. It represents a hypothesis that is mainly

aerosol physicists who, according to the expert, understandably do not have medical

understandably unable to assess medical correlations from their field of expertise. The 'aerosol' theory

theory is extremely harmful to human coexistence and leads to the fact that people no longer feel

people can no longer feel safe indoors, and some are even afraid of infection and some even fear infection from 'aerosols' outside buildings. Together with transmission, the 'aerosol' theory means that every fellow human being can be seen as a infection risk in every fellow human being.

The change in policy on masks, first fabric masks in 2020, then since masks or FFP2 masks since the beginning of 2021, lack any clear line.

Even if OP masks and FFP masks are both medical masks, they have different functions and are therefore not interchangeable.

have different functions and are therefore not interchangeable. Either the policy, who made these decisions did not understand what each type of mask is suitable for, which type of mask is suitable, or they do not care, but only about the symbolic value of the mask. value of the mask. From the expert's point of view, the policy makers' mask decisions are not comprehensible.

The expert does not believe that the policy decisions on masks are comprehensible and, to put it mildly, implausible.

The expert further points out that there have been no scientific studies on the use of on spacing outside of medical patient care.

In summary, in her opinion, and to the conviction of the court, only the following rules can be established

the following rules can be established:

1. keep a distance of about 1.5 m (1 - 2 m) in case of vis-à-vis contacts if

of both persons has symptoms of a cold, can be described as a sensible measure.

can be described as a sensible measure. However, it is not scientifically proven; there is only evidence for it or it can be

there is only evidence or can be said to be plausible that it is an effective measure to protect effective measure to protect against contact with pathogens through droplets of respiratory secretion if the person

if the person in contact has signs of a cold. An all-round distance

is not appropriate to protect oneself when the contact has a cold.¹⁶⁹ 2.

2. keep an all-round distance or even just a vis-à-vis distance of about 1.5 m (1 - 2 m) if none of the people present has signs of a cold is not supported by scientific data.

not supported by scientific data. This, however, does not make it easier for people to live together and especially the carefree contact between children is severely impaired.

3. close contacts, i.e. between people with a cold.

3. close contact, i.e. less than 1.5 m (1 - 2 m), between pupils or between teachers and pupils or between colleagues at work.

teachers and pupils or between colleagues at work, etc., do not pose a risk even if one of the two has even if one of the two people in contact has signs of a cold, because the duration of such contact at school or with adults anywhere in public is far too short for it to lead to adults is far too short for droplet transmission to occur. This is also shown by studies from households where, despite living in close proximity with numerous skin and mucous membrane contacts, only a few members of the household become ill when one of them has a respiratory respiratory infection.

The reviewer convincingly highlights the problem of mathematical modelling.

Mathematical modelling (also called mathematical estimation) is used by the weather forecasting and climate research, but have also been used for many years to predict the used for many years to predict the course of epidemics and the influence of various preventive prevention measures. They are used especially when there is only little meaningful data from direct studies. In a very large part of all studies on SARS-CoV-2 (e.g. effectiveness of masks) are mathematical modelling mathematical modelling, which has very limited validity because the results do not reflect results do not reflect 'real' life, but are based on assumptions. From the results are dependent on these 'adjusting screws', which therefore reflect a simplified of reality. Such studies can therefore only ever provide 'if-then' results. On the one side of the spectrum, there are purely theoretical theoretical modelling and, on the other, those that work with as much clinical-epidemiological data as is available.

data as is available. However, the result always has, as the the reviewer explains in detail, the result has only a very limited significance, and the quality of the quality of the scientific evidence is moderate at best. The results of such studies in the SARS-CoV-2 are often overestimated in their relevance to reality and, if positive reality and, if positive, are taken as proof of the effectiveness of interventions. measures. This was repeatedly observed in the course of the pandemic.

even among scientifically active physicians and bio-scientists, as the expert explicitly points out.

doctors and bio-scientists.170

The expert also points to this problem in the question of which transmission rates of symptomatic of symptomatic, pre-symptomatic and asymptomatic people are to be expected.

are to be expected. According to her, pre-symptomatic transmission is possible, but not inevitable. inevitable. In any case, according to her, when evaluating real contact scenarios, they are than with mathematical modelling.

