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

the district court of Weimar by ...
by way of temporary injunction:

I. **The principals and teachers of the schools of the children A, born on ..., and B, born on ..., namely the Staatliche Regelschule X, Weimar, and the Staatliche Grundschule Y, Weimar, as well as the superiors of the principals are prohibited from ordering or prescribing the following for these and all other children and pupils taught at these schools:**

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

II. **To the heads and teachers of the schools of the children A, born on ..., and B, born on ..., namely the Staatliche Regelschule X, Weimar, and the Staatliche Grundschule Y, Weimar, as well as to the superiors of the School administrators are offered to maintain face-to-face instruction at the school for these and all other children and students taught at these schools.**

III. **Court costs shall not be charged. The children involved shall not bear any costs. The parties shall bear their own out-of-court costs.**

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

Reasons

Outline:

A: Facts

A: Facts

I. Introduction

For the children mentioned by name in the operative part, their mother, who is jointly entitled to custody with the children's father, initiated "child protection proceedings pursuant to section 1666 (1) and (4) of the German Civil Code" in a written submission dated 13 March 2021 to the Local Court - Family Court - Weimar.
The children attend the Staatliche Regelschule X and the Staatliche Grundschule Y in Weimar; the older son, aged 14, attends the eighth grade, and the younger son, aged 8, attends the third grade.
Their mother contends that the compulsion imposed on her children in their schools to wear face masks and to maintain minimum distances from each other and from other persons endangers the welfare of her children.
The children would be physically, psychologically and pedagogically damaged without any 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 conventions.
School administrators and teachers should be specifically ordered by the court under Civil Code section 1666(4) to rescind the relevant orders.
To the extent that these orders were based on state regulations, such as statutory ordinances, school administrators and others could not rely on them because they were unconstitutional.
The obligation in Article 100 (1) of the Basic Law to submit a possibly unconstitutional law to the Federal Constitutional Court or to a Land constitutional court expressly applies only to formal laws of the Federation and the Länder, but not to substantive laws such as statutory instruments. According to the established case law of the Federal Constitutional Court (fundamentally BVerfGE 1, 184 ((195 et seq.)), each court must decide for itself whether they are compatible with the constitution, as already stated in AG Weimar, judgment of January 11, 2021 - 6 OWi - 523 Js 202518/20 -, juris.

Insofar as a decision on the merits is not possible in the short term, the court may issue a temporary injunction in accordance with sections 49 et seq. of the Family Proceedings Act.

In addition, the court may take measures to ensure future compliance with the 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 with the proviso that the

To have the Infectious Diseases Protection Act declared null and void, which could otherwise cause new hazards for children in the future as an enabling basis. The Federal Constitutional Court may be asked to combine this separate part of the proceedings with 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.

The court thereupon instituted the present temporary injunction proceedings 9 F 148/21 and the parallel main proceedings 9 F 147/21 and appointed the lawyer named in the heading as counsel for the children in accordance with § 158 FamFG.

II. The provisions of the Free State of Thuringia on the masking requirement applicable to children in schools

For the children, the provisions of the general decree of 31.03.2021 for the enforcement of the Thuringian Ordinance on Infection Protection Rules for Containing the Spread of Coronavirus SARS-CoV-2 in Child Day Care Facilities, Other Youth Services, Schools and for Sports (ThürSARS-CoV-2-KiJuSSp-VO), insofar as it orders in No. 7 the wearing of a mouth-nose covering and a qualified face mask, as well as against the legal regulations cited by the general decree.
The provisions at issue have the following overall wording:

1.

General decree dated 31.03.2021 on the enforcement of the Thuringian Ordinance on the Infection Protection Rules for Containing the Spread of the Coronavirus SARS-CoV- 2 in Child Day Care Facilities, Other Youth Services, Schools and for Sports (ThürSARS-CoV-2-KiJuSSp-VO)

General ruling

Pursuant to Section 2 (2) in conjunction with Section 15 Sentence 1 and Section 37 Sentence 1 of the Thuringian Ordinance on Infection Protection Rules to Control the Spread of Coronavirus SARSCoV-2 in Child Day Care Facilities, Other Youth Services, Schools and for Sports (ThürSARS-CoV-2-KiJuSSp-VO) of 13. February 2021 and pursuant to § 35 sentence 2 Thuringian Administrative Procedure Act of December 1, 2014 (GVBl. p. 685), the Thuringian Ministry of Education, Youth and Sports (TMBJS) in consultation with the Thuringian Ministry of Labor, Social Affairs, Health, Women and Family (TMASGFF) issues

for the Free State of Thuringia
the following general decree:
...
No.
7.
According to § 38 para. 5 ThürSARS-CoV-2-KiJuSSp-VO, pupils from the completed sixth year of life and teachers of state schools are obliged to wear a qualified face mask according to § 5 para. 3 3rd ThürSARS-CoV2- SonderEindmaßnVO within the school building. For pupils in grades 1 to 6, the use of a face mask according to § 6 para. 3 to 5 2nd ThürSARS-CoV-2- IfS-GrundVO is sufficient. The obligation to wear a qualified face mask applies to students from grade 7 and to teachers of all state schools in each grade level also during lessons.
The mask requirement for students does not apply to physical education classes. A break from wearing the face mask or mouth-nose covering must be ensured at regular intervals, which should take place outdoors or during the ventilation break. The obligation does not apply when taking meals, although it must be ensured that a minimum distance of 1.50 m is maintained. The school management shall decide on further exceptions to the obligation in individual cases at its due discretion.

2.

Thuringian Ordinance on the Update of the Measures Required to Control the Spread of the Coronavirus SARS-CoV-2 in Daycare Facilities for Children, Other Youth Services, Schools, and for Sports Operations From February 13, 2021

Based on § 32 sentence 1 of the Infection Protection Act (IfSG) of July 20, 2000 (BGBl. I p. 1045), last amended by Article 4a of the Act of December 21, 2020 (BGBl. I p. 3136), in conjunction with § 7 para 2 of the Thuringian Ordinance on the Regulation of Responsibilities and the Transfer of Authorizations under the Infection Protection Act (ThürIfSGZustVO) 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 Sports in agreement with the Ministry of Labor, Social Affairs, Health,
Women and family
and due to § 32 sentence 1 in conjunction with §§ 28, 28a, 29, 30 paragraph 1 sentence 2 and § 31 IfSG in conjunction with § 7 paragraph 1 ThürIfSGZustVO decrees the Ministry of Labor, Social Affairs, Health, Women and Family:
....
§ 37

Changed presence for students during the "Yellow II" phase

The Ministry may order measures for increased protection against infection pursuant to Sections 38 to 40 statewide or for specific regions. These measures change school operations statewide or regionally for all students and restrict the entitlement to funding under Section 10 (2) ThürSchulG. The organizational implementation on site is the responsibility of the school administrators within the scope of their professional responsibility.

§ 38

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

…

(5) The Ministry may, in accordance with Section 2 (2), extend the obligation to use a mouth-nose covering in accordance with the requirements of Section 6 (3) to (5) 2nd ThürSARS-CoV-2- IfSGrundVO or a qualified face mask in the sense of Section 5 (3) 3rd ThürSARS-CoV-2-SonderEindmaßnVO for pupils from grade 7 and for all teachers to lessons; Section 5 (2) sentence 2 3rd ThürSARS-CoV-2- SonderEindmaßnVO shall apply accordingly. A break from the use of the mouth-nose covering or the qualified face mask must be ensured at regular intervals. The school management decides on exceptions from the obligation according to sentence 1 according to dutiful discretion.

3.