From a systematic review with meta-analysis published in December 2020 on Corona transmissions in households, she finds a higher but still not excessive transmission rate for symptomatic index cases of 18%, compared to an extremely low transmission in asymptomatic cases of only 0.7%. The

possibility that asymptomatic people, formerly known as healthy people, transmit the virus, is therefore meaningless.

In conclusion, the expert states in response to evidence questions 1, 3 and 4:

There is no evidence that face masks of different types increase the risk of infection by SARS-CoV-2 at all, or even significantly. This statement applies people of all ages, including children and adolescents, as well as asymptomatic, presymptomatic asymptomatic, pre-symptomatic and symptomatic people.

On the contrary, it is more likely that the even more frequent hand-face contacts when wearing masks could

the risk of coming into contact with the pathogen oneself or of exposing other people to it. or to bring other people into contact with it.

For the normal population, there is no risk of infection, either in the public or private sphere, that could be

risk of infection that could be reduced by wearing face masks (or other measures). could be reduced.

There is no evidence that compliance with distance regulations can reduce the risk of infection. reduce the risk of infection. This applies to people of all ages, including children and adolescents. and adolescents.

These results are confirmed by the extensive findings of the expert Prof. Dr.

Kuhbandner. According to these findings, too, there is no high-quality scientific evidence that wearing face masks can significantly reduce the risk of infection.

can be significantly reduced. The recommendations of the RKI and the S3 guideline of the

of the professional societies are based on observational studies, laboratory observational studies, laboratory studies on the filter effect and modelling studies, which provide only low and very low evidence, because the underlying methodology of such studies does not allow 171

underlying methodology, no really valid conclusions can be drawn from such studies on the effect of masks in

masks in everyday life and in schools. In addition, the results of the individual studies are heterogeneous and more recent observational studies also provide contradictory findings.

findings.

Regarding the randomised controlled trials on the effect of mask wearing that have existed so far of mask-wearing, the expert points out that they do not show any effectiveness of masks.

of masks. On the contrary, the only comprehensive randomised controlled study on the use of study on the use of cotton masks indicates that cotton masks may even even increase the risk of infection. The handling of the mask plays a role here.

which, if poorly handled, can have a negative effect on the risk of infection.

can have a negative effect. However, handling problems are unavoidable for schoolchildren, especially younger ones.

handling problems are unavoidable. The expert Prof. Dr. med.

Kappstein had already pointed out that the handling problem leads to the fact that the masks not only does no good from the point of view of preventing infections, but even but actually does harm.

In addition, the achievable extent of the reduction in the risk of infection through the risk of infection by wearing masks in schools is very small, because even without masks infections occur very rarely in schools. Accordingly, the absolute reduction in risk is so that it cannot be used to combat a pandemic in any relevant way.

According to the expert's explanations, the current alleged increase in the number of infec the expert, it is highly probable that the current increase in the number of the number of tests carried out on children has risen sharply in the preceding weeks. Since the risk of infection in schools is very small, even a possible increase in the rate of even a possible increase in the infection rate of the new virus variant B.1.1.7 to the extent studies, it is not to be expected that the spread of the virus in schools will increase

spread of the virus in schools.

This small benefit is offset by numerous possible side effects with regard to physical, psychological and social well-being.

physical, psychological and social well-being of children, from which many children would have to suffer

many children would have to suffer in order to prevent a single infection.

The expert presents these, among other things, on the basis of the side-effect register published in the scientific journal *Monatsschrift*

Pediatrics, among other sources. 3.

3) The unsuitability of PCR tests and rapid tests to measure the infection incidence¹⁷²

The expert Prof. Dr. med. Kappstein already points out in her expert opinion that

only genetic material can be detected with the PCR test used,

but not whether the RNA originates from viruses that are capable of infection and thus replicable (= capable of reproduction).

replicable) viruses.