Third Thuringian Ordinance on Extraordinary Special Measures to Contain a Surge in the Spread of the SARS-CoV-2 Coronavirus (Third Thuringian SARS-CoV-2 Special Containment Measures Ordinance -3. ThürSARS- CoV-2-SonderEindmaßnVO-) of 12.03.2021

First Section Priority

of Application

§ 1 Priority of application

(1) Supplementary to the provisions of the Second Thuringian SARS-CoV-2- Infection Protection Basic Regulation (2. ThürSARS-CoV-2-IfS-GrundVO) of July 7, 2020 (GVBl. S. 349), as amended from time to time, and the provisions of the Thuringian Ordinance on the Infection Protection Rules for Containing the Spread of the SARS-CoV-2 Coronavirus in Child Day Care Facilities, Other Youth Services, Schools and for Sports Operations (ThürSARSCoV-2-KiJuSSp-VO) of February 13, 2021, as amended from time to time, 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 Second Thuringian SARS-CoV-2 Infection Prevention Basic Ordinance

and the Thuringian Ordinance on Infection Protection Rules for Containing the Spread of the Coronavirus SARS-CoV-2 in Child Day Care Facilities, Other Youth Services, Schools and for Sports Operations.

(3) Further orders and measures according to § 13 2nd ThürSARS-CoV-2- IfSGrundVO remain unaffected. For further orders according to sentence 1, the prior consent of the highest health authority must be obtained in the cases of §§ 6a and 6b.

....

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

(1) In addition to § 6 para. 1 and 2 2nd ThürSARS-CoV-2-IfS-GrundVO, the obligation to use a mouth-nose covering also applies to

1. in all closed 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 with public traffic in city centers and in the public open air, where persons are either in a confined space or not only temporarily,
3. in front of retail stores and in parking lots,
4. in the case of assemblies in accordance with Section 8 (1) Sentence 1 No. 1 2nd ThürSARS-CoV-2-IfS-GrundVO,
5. at events and meetings for religious and ideological purposes according to § 8 para. 1 sentence 1 no. 2 2nd ThürSARS-CoV-2-IfS-GrundVO and
6. in the case of events organized by political parties pursuant to Section 8 (1) Sentence 1 No. 3 2nd ThürSARSCoV-2-IfS-GrundVO.

The competent authorities pursuant to Section 2 (3) ThürIfSGZustVO shall determine the locations pursuant to sentence 1 no. 2 and identify them. Regulations on the use of a mouth-nose covering are reserved for the facilities and offers according to § 1 para. 1 sentence 1 nos. 1 to 4 ThürSARSCoV-2-KiJuSSp-VO to the separate orders of the ministry responsible for education.

(2) Persons 15 years of age or older must use a qualified face mask in place of the mouth-to-nose covering:

1. for events and meetings for religious and ideological purposes in accordance with Section 8 (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 public transport according to § 6 para. 1 2nd ThürSARS-CoV-2-IfS-GrundVO,
3. as customers in stores and service establishments open to the public or when using services and offers open to the public,
4. during the theoretical lessons in closed rooms of the driving and flying schools, the theoretical driving and flying license examination as well as practical

Training and practical driving and flying license examination in closed driving and flying school aircraft,

5. At meetings of municipal bodies, Page 5 of 19 6. As physicians or therapists, in each case including their staff, and as patients in medical practices, practices of psychotherapists and physiotherapists, or other outpatient facilities serving medical and therapeutic care, except in treatment rooms if the nature of the service does not permit this.

Sentence 1 applies accordingly to children from the completed sixth to the completed 15th year of life with the proviso that the use of a mouth-nose covering according to the specifications of § 6 para. 4 2nd ThürSARS-CoV-2-IfS-GrundVO is sufficient. In addition, every person is required to use a qualified mouth-nose covering, especially in closed rooms in situations where closer or longer contact with other persons is unavoidable.

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

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

Approved qualified face masks according to sentence 1 are published on the website of the 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 SARS CoV-2 Occupational Health and Safety Ordinance of January 21, 2021 (BAnz AT 22.01.2021 V1), as amended, shall remain unaffected.

4.

Second Thuringian Ordinance on Basic Infection Protection Rules for Containing the Spread of the Coronavirus SARS-CoV-2 (Second Thuringian SARS- CoV-2 Infection Protection Basic Ordinance -2. ThürSARS-CoV-2-IfS-GrundVO-) of 12.03.2021

…

§ 6 Use of a mouth-nose covering

(1) In closed vehicles of public transport, especially in railroads, streetcars and buses, in cabs, in coaches and in other means of public transport, passengers are obliged to use mouth-nose covering.

(2) In stores open to the public, customers are required to use mouth-to-nose covering.

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

1. Children up to the age of 6,
2. Persons for whom the use of an oral-nasal covering is not possible or unreasonable due to disability or for health or other reasons; this must be made credible in a suitable manner,
3. groups of persons as defined in Section 1 (2) in coaches and other means of transport as defined in paragraph 1, provided that they use the means of transport exclusively for themselves and there is no public traffic.

(4) Self-sewn or self-made cloth masks, scarves, shawls, hoods and head masks as well as other coverings of the mouth and nose can be used as mouth-nose coverings. The mouth-nose covering should fit snugly and fit well.

(5) The prohibition of the use of anti-constitutional symbols and other prohibited symbols, in particular in accordance with Sections 86a and 130 of the German Criminal Code and in accordance with the provisions of association law, 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, attends the 8th grade of the Staatliche Regelschule X in Weimar. He therefore falls within the scope of the general ruling.

The counsel for the parties submits that the first party must wear a mask in the school building and in the classroom up to his seat, after which he is usually allowed to remove the mask. In the schoolyard, a mask must also be worn if the distance of 1.50 m cannot be maintained. The students would be continuously asked to wear a qualified mask all day, even in class, although they were not yet 15 years old.

In the week from 08.03.2021 to 12.03.2021, a qualified mask had to be worn even in physical education classes. According to the principal, the child had to wear the mask all day.

Since masks have been compulsory, the party to 1) no longer likes to go to school. He has severe headaches and often feels nauseous when he wears a mask. Minor infections, such as colds and mild coughs, increase when he wears a mask. These infections also last longer than usual. The party to 1) is very nauseous two to three times a week when he wears the mask. He had headaches mostly after school and at the end of the day.

of the teaching day, but then so much so that he almost had to throw up from the pain.
The party to 1) had submitted a mask certificate on 22.03.2021. As a result, he was discriminated against and insulted by his teacher. He had to sit in the back corner of the classroom and was no longer addressed by name, but only as "You without mask". On 23.03.2021, the principal then called the parents of the party to 1). He informed them that the certificate of the party to 1) had been taken note of, but that it did not exempt him from the mask obligation at school. The issuance of a mask exemption was the responsibility of the principal, he continued. According to the principal, a doctor could not exempt party 1), it was only up to the principal to do so. According to the principal, all students from the 7th grade onwards would have to wear a so-called qualified mask. Purely actually, however, the masks are often not worn in class, these are then the mask breaks.
The party to 1) had to wear a mask or keep his distance in the schoolyard during the break, there was to be no direct contact. He doesn't think this is so great, because that is the only time when he can talk to his classmates.
There is no risk assessment.
The teachers did not pay attention to correct handling of the mask or changing it when it became 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, at the age of 8, attends the 3rd grade of the State Elementary School Y in Weimar. He therefore falls within the scope of the general ruling.
The counsel for the parties submits that the second party must wear a fabric mask/hose scarf in the school building and in the classroom until he is seated. On the way to lunch and in the dining room, a mask must also be worn until the second party sits at the table with his food. He was allowed 15 minutes to eat, and was not allowed to eat in peace. In the after-school care rooms, the children should also wear masks, so the after-school care worker goes out a lot to reduce the mask times.
No masks need to be worn in class at this time, these are the mask breaks.
Since the obligatory wearing of the mask, the second party no longer likes to go to school. He has increased headaches, sometimes with nausea. In addition, the participant to 2) often has abdominal pain. Severe headaches and nausea occur about once or twice a week. Participant 2) has abdominal pain about four times a month, and then

but also with vomiting. The party to 2) had headaches and indisposition in temporal connection with the wearing of the mask, abdominal pain he had mostly at night. He cries in his sleep and sleeps very restlessly. At school, the second patient did not dare to say anything when he was feeling bad.
The problems were not discussed with the school administration because the parents were afraid of reprisals against their child and wanted to protect it.
There was no risk assessment. The teachers did not pay attention to correct handling of the mask or to changing the mask when it became wet. The teachers also did not explain anything about wearing the mask.
In addition, the second party had already been told by another teacher that he should not wear a tube scarf but a real mask. The party to 2) was then so disturbed that he now reluctantly went to school.

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

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

Encroachments on these fundamental rights - regardless of whether caused by private individuals or public officials - could not be assessed differently from an objective threat to the ***"Best interests of the child***" as defined in §§ 1666 BGB, 157 FamFG.

The school-internal order to wear masks and to keep a spatial distance to other persons violated, just like the underlying containment order of the Free State of Thuringia, concretely 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: on upbringing and care by parents (also with regard to measures for health care and care to be provided by children).
  "Items").

In addition, **children's rights and claims for protection under international conventions were** concretely 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 private life, his family, his home;
Art 16(2) - on legal protection against assault; 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, Adherence to specific goals of schooling;
Art 37a - Prohibition of torture, degrading treatment;
Art 37 d - special legal protection in case of deprivation of liberty;

from the **Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment of 10.12.1984 (BGBl. 1990 II S. 246):**

Art. 1
(1) For the purposes of this Convention, "torture" means any act by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person ...
Art. 2
(1) Each State Party shall take effective legislative, administrative, judicial or other measures to prevent torture in all areas under its jurisdiction.
(2) Exceptional circumstances of whatever nature, whether war or threat of war, domestic political instability, or other public emergency, may not be invoked as a justification for torture.
(3) An instruction issued by a superior or a holder of public authority may not be invoked as a justification for torture.
Art. 4
(1) Each State Party shall ensure that under its criminal law all acts of torture are criminal offences. The same shall apply to attempted torture and to acts committed by any person which constitute complicity or participation in torture.
(2) Each State Party shall punish such offences with appropriate penalties which take into account the gravity of the offence.

Art. 5

(1) Each State Party shall take such measures as may be necessary to establish its jurisdiction over the offences referred to in Article 4 in the following cases;

from the **European Convention on Human Rights**

Art. 8

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

(2) A public authority may interfere with the exercise of this right only to the extent that the interference is provided for by law and is necessary in a democratic society for national security or public safety, for the economic well-being of the country, for the maintenance of order, for the prevention of crime, for the protection of health or morals, or for the protection of the rights and freedoms of others;

by exceeding the limits set by the **International Covenant on Civil and Political Rights of 19.12.1966 (BGBl 1973 II 1553):**

Art 4

(1) in the event of a **public emergency threatening the life of the nation** and officially proclaimed, States Parties may take measures suspending their obligations under the present Covenant to **the extent strictly required by the situation,** provided that such measures are not inconsistent with their other obligations under international law and do not discriminate solely on the basis of race, color, sex, language, religion or social origin.

(2) Based on the above provision, Articles 6, 7, 8 (paragraphs 1 and 2), 11, 15, 16 and 18 may not be repealed.

(3) Any State Party exercising the right to abrogate obligations shall promptly communicate to the other States Parties, through the intermediary of the Secretary-General of the United Nations, the provisions which it has abrogated and the reasons for doing so. By the same means, a further communication shall indicate the date on which such action shall cease.

For personal liberties, see, e.g., Art. 9, 12, Art. 17.

(1) No one shall be subjected to arbitrary or unlawful interference with his or her private life, family, home and correspondence, or to unlawful impairment of his or her honor and reputation.
(2) Everyone is entitled to legal protection against such interference or impairment.

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

An encroachment on these rights of the child under the Basic Law and international conventions could not be assessed differently from an objective endangerment of the "best interests of the child" within the meaning of §§ 1666 BGB, 157 FamFG, irrespective of who the encroachment originated from.

If the law, not least on the basis of Articles 2, 1 and 6 of the Basic Law in § 1631 (2) of the Civil Code, prohibits parents from certain forms of upbringing and makes this a punishable offence in §§ 223 et seq. and 171 of the Criminal Code, among other things, similar treatment cannot be lawful simply because it is carried out by or on behalf of state officials. This is underscored not least by the stricter penalties for violations of the law by public officials.

Accordingly, if every restriction of the special rights of the child, whether under the Basic Law or international conventions, required special justification, it was subject to the constitutional requirement of proportionality in each individual area.

In this respect, what the Federal Constitutional Court and the Federal Court of Justice had said about the admissibility of separating a child from its parents must also apply here:

BVerfG v. 24.3.2014 - 1BvR 160/14 - ZKJ 2014, p. 242 ff:
It cannot be established with sufficient certainty that the separation of the children is suitable for eliminating or mitigating the dangers assumed by the courts. It is true that separation would in principle be suitable for eliminating the dangers that the courts believe exist for the children with the mother.
eliminate. However, the separation of the child from parents regularly evokes independent burdens, because the child can suffer from the separation even if his or her well-being was not secured with the parents. A measure

cannot be regarded without further ado as suitable for safeguarding the welfare of the child if it may in turn have adverse consequences for the welfare of the child. Such negative consequences of a separation of the child from its parents and an external placement are to be taken into account (see) and would have to be compensated for by the elimination of the established

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

(S. 244,245)

From the BGH decision dated 26.10.2011 - Az:12 ZB 247/11= ZKJ 2012, 107 ff:

... Suitability is not only lacking if the measure cannot eliminate the endangerment of the child's welfare. Rather, the measure is also unsuitable if it is accompanied by other impairments to the best interests of the child and these are not outweighed by the elimination of the identified danger.

become inappropriate if, in turn, they have other concerns for the child's welfare.

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The child's situation at risk is not improved due to the fact that the child's situation is endangered. (ZKJ P. 109)

According to these principles, an intervention is only permissible if**, prior to a restriction of the** child's **fundamental rights, a** concrete weighing of the possible dangers to the child (or to others) has been carried out, irrespective of the dangers to the child (or to others) that are to be averted, and which are threatened by the orders and executive measures that are specifically carried out to avert them.

Measures would have to be omitted if there were no concrete findings from which a legally significant preponderance of the dangers to be averted could be derived.

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

There was a lack of both a comprehensible determination of existing concrete dangers for higher-value legal interests of others through children (cf. on this, e.g., **Reiss, Bhakdi: *Corona False Alarm?* GOLDEGG 2020**) as well as a concrete determination of the dangers to be expected through the measures themselves for the affected children as well as a concrete weighing of the two.

For further details of the suggestion, please refer to the brief dated March 13, 2021.

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

The court issued detailed legal guidance on March 16, 2021, and updated it on March 25, 2021. The Free State of Thuringia and the heads of the schools attended by the children were involved in the proceedings.

With the legal notices, the Free State of Thuringia and the school administrations involved were requested to comment in detail on all issues raised in the suggestion regarding this procedure and, in addition, on the issues listed below, which took the following form in the updated version of 25.03.2021:

"The opinion should state the scientific evidence for all factual claims on all questions and support them with citation of accessible sources.