The expert Prof. Dr. rer. biol. hum. Kämmerer also confirms in her

molecular biology expert opinion that a PCR test - even if it is carried out

correctly - cannot provide any information on whether a person is infected with an active pathogen or not.

infected with an active pathogen or not.

This is because the test cannot distinguish between "dead" matter*, e.g. a completely harmless

harmless genome fragment as a remnant of the body's own immune system's fight

immune system's fight against a cold or flu (such genome fragments are still found

many months after the immune system has "taken care" of the problem) and

"living" matter, i.e. a "fresh" virus capable of reproducing.

PCR is also used in forensics, for example, to identify residues from hair remains or other trace materials by means of PCR.

DNA from hair residues or other trace materials by means of PCR in such a way that the

the genetic origin of the perpetrator(s) can be identified ("genetic fingerprint").

Even if the PCR, including all preparatory steps (PCR design and establishment of the

(PCR design and establishment, sample collection, preparation and PCR execution) everything is

is done "correctly", and the test is positive, i.e.: detects a genome sequence that is also

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 has been infected with a replicating SARS-CoV-2 virus.

infected with a replicating SARS-CoV-2 and is therefore infectious = dangerous to others.

dangerous.

Rather, for the determination of an active infection with SARS-CoV-2, further, and specifically methods, such as the isolation of replicable viruses, must be used.

must be used.

Regardless of the basic impossibility of detecting an infection with the SARS-CoV-2 virus with the virus SARS-CoV-2 with the PCR test, the results of a PCR test also depend on the

according to the expert Prof. Dr. Kämmerer, the results of a PCR test depend on a series of

parameters which, on the one hand, cause considerable uncertainties and, on the other hand, can be deliberately

manipulated in such a way that many or few (apparently) positive results are obtained.

positive results are achieved.

Of these sources of error, two striking ones are to be singled out.¹⁷³

One of these is the number of target genes to be tested. According to the specifications of the of the WHO from the original three to one.

The expert calculates that the use of only one target gene to be tested in a mixed population would result in

target gene to be tested in a mixed population of 100,000 tests with not a single person actually infected person due to a mean error rate determined in an Instand ring test.

error rate, the result would be 2,690 false positives. Using

3 target genes, there would only be 10 false positives.

If the 100,000 tests carried out were to be representative of 100,000 citizens of a

of a town or district within 7 days, this reduction in the number of target genes used alone would result in

reduction of the target genes used with regard to the "daily incidence" alone would result in a difference of

of 10 false positives compared to 2690 false positives, and depending on that

the severity of the restrictions on citizens' liberty taken.

If the correct "target number" of three or even better (as e.g. in

Thailand) up to 6 genes had been used for the PCR analysis, the rate of positive

positive tests and thus the "7-day incidence" would have been reduced almost completely to zero.

On the other hand, the so-called ct value, i.e. the number of amplification/doubling steps, is one of the sources of error.

/doubling steps up to which the test is still considered "positive".

The expert points out that, according to unanimous scientific opinion, all

"positive" results that are only detected after a cycle of 35 have no scientific (i.e. no

scientific (i.e. not evidence-based) basis. In the range ct value 26-35

the test can only be considered positive if it is matched with viral culture. The RT test

RT-qPCR test for the detection of SARS-CoV-2, which has been propagated worldwide with the

(and all other tests based on it as a blueprint) was set to 45 cycles without any

was set to 45 cycles without defining a CT value for "positive".

In her expert opinion, the expert cites further 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 court's legal notice).

According to this, if the test result does not correspond to the clinical findings of an examined person, a new sample must be taken and

a new sample must be taken and a further examination must be carried out.

and differential diagnostics must be carried out; only then can a positive test be counted.

positive test can be counted. <https://www.who.int/news/item/20-01-2021-who-informationnotice-for-ivd-users-2020-05>

In Thuringia and nationwide, this requirement is as little observed as

multiple counts are excluded in the case of multiple testing of the same person (No.

13 of the court's legal guidance).¹⁷⁴

According to the expert opinion, the rapid antigen tests used for the mass test cannot

in the expert opinion, the rapid antigen tests used for the mass test cannot provide any information on infectivity, as they can only detect protein components without any connection to an intact, reproducible virus.

can be detected.

In order to allow an estimation of the infectivity of the tested persons, the respective positive test would have to be

positive test (similar to the RT-qPCR) would have to be compared individually with the

viruses from the test sample (similar to RT-qPCR), which is not possible in the extremely

This is impossible under the extremely variable and unverifiable test conditions.

Finally, the expert points out that the low specificity of the tests causes a high rate of false positive results.

of false positive results, which entails unnecessary personnel (quarantine) and social (e.g. schools) costs.

(quarantine) and social consequences (e.g. schools closed, "outbreak reports") until they until they turn out to be false alarms. The error effect, i.e. a high number of false positives, is particularly strong in tests on symptomless people.

It should be noted that the PCR test used, as well as the rapid antigen tests, antigen rapid tests, as proven by expert opinion, are in principle not suitable for the with the SARS-CoV-2 virus. In addition, there are the sources of error described and and other sources of error listed in the expert opinion with serious effects, so that an adequate adequate detection of SARS-CoV-2 infections in Thuringia (and nationwide) is not exists in Thuringia (and nationwide).

In any case, the term "incidence" is misused by the state legislator. For "Incidence" actually means the occurrence of new cases in a (repeatedly tested and possibly (repeatedly tested and, if necessary, medically examined) in a defined group of people in a defined period of time.

period of time, cf. no. 11 of the legal notes of the court. In fact, however undefined groups of persons are tested in undefined periods of time, so that what is called the incidence" is simply a matter of reporting data.

According to a meta-study by the medical scientist and statistician John Ioannidis, a medical scientist and statistician and one of the most cited scientists worldwide, which was published in a WHO bulletin in October 2020. is 0.23%, which is no higher than for moderate influenza epidemics.

https://www.who.int/bulletin/online_first/BLT.20.265892.pdf

Ioannidis also concluded in a study published in January 2021 that lockdowns have no significant benefit.

https://www.who.int/bulletin/online_first/BLT.20.265892.pdf#175

4. the violation of the right to informational self-determination through rapid tests in schools

The right to informational self-determination as part of the general right of personality in Article 2(1) of the German Basic Law is the right of the individual

right to decide for oneself on the disclosure and use of one's personal data.

personal data. Such personal data also includes a test result. A

Furthermore, a test result is a personal health "data" in the sense of the General Data Protection Regulation (GDPR), which in principle is nobody's business.

This encroachment on fundamental rights is also unconstitutional. Because with the concrete procedures of the

testing in schools, it seems unavoidable that numerous other persons (fellow pupils (fellow pupils, teachers, other parents) would become aware of a "positive" test result, for example. test result, for example.

This applies accordingly when similar test barriers are erected for access to shopping or cultural events.

or to cultural events.

In addition, any compulsory testing of schoolchildren ordered by state law is already not covered by the Infection Protection Act - irrespective of the fact that this in turn is not covered by the Infection Protection Act - irrespective of the fact that the latter itself is subject to considerable constitutional concerns.

Pursuant to § 28 IfSG, the competent authorities can take the necessary protective measures in the manner specified therein if

necessary protective measures if "sick persons, persons suspected of being ill, suspected of being infected or excretors" are identified. According to § 29 IfSG and must then also tolerate the necessary examinations.

necessary examinations.

In its decision of 02.03.2021, ref. no. 20

NE 21.353, the Bavarian Administrative Court refused to classify employees in nursing homes as ill, suspected of being ill or excreted. This should also apply to pupils. But classification as suspected of being infected is also out of the question.

According to the case law of the Federal Administrative Court, the following are considered suspected of being contagious

of § 2 No. 7 IfSG is anyone who has had contact with an infected person with a sufficient degree of infected person; a mere remote probability is not sufficient. What is required is,

It is necessary that the assumption that the person concerned has ingested pathogens is more probable than the opposite.

than the opposite. The decisive factor for a suspicion of infection is exclusively the probability of a past infection, cf. judgement of 22.03.2012 - 3

C 16/11 - juris marginal no. 31 ff.176

The BayVGH, loc. cit., has rejected this for employees in nursing professions. For schoolchildren nothing else applies.