1. What exactly are the objectives of the Free State of Thuringia with the measures, in particular the mandatory wearing of masks by schoolchildren and the distance regulations that apply to them?
2. Is there evidence-based proof of the benefits of these measures with respect to spread with the SARS- CoV-2 virus?
3. Have the possible physical effects of the mask requirement in particular, but also of the distance requirements for children, been examined on the basis of evidence, especially with regard to the different breathing volumes of adults and children? What results, based on which studies and sources, did the Free State of Thuringia arrive at?
4. Have the possible psychological effects of the mask requirement in particular, but also of the distance requirements for children, been examined in an evidence-based manner? Were the possible consequences due to possibilities of only reduced communication, possible dangers due to distorted perception of facial expressions and emotions, and possible dangers for psychosocial development examined? What results did the Free State of Thuringia arrive at based on which studies and sources?
5. Has the proportionality of the measures in terms of the benefits (both for the schoolchildren themselves and for third parties) versus the possible negative effects for the schoolchildren and third parties been examined and assessed in a comprehensible manner?
6. How is the incidence of infection with the SARS-CoV-2 virus determined?

7. As far as the RT-q-PCR test is used for this purpose: Which test or tests (manufacturer/test name) is/are performed in laboratories in Thuringia? How are the laboratories accredited that perform the test? What test controls are used? How do the authorities monitor the reliability of the test performance? Are independent interlaboratory tests performed on a regular basis?
8. How many gene segments and which ones were and are examined in the RT-q-PCR test in Thuringia? Up to which amplification/doubling steps (ct value) was and is the test evaluated as "positive" in Thuringia?
9. Is the RT-q-PCR assay capable of detecting a replicable and passable SARS-CoV-2 virus?
10. What is the sensitivity and specificity of the RT-q-PCR tests used? As far as is known, these parameters have been determined in practice by a German institution only once so far according to a test design recognized for an interlaboratory comparison, namely by INSTAND, a society for the promotion of quality assurance in medical laboratories e.V., which cooperates with the WHO, among others. This comes in its 51-page "Commentary on the Extra EQA Test Group 340 Virus Genome Detection-SARS-CoV-2" by Prof. Dr. Heinz Zeichhardt, Charité - Universitätsmedizin Berlin, and Dr. Martin Kammel - in cooperation with the Charité, Universitätsmedizin Berlin, Institute of Virology, the National Consultant Laboratory for Coronavirus Prof. Dr. Christian Drosten, Dr. Victor M. Corman et al. - of 2.5.2020, updated on 3.6.2020, with regard to 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 excluded. Is 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).
    If this false-positive rate of between 1.4 and 2.2% is included - let this be shown verbally and mathematically - what remains of the "incidences" currently reported for Thuringia, assuming realistic prevalences? https://www.instand-ev.de/ringversuche-online/ringversuche-service.html#rvp//340/-2020/

11. What exactly is meant by "incidence"? As far as known to the court, this term means the occurrence of new cases in a (repeatedly tested) defined group of persons in a defined period of time, whereas according to the information available to the court, the testing actually

undefined groups of persons in undefined periods of time, which would mean that the so-called "incidences" would only be simple reporting data. If this is the case, how does this affect the validity 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? 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 further examination must be carried out as well as 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-users- 2020-05
13. Is it ensured that persons who have been tested more than once are not treated each time as a new

    "Case" be counted? How is this done, if necessary?
14. How does the additional introduction of rapid tests affect the identification of the incidence of infection? Will those testing negative also be counted in the rapid tests? How is it ensured that the combination of a positive rapid test and a negative RT-q-PCR test does not then appear as "positive" in the statistics or that "positive" is only counted as "positive" once for both tests (analogous to question 13)? Are those tested negative in the rapid test also included for the determination of a realistic infection rate?
15. Does the other party assume that asymptomatic positives can be contagious, i.e., pass on the SARS-CoV-2 virus? If the answer is yes, please quantify this and provide the scientific evidence. Will this include consideration of the study from Wuhan, China, published on 11/20/2020, with approximately 10 million participants? Researchers in this study concluded that the detection rate of asymptomatic positive cases in Wuhan after the previously implemented lockdown was very low at 0.303/10,000, and there is no evidence that the identified asymptomatic positive cases were infectious at all. https://www.nature.com/articles/s41467-020-19802-w
16. Does the Other Party assume that pre-symptomatic positives can be contagious, i.e., pass on the SARS-CoV-2 virus? If the answer is yes, please quantify this.
17. What is the infectivity of symptomatic positive test persons?
18. Is testing currently still looking for and testing for other viruses, such as influenza?"

By order also dated 25.03.2021 in the parallel main proceedings 9 F 147/21, a taking of evidence was ordered. The order has the following content regarding the evidentiary issues:

"Evidence shall be taken on the issues listed below under I. by obtaining written expert opinions.
The appraisal shall expressly include the issues raised in the court's updated legal guidance dated March 25, 2021.

I. Evidence shall be taken on the following questions:

1. Can wearing face masks of different types (appreciably) reduce the risk of infection with SARS-CoV-2 coronavirus? A distinction should be made between children in particular and adults in general and between asymptomatic, pre-symptomatic and symptomatic individuals.
2. What physical, psychological, and educational harm can result from wearing masks, especially in children?
3. Is there any risk of infection at all that could be lowered by wearing face masks (or other measures)?
4. Can compliance with spacing requirements reduce the risk of infection, especially in children?
5. Might children even provide "protection" from spread with SARS-CoV-2 coronavirus in the sense that they are more likely to slow the spread of the virus and more likely to protect against severe covid-19 illness?
6. What is the methodological level and, if applicable, what are the methodological deficiencies of existing studies on the incidence of infections in schools and on the effectiveness of measures such as wearing masks and keeping a distance in schools?
7. What is the power of the RT-q-PCR assay and currently used rapid tests to detect SARS-CoV-2 coronavirus infection?"

Prof. Dr. med. Ines Kappstein and Prof. Dr. Christof Kuhbandner were appointed as experts for the questions I.1. - 6. Prof. Dr. rer. biol. hum. was appointed as an expert for question I.7. Ulrike Kämmerer was appointed.

Prof. Dr. med. Ines Kappstein, hygienist, is a specialist in microbiology, virology and infection epidemiology as well as a specialist in hygiene and environmental medicine. Her habilitation was in the field of hospital hygiene. From 1998 to 2006, she worked at the Klinikum rechts der Isar of the Technical University of Munich. From 2006 to 2016, she was chief physician of the hospital hygiene department at Kliniken Südostbayern AG in the districts of Traunstein and Berchtesgadener Land. Since 2017, she has been in charge of several acute, specialist and rehabilitation clinics in an independent capacity.

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.

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

VI. Statement of the procedural counsel

The lawyer appointed as guardian ad litem submitted a comprehensive statement on all factual and legal issues in a written submission dated April 6, 2021, comprising almost 170 pages. Reference is made to this for further details.

VII. Comments from other interested parties

A statement by the Free State of Thuringia and the children's schools has not been made within the time limit set in the present temporary injunction proceedings.

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

Prof. Dr. med. Ines Kappstein, hygienist, is a specialist in microbiology, virology and infection epidemiology as well as a specialist in hygiene and environmental medicine. Her habilitation was in the field of hospital hygiene. From 1998 to 2006, she worked at the Klinikum rechts der Isar of the Technical University of Munich. From 2006 to 2016, she was chief physician of the Department of Hospital Hygiene at the Kliniken Südostbayern AG of the districts of Traunstein and

Berchtesgadener Land. Since 2017, she has been in charge of several acute, specialist and rehabilitation clinics on a self-employed basis.

The expert rendered her opinion, which is incorporated herein in its entirety, as follows:

I will comment on the evidentiary questions to the extent that I can deal with them from my professional background of infection control - with particular reference to the transmission of infectious agents and the development of infections. This applies to questions **1.** and **3.** which are summarized in **part A.** , **part B.** and **part C. of** the expert opinion, as well as to question **4**.

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

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

1. For work in **hospital hygiene** (= prevention of infections in connection with the medical care of patients, so-called nosocomial or hospital-acquired infections), one must have knowledge of the transmission routes of infectious agents, from which the infection protection measures required in individual cases (so-called hygiene measures) can be derived. Hand hygiene (usually in the form of hand disinfection) plays the most important role here. Masks (as so-called OR masks = surgical masks) have been used comparatively rarely outside the OR department, and then only selectively for close vis-à-vis contacts with patients with respiratory infections. FFP masks (usually as FFP2 masks) have been used almost exclusively when entering the room of patients with open tuberculosis of the respiratory tract (or also during bronchoscopy of patients with suspected tuberculosis).

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

(a) Contact. (1) Pathogen transmission **through direct contact** (= physical contact) of an infected person with a non-infected person. (2) Pathogen transmission by **indirect contact** via shared objects or surfaces with which an infected person has previously had contact or which have been contaminated with infectious material from an infected person and which are subsequently used by an uninfected person.

In the case of both direct and indirect contact, the pathogens usually only reach the skin of the (as yet) uninfected contact person primarily, especially the hands. Respiratory viruses must subsequently be brought to their ports of entry in the area of the mucous membranes of the upper respiratory tract (eyes, nose, mouth). This is usually done by frequent and mostly unconscious hand-face contacts. Presumably, a rapid sequence of the various steps is usually required for effective transmission of infectious pathogens with subsequent infection of the contact person. Such contacts characterize the coexistence of people especially in the private sphere, but also, although less so, in the public sphere. Whenever several people are together in a confined space over a longer period of time (e.g., break-time conversations among colleagues, celebrations),

direct and indirect contact as well as droplets (see below) must be considered as transmission routes.

(b) Droplets. Specific form of contact transmission by droplets (> 5 µm in diameter) of respiratory secretions in close vis-à-vis contact (< 1 - 2 m) with a duration of at least 15 min between an infected and a non-infected person.

For example, situations are involved in which two persons stand opposite each other at a distance of less than 1 - 2 m vis-à-vis = face-to-face or from (face) to (face) and talk to each other. In principle, it is possible that the respiratory droplets released by the infected person when speaking will hit the mucous membranes of the face of the person opposite and not (yet) infected (eye, nose, mouth), i.e. that the pathogens will be transmitted in this way.

Contact transmission and droplet transmission have been considered the key modes of transmission for respiratory pathogens for decades, predominantly on the basis of epidemiological studies.

(c) Air. Inhalation of infectious particles (< 5 µm in diameter) freely suspended in the air.

The transmission of the pathogen through the air (aerogenic transmission) was previously only considered significant in the case of tuberculosis of the respiratory tract (lungs, larynx) and is even the only natural transmission route in tuberculosis, but only if the infected person has a so-called open tuberculosis of the respiratory tract, whereby the tubercle bacteria are released via the exhaled air of the infected person. The air in the room contaminated with the tuberculosis pathogens is inhaled by persons present at the same time (or by persons who enter the room after the infected person has left it). Tubercle bacteria suspended in the air can penetrate as far as the alveoli (= pulmonary alveoli), and this is precisely where these pathogens must reach in order to trigger tuberculosis in the first place. However, whether other persons breathing this room air have the pathogen contact required for an infection to occur depends, among other things, on the size of the room and thus on its air volume, on the ventilation of the room and thus on the dilution of the pathogen in the air, and not least on the amount of the pathogen that the infected person releases (or has released), for example, when coughing, and thus on the probability that other persons will come into contact with contaminated air during inhalation.

Exactly this transmission route was postulated in spring 2020 soon after the appearance of Sars-CoV-2 as a significant transmission route for this new pathogen. In the course of 2020, the idea of the so-called aerosol transmission of SARS-CoV-2 has become so dominant in the international literature as well as in the media - however, not supported by corresponding announcements of the international health authorities - that various 'hygiene measures' (e.g. air purification devices, ventilation) have been demanded for months now in order to reduce this allegedly high risk (see **part C.**). Already with regard to influenza viruses, it has been discussed for years whether they might also be transmissible through the air, but no confirmation was found. De facto, measures to protect against transmission of the pathogen were never established in hospitals, even in the case of influenza, which were aimed at transmission via the air. The recommendations of the RKI, for example, did not and still do not provide for this.

3. A great many results from studies of the effectiveness of non-pharmaceutical interventions to contain the pandemic, such as public masks in particular, are based on **mathematical modeling**, the specifics of which will be briefly reviewed here:

   Mathematical modeling (also called mathematical estimation) is well known from weather forecasting and climate research, but has also been used for many years to predict the course of epidemics and the influence of various preventive measures. They are used especially when there is little meaningful data from direct studies. A very large proportion of all studies on SARS-CoV-2 (e.g., effectiveness of masks) are mathematical modeling exercises that have very limited power because their results do not reflect 'real' life but are based on assumptions. The results depend on these 'set screws' and therefore reflect a simplified picture of reality. Such studies can therefore only ever provide 'if-then' results. On one side of the spectrum there are purely theoretical modeling studies and on the other side there are those that work with as much clinical epidemiological data as is available. Invariably, however, the result has very limited validity, and the quality of the scientific evidence is moderate at best. However, the results of such studies in the context of SARS-CoV-2 are often vastly overestimated in their relevance to reality and, if positive, are taken as evidence of the effectiveness of interventions. This could be observed repeatedly in the course of the pandemic, even among scientifically active physicians and among bioscientists.

Answering the questions of evidence

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

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

A. Masks

This section describes the literature that supports the effectiveness of masks in public places (e.g. stores, public transport, schools, offices, etc.), the published studies that speak against the effectiveness of masks, and the statements that can be made about pathogen transmission from asymptomatic, pre-symptomatic and symptomatic persons. All statements apply equally to adults, adolescents and children.

The RKI's 'reassessment': what was the rationale for masks?

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

The 're-evaluation' of the RKI resulted in the fact that masks should not be worn to protect the wearer (= *self-protection*, in particular as for medical staff during patient care in hospitals), but to protect fellow humans (= *external protection;* Engl. *source control, i.*e. to protect other humans from the pathogen source),

this, however, not from people with symptoms of upper respiratory tract infections (sore throat, cold, cough), but from - clinically - healthy people (the people with symptoms should stay at home anyway).

The RKI recommends masks in public ('... *as a further building block to protect risk groups ...'* [1]), so that the wearer of the mask, who may already be infected unnoticed and already excreting the pathogen in the respiratory secretion, cannot release his respiratory droplets unhindered, e.g. when speaking. The droplets should be retained to a significant extent by the mask, thus preventing 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 who do not (cannot) know it yet, because they do not yet have any symptoms (pre-symptomatic) or will not develop any at all (asymptomatic), protect *all* other people they meet from a possible contact with the pathogen through their mask. Ultimately, this should directly or indirectly protect in particular those people who have an increased risk of severe infection by SARS-CoV-2 due to old age and / or certain chronic diseases, because for all other people, the virus is known to pose no danger (according to current knowledge, this also applies to the new variants), because they either, as is typical for influenza, for one to two weeks more severe illness and have to lie in bed (with eg.In most cases, however, they develop only mild respiratory symptoms (as in the case of a common cold) or do not become ill at all.