5 The right of children to education and schooling

Schoolchildren are not only subject to compulsory schooling under Land law, but 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 which is applicable law in Germany.

According to this, all contracting states must not only make attendance at primary school compulsory and

compulsory and free of charge for all, but also to promote the development of

of various forms of general and vocational secondary education, make them available to all

and vocational education, make them available and accessible (!) to all children, and take appropriate

appropriate measures, such as the introduction of free education and the provision of financial

financial support in case of need. The educational goals from Article 29 of the UN Convention on the Rights of the Child are to be observed.

6. result

The compulsion imposed on school children to wear masks and to keep their distance from each other and from third parties is damaging.

to third persons, harms the children physically, psychologically, pedagogically and in their psychosocial

their psychosocial development, without providing more than a marginal benefit for the children

for the children themselves or third parties.

Schools do not play a significant role in the "pandemic".

The PCR tests and rapid tests used are not in themselves suitable in principle and even in their not in themselves suitable for detecting an "infection" with the SARS-CoV-2 virus.

According to the expert reports, this is already clear from the Robert Koch Institute's own calculations.

calculations of the Robert Koch Institute. According to RKI calculations, as expert witness Prof. Dr.

Kuhbandner explains, in mass testing with rapid tests, irrespective of the symptoms

symptoms, the probability of actually being infected when receiving a positive result is

of being infected at an incidence of 50 (test specificity 80%, test sensitivity 98%) is only two percent.

percent. This would mean that for every two true-positive rapid test results, there would be 98 false-positive rapid test results, all of which would then have to be retested with a PCR test.¹⁷⁷

177

A (regular) compulsion to mass test asymptomatic people, i.e. healthy people, without any healthy people, for which there is no medical indication, cannot be imposed, because it is out of proportion to the effect that can be achieved. At the same time, the

At the same time, the regular compulsion to take the test puts the children under psychological their ability to go to school is constantly put to the test.

Based on surveys in Austria, where no masks are worn in primary schools, but they are but rapid tests are carried out three times a week throughout the country

According to the expert Prof. Dr. Kuhbandner:

100,000 primary school pupils would have to put up with all the side-effects of mask-wearing for a week.

of wearing masks for a week in order to prevent only one infection per week.

per week.

To describe this result as disproportionate would be a completely inadequate description.

description. On the contrary, it shows that the state legislator regulating this field

has become distanced from the facts to an extent that seems historic.

historical proportions.

With the ordering of such measures, the welfare of the children is endangered, as shown,

§ 1666 BGB. Teachers are therefore not allowed to order them. Reference is made to the corresponding

The teachers are therefore not allowed to order such measures.

the general decree cited, since they are unsuitable for achieving the intended goals, but in any case objectives, but in any case because of their disproportionate nature.

principle of proportionality and are therefore unconstitutional and void.

Furthermore, the children have a legal right to accessible schooling.

According to the current state of the investigation, it seems very likely that this result will be confirmed in the main proceedings.

result will be confirmed in the main proceedings. Further explanations are reserved for a decision there.

When issuing a temporary injunction, the disadvantages that arise from the

disadvantages that would arise if the arrangement sought by the parents of the children were initially the family court does not initially make the arrangement sought by the children's parents in the temporary

but then later in the main proceedings, and the effects that result if the family court does not the family court does not make the arrangement sought by the parents of the children in the interim the parents of the children in the temporary injunction proceedings, but does not confirm it later in the

is not confirmed.¹⁷⁸

The disadvantages for the children if the settlement sought is delayed by the family court outweigh the disadvantages for the children if the settlement sought is delayed by the family court.

by the family court outweigh the disadvantages for the children.

The parents are in any case not in a position to avert the danger, § 1666 BGB. With a view the imminent end of the Easter holidays, there is also an urgent need to act immediately. to take immediate action.

After all this, the decision evident from the operative part was required. Since the classmates of the children named in the operative part are affected in the same way, the court also made its made its decision for them as well.

The decision on costs is based on § 81 of the Family Proceedings Act.