In the spring of 2020, a discussion developed internationally among experts about the possible benefit of masks for the protection of fellow humans (*protection of others)* from clinically healthy but already infected and thus potentially infectious people, that masks should not be worn for self-protection but for '*altruism and solidarity*' (= *protection of others*) [2]. This ultimately led to the mask recommendation of the RKI, which is therefore about '*external protection*' - and not about self-protection, especially of persons from risk groups. The fact that self-protection also played a role because of the new variants of the virus was only then emphasized by politicians, and this was the reason for the obligation to wear medical masks (OP masks or FFP2 masks) instead of the everyday masks made of fabric. For all persons who do not have to deal professionally with how infectious agents are transmitted, masks as protection against a respiratory virus should be quite plausible, whereby the idea of self-protection is certainly always leading.

At no point in the article about the 'reassessment' does the RKI explicitly say that there is a scientific basis (in the sense of scientific proof or evidence
evidence) for the use of masks in public [1]. This conclusion is merely suggested by the ambiguous wording of the text. The RKI article was published online in advance, as is common practice in journals today, as early as April 14, i.e., immediately after Easter 2020. Thus, the RKI statement was available in time for the German government's decision on the relaxation measures of the first lockdown, which were announced for one week after Easter 2020. In print, the article did not appear until May 7, 2020, about a week after the introduction of the mask requirement (and this date is - see below - still relevant). It is interesting that the President of the RKI on April 28.

2020, i.e. on the day of the decision by the German government to make masks mandatory, spoke in an interview with the 'Deutsches Ärzteblatt' about the '*low added value' of* masks, which, however, would only come into effect if they were used '*correctly*' [3].

The official presentation of the RKI's mask recommendation in [1] was soon modified somewhat, as just six days after the May 7, 2020 print version of the article, on May 13, 2020, under the heading '*Answers to Frequently Asked Questions (FAQ)*', the RKI expressed a cautious view on third-party protection by masks:

> '*A protective effect has not yet been scientifically proven, but it seems plausible.* '

However, in the further course it did not remain also thereby, because since 15 July is to be read there now:

> '*For this foreign protection by MNB* (= mouth-nose-covering) *there is now first scientific evidence.* '

This presentation remains current, most recently as of 02/17/2021.

However, indications are not proofs. The question arises: What are '*first scientific indications*' and in addition: why 'in *the meantime*'? The evidence should in itself have been given with the publication of the mask recommendation [1]. Therefore, I asked the RKI via e-mail of 19.07.2020 for the scientific literature on which this statement is based and received as e-mail of 21.07.2020 a list 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] first on the basis of the specialist literature cited therein. This is followed by a presentation of the more recent publications, i.e., those that appeared after the RKI article and were cited by scientists as well as by the media as evidence of the effectiveness of masks among the general public. Finally, the publications that did not find any benefit of masks are compiled.

The RKI recommends in its article

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

This recommendation is based

> '*on a reassessment based on growing evidence that a high proportion* (emphasis added for this opinion) of *transmissions occur unnoticed, even before the onset of disease symptoms*'.

In its article, the RKI states that a "*high proportion of transmissions* go *unnoticed*", but does not refer to a source. In the literature list of the article, however, there are two publications to which the RKI presumably referred in its statement (and perhaps only the literature references to them were forgotten in the text). The first is a mathematical estimate, according to which the presymptomatic transmission is said to have been very high, namely between 48% and 77% [4]. The result of the second publication is also based on a mathematical estimate.

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

On the Internet pages of the RKI, under *FAQ > Infection protection measures > What should be observed when wearing an MNB in public?* ' of 15 July and 21 August then no longer '*high proportion*', but only '*certain proportion',* in order to finally speak of a '*relevant proportion' in* the FAQ since 7 September (most recently in the version of 17.02.2021) (emphasis for this expert opinion). Literature references are not available there (and are 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]. This article, entitled '*Weighing the duration of quarantine and isolation in COVID-19*', states:

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

In the cited publication by He et al., a mathematical estimate is made based on assumptions about how the viral load could be distributed in the respiratory secretion before symptoms occur [7]. A critical commentary on this article was published on August 17, 2020 (i.e., a good 5 weeks before the online publication of the new RKI article [6]), which has since been referred to when accessing the article by He et al. directly 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: Evaluation of real-world contact scenarios found much lower rates of presymptomatic transmission, such as 12.6% (China; published in June [9]) or 6.4% (Singapore; already published in April [10]. The mathematical estimates [4, 5, 7] cited by the RKI in [1, 6] are theoretical results that are significantly higher compared to real-world results (see below).

Evaluating contact constellations from contact tracing studies is tedious and lengthy. However, when clarifying such questions, it is important to evaluate real scenarios, because it then becomes clear what kind of contacts were involved. In the study from Singapore, for example, 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 pathogen transmission, i.e. situations with close continuous contact, in the case of the couples even with mucosal contact [10]. In such living situations, presymptomatic (as well as asymptomatic) transmissions are to be expected (and yet they are rare; see below). The situation is different in the usual contacts in public spaces between people who do not get (that) close to each other or at most pass each other briefly or stand behind each other.

In its article [6], the RKI neither considers nor quotes the critical article [8], 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) [9] and / or Singapore (published on April 1, 2020) [10], which are quoted in the critical article [8]. Thus, the RKI does not follow the rules of evidence-based medicine to include all available data from scientific studies in its considerations. Instead, the RKI refers to only one study that obtained a theoretically determined and very high rate of presymptomatic transmission from a model calculation. The transmission rates determined from real-life scenarios in contact tracing, which are much lower, are not listed. This makes the risk of presymptomatic, i.e., 'unnoticed' transmission appear high, and according to the RKI, this is precisely what prompted the '*reassessment*' ('*high rate*'). According to the rules of (in Germany so-called) evidence-based medicine, which have been established for decades, it is incomprehensible that the RKI did not mention and thus did not discuss the critical statement [8] and the articles from China [9] and Singapore [10] cited in it, but published months earlier.

The same can be observed in a review by other authors published in mid-September 2020 (according to the designation systematic), which is cited by the RKI in the COVID-19 profile [11]. Not only is relevant literature on the topic in question missing there (so that it is de facto not a systematic review), reporting much lower asymptomatic or presymptomatic transmission, but all results are presented together without distinguishing by epidemiological context: However, it is a significant difference whether a pathogen transmission takes place in families, where close physical contact and mucosal contact is the rule, or in public spaces, where such contacts among people do not occur as a rule. It is therefore important in such studies to evaluate the respective settings separately.

In any case, it is inadequate in scientific discourse (and especially in systematic reviews) to cite selectively, because a selective, and thus at least potentially interest-driven selection of publications is not part of today's established scientific principles. Thus, the basis for the RKI's '*reassessment*' is missing, because the '*unnoticed transmission*' is precisely not supported by scientific data, and this was already true when the RKI article appeared online in April 2020 [1]. However, at the same time, the topic was being discussed internationally (e.g. CDC), so that the RKI certainly simply joined this current [12].

The fact that infected persons are potentially infectious even before the onset of symptoms (and usually excrete even more viruses than during the symptomatic phase of the disease) has long been known from other viral infections whose pathogens are also excreted via the respiratory secretions (e.g. influenza, measles). The fact that this is also the case with an infection with the new coronavirus was therefore nothing new or to be expected for the experts. Since mid-February, this has been reported in the international literature with regard to the new coronavirus (compilation in [13]). This also applies to all respiratory infections that are asymptomatic (e.g. influenza in approx. 1/3 of cases; see RKI guide), i.e. these persons are also potentially or principally infectious for their environment.

In reality, however, this only means that it is possible, but not that these persons necessarily also spread the respective pathogen: There are now further data on the extent of ('*unnoticed*') pathogen spread in the case of pre-symptomatic or asymptomatic virus excretion, which show that it is only a small proportion (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 such contact tracing studies as discussed above. One day later, a certain clarification by the same WHO employee followed [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 staff member somewhat qualified her clear position of 08.06.2020 the following day, but did not revise it, it remained the WHO's statement, namely that most transmissions originate from people who have symptoms, and that it was not clear how many transmissions are due to people who do not (yet) have symptoms.

Overall, virus excretion before the onset of clinical disease is therefore nothing new, but could also have been included in the considerations for the new coronavirus from the beginning. However, it was implicitly presented by the RKI as if this had been unforeseeable ('*increasing evidence*' [1]), and was taken up by the media, like so much else, without asking how this actually relates to other viral 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. by noroviruses, in which the pathogen is excreted via the intestine), infectivity does not only begin with the appearance of clinical symptoms; rather, infected persons can already excrete viruses at the end of the incubation period and, what is more, in large numbers, when they do not even suspect that they have an infection (and will, for example, already be ill the next day). For a numerical '*relevant'* (according to the RKI since September 7, however the term is meant) role of pre- or asymptomatic persons in the transmission of the new coronavirus, however, there is no evidence. This is most likely because in infected persons without the clinical symptoms of upper respiratory infection, i.e., without coughing and sneezing, pathogen transmission occurs primarily in close contact, i.e., especially in mucosal contact, as in couples and in families, but just generally not in the usually very brief encounters of people in public spaces as well as not in schools. The theory of aerosol transmission will be presented and discussed in **part C.**

In spring, the outbreak at Webasto near Munich was cited as an important example of transmission from asymptomatic or pre-symptomatic persons [16]. The authors of the study - which was published very prominently in the New England Journal of Medicine (NEJM; along with *The Lancet,* one of the two most respected medical journals in the world), albeit only as a 'letter to the editor' (but quickly, because it was not peer-reviewed) - assumed that the Chinese employee (the so-called index case or patient 0), who had arrived from Shanghai shortly before and was already infected, had no symptoms during her stay in Germany. However, this turned out to be incorrect only a few days after the publication appeared and was made public by a science journalist in early February [17]. The authors had only asked the German employees of the company on site about the state of health of the Chinese employee and not her herself. Only the Bavarian State Office for Health and Food Safety (LGL) and the RKI contacted her directly shortly after the publication appeared. During the telephone conversation (with a Chinese interpreter), it turned out that the employee from China was already (slightly) symptomatic during her stay in Germany and had taken a one-time painkiller and anti-inflammatory drug (paracetamol) right at the beginning [18]. This first publication on the case therefore had to be supplemented by a precise description of her state of health during the stay in Germany. Since then, if one accesses the article at NEJM, there is an additional corresponding supplement. The title of the article has remained the same and thus still suggests a
asymptomatic' transmission. This apparently asymptomatic case was one of the reasons for the compulsory use of masks in Germany. In the complete description of this outbreak published a few months later, there was no longer any mention of asymptomatic contact [19].

In September 2020, another article (systematic review with meta-analysis as preprint, in December as final publication) on the proportion of asymptomatic cases in all cases and on the extent of asymptomatic transmission was published [20]. Accordingly, asymptomatic transmission was very rare (between 0% and 2.2%) and symptomatic transmission, although more frequent (between 2.8% and 15.4%), was also rare in 4 of the 5 studies, with a maximum of 5.1%, and was thus in any case much less frequent than would be expected in symptomatic individuals. The relative risk of asymptomatic transmissions was 42% lower starting from asymptomatic cases than from transmissions starting from symptomatic cases in the analysis of these five studies reporting secondary infections in asymptomatic and symptomatic persons. The authors conclude that it is unlikely that asymptomatic transmissions are a significant driver in the emergence of clusters (temporal and local clusters or outbreaks) or in the transmission of infection in the general public, and therefore the importance of asymptomatic cases in the spread of infection should be considered with caution. Incidentally, the authors criticize the unclear definitions of asymptomatic cases in the studies they evaluated. Indeed, this could lead to mixing asymptomatic cases with low-symptomatic cases (see above [16]). If this were to occur frequently, the frequency of true asymptomatic cases would be significantly lower, and so would their proportion of transmissions.

In late November 2020, a study was published from China reporting the outcome of a PCR screening program across Wuhan between May 14 and June 1, 2020

reported [21]. Almost 10 million (!) people were studied. No new symptomatic cases were found, but 300 asymptomatic individuals were found. No positive case was found among the close contacts of these asymptomatic persons (N = 1,174). Thus, there was no evidence of asymptomatic transmission, although only close contacts were examined in each case.

A systematic review with meta-analysis on Corona transmission in households appeared in December 2020 and, as expected, found a higher transmission rate starting from symptomatic index cases (18.0%) than starting from asymptomatic cases, where the transmission rate was as low as 0.7% [22]. This result is of particular interest because there is agreement (albeit for different reasons) that the risk of respiratory pathogen transmission is particularly high indoors and negligible outside buildings, i.e., in the 'fresh' air, but nevertheless the asymptomatic transmission rate in households was extremely low, despite living together in relatively confined spaces with numerous direct (including via skin and mucous membranes) and indirect contacts and thus hardly escaping pathogen contact per se if a member of the household is infected. Therefore, if pathogen transmission from asymptomatic persons should play a role, this should be particularly evident in close households,
i.e. close skin and mucous membrane contacts in households (= indoor areas). However, the risk of pathogen transmission from asymptomatic persons during fleeting contacts in public spaces has never been investigated. Nevertheless, despite these data, nearly 80 million people in Germany still have to wear masks on numerous occasions in public, even outside enclosed spaces (and this is considered pointless even by aerosol physicists; see **Part C.**), wear masks.

In January 2021, another mathematical estimate appeared on the question of how frequently asymptomatic persons transmit the new coronavirus [23]. Based on their assumptions, the authors conclude that at least 50% of all new SARS-CoV- 2 infections are due to contacts with asymptomatic persons, i.e., a result as often seen in modeling studies: high transmission rates but no real contact evaluations.

Another review (so-called 'living systematic review', i.e., to which updates are planned on an ongoing basis) was submitted in September 2020 and accepted in January 2021 [24]. The international team of authors aimed to determine the likelihood of infected individuals with varying symptom status being infectious to contacts, resulting in secondary cases with evidence of SARS-CoV-2. For the analysis of the rate of secondary cases starting from asymptomatic persons, 10 studies could be evaluated, yielding an overall transmission rate of 1%. For symptomatic cases, the overall transmission rate was 6% and for presymptomatic cases, 7%. Again, this evaluation of real-life studies showed that starting with asymptomatic individuals resulted in significantly fewer secondary cases than symptomatic or presymptomatic individuals, but these were also rarely associated with secondary cases. Most transmissions could be attributed to secondary cases living with index cases or to pathogen transmissions resulting from group activities, such as shared meals or board games, all of which were again situations of direct contact, indirect contact, or droplet contact (vis-à-vis < 1 - 2 m).

The likelihood of transmission is also thought to depend on the viral concentration in respiratory secretions, as outlined in a study conducted in Spain in the spring of 2020 [25]: thus, the transmission rate ranged from 12% at a concentration of < 106 RNA copies per mL to 24% at ≥ 1010 RNA copies per mL in respiratory secretions. The duration to the appearance of the first symptoms shortened successively with increasing viral concentration: 7 days in subjects with initial < 107 RNA copies per mL, 6 days in subjects with concentrations between 1 x 107 and 1 x 109 RNA copies per mL, and 5 days at ≥ 1 x 109 RNA copies per mL. A large proportion (approximately two-thirds) of cases included in the study were not associated with secondary cases. Transmission events were significantly more likely to originate from index cases with high viral concentrations in respiratory secretions. Similarly, exposure in a shared household was associated with a higher risk of transmission, but there was no association with the presence of cough in the index case. The authors concluded from the results of their study that viral concentration in respiratory secretions plays a greater role than the presence of typical respiratory symptoms, such as cough in particular. The authors did not find a correlation with the use of masks in terms of reduced risk of transmission (the same conclusion was reached by the authors of another study [26]). Based on the significance of the virus concentration in the respiratory secretion, the authors suggest that the risk of transmission should be divided into low and high risks based on the RNA concentrations measured in people who have tested positive.

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 respiratory secretions is a problem both for the person tested positive and for their 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 virus RNA detection), but quantitative results (i.e., the number of RNA copies per mL of respiratory secretion of each individual tested positive), one could assess the risk of transmission in individual cases - and avoid unnecessary quarantine measures in numerous cases. The indication of the Ct values (cycling threshold: low values = high viral load in the initial sample), although this only allows a semi-quantitative indication of the RNA copies per mL, would in any case be better than the purely qualitative results. However, since the Ct values also depend on the PCR devices (cyclers) available in the various laboratories, which are, however, quite different, and, in addition, on the test reagents used in each case, it is possible to compare the results from the same laboratory with one another, but not with the results from other laboratories, as long as each laboratory does not draw up a calibration curve on the basis of external reference samples with a defined concentration, which is what makes it possible to compare its own laboratory results with the results from external laboratories in the first place. In its information of January 2021, the WHO also pointed out that, on the one hand, the Ct values should be stated in the findings and that, on the other hand, the test results must always be seen in connection with the medical history and clinical findings [28].

The fact that since the appearance of the new coronavirus PCR tests are increasingly being carried out on clinically healthy persons contradicts an old rule in the (serological) diagnosis of infections (antibody detection), which is already taught in medical school, namely that one should not treat 'titers', but only patients, i.e. one should make treatment dependent on whether the patient has symptoms that are consistent with the result of

laboratory examination, because laboratory results often have no significance for the individual patient. This principle has been abandoned in the case of the new coronavirus: people without clinical symptoms are examined and, if the PCR is positive, are declared 'infected' - and sent into quarantine, among other things, and this, on top of everything else, with a test, the PCR, with which, as is well known, traces of nucleic acid can be detected in a sample.

In addition, a PCR always detects only the genetic material of the respective virus (RNA in the case of coronaviruses) by multiplying (= copying) it until the PCR instrument displays a positive result: the Ct value read in this process can be used to infer the amount of virus material in the original sample. The relationship is inversely proportional: a low Ct value means a lot of virus in the original sample and vice versa.

However, PCR cannot determine whether the RNA originates from viruses that are capable of infection and thus replication. In order to prove the potential infectivity, one would have to try to cultivate the virus in a cell culture from the same sample. However, this does not mean that the detected virus would also be able to cause an infection in a person who is in principle susceptible (see **part C.**). Thus, when one speaks of e.g. 'virus detection' in the context of a PCR, this is not correct in itself: it is a simplification (one says 'virus', but means only the genetic material).

Résumé of the 'reassessment' of the RKI

The RKI gave as a reason for the '*re-evaluation*' of masks for the population in public spaces [1] that there is '*increasing evidence*' that one can be infectious even before the first symptoms appear, i.e. at a time when there is still no evidence that one is infected. However, this has long been known from other viral infections and in no case means that the pathogen is then actually transmitted, but only that transmission is possible depending on numerous other factors. The RKI relied on mathematical estimates, which used their models to calculate a very high proportion of such transmissions, as evidence that there is a high risk of so-called unnoticed transmissions. However, the RKI omitted results from contact tracing studies published previously (i.e., before the RKI article appeared), from which more realistic data were obtained. 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 to work '*according to the respective state of medical and epidemiological science* ...'.

Importance of experimental mask studies

For as long as masks have existed, there have been studies on the filtering effectiveness of various mask materials (whether for normal medical masks, also known as surgical masks, or for FFP respirators), and each manufacturer has to meet various test criteria in order to be able to market the various masks. We will not go into this in detail here, because the mask issue under discussion in this report is not about whether masks are in principle effective in terms of their material, i.e. their filtering effectiveness for larger and smaller to the smallest particles, but whether they are suitable for the given epidemiological situation, for

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 then also included schools - have a benefit. Such a benefit, e.g. when shopping for groceries, looking for clothes in a fashion store, or riding public transport, cannot be derived from the respective filter effectiveness of the masks used, but - based on the possible transmission paths of the pathogen - only from the concrete possible contact situations between people standing next to or behind each other or passing each other oncoming or passing each other from behind, even if the respective distance is very small (up to crowding).

The most important criterion for assessing the associated risk of infection is that these contacts are short in each case, even though the distance between them may be close, which is indeed the case in
normal' times occurs again and again. In the epidemiological context of encounters between people unknown to each other in public spaces, contact with respiratory infectious agents sufficient for pathogen transmission is thus almost always extremely unlikely. 'Almost always' here means: as long as someone does not cough directly into the face of another person at a short distance (which hardly anyone in public, other than perhaps in private, will ever have experienced) or as long as one does not have a (longer) conversation, i.e. of at least 15 min duration, while not keeping 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 recognized in the analysis of contact situations that in respiratory infections a vis-à-vis contact between an infected and a non-infected person is important, but it must also last a certain and not too short minimum time so that pathogen contact can take place at all. A short contact, even if one should feel the breath of the other person while passing by, is not associated with a realistic risk of pathogen transmission. However, if a conversational contact of presumably longer duration should occur in a public space, one can simply keep an appropriate distance. A mask obligation for all people is therefore not needed to prevent such potential pathogen contacts, and all other transmission risks ('unnoticed' transmission and 'aerosol' transmission) are not supported by the necessary scientific data and thus remain hypotheses - if necessary until corresponding evidence is available.

In this respect, when assessing whether masks are 'effective' in public spaces, the question of what filtering effectiveness professional or fabric masks are likely to have does not arise, apart from the fact that it will never be possible to make even an approximately accurate statement about (even self-sewn) fabric masks anyway. Nor is the question of whether fabric masks can be made 'better' to protect public health [29]. Similarly, the question of what improvement should be associated with the use of medical masks (OP or FFP2 masks), which have been mandatory for shopping and public transport since the beginning of 2021, is completely open, because the basic effectiveness of masks (of whatever type) always depends on how they are used, i.e. whether they are worn correctly at all (see **Part B.**). In any case, the way the population has been wearing masks for the past year (regardless of whether it was the - often self-sewn - fabric masks for nine months or medical masks since the beginning of 2021), masks are ineffective because they do not fit tightly to the face and by no means always cover the mouth and nose, and if not even adults can handle masks correctly of any kind, how are children supposed to manage it. Masks that are not used '*correctly*' (as the

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

Thus, if it is stated that masks '*work*' because the material can in principle retain droplets and particles, this is no basis for proving a concrete efficacy to the effect that transmission of the new coronavirus can thereby be prevented or at least reduced and the '*infection pressure and thus the rate of spread of COVID-19 in the population*' can be reduced [1]. A general mask obligation cannot be justified with such vague prospects. This would require data from appropriately informative epidemiological studies.

The scientific basis of the RKI

Whether the RKI had such data or whether they were presented by other authors after the publication of the RKI article, and which data are cited as evidence at all, will now be presented in the following. These explanations are necessarily extensive, because a substantial part of these publications is cited by scientists and by the media to prove that the effectiveness of masks has been proven. However, in order to be able to answer the question of whether these studies are actually suitable for this purpose, they must be examined in detail.

1. Study from Hong Kong

Much weight was given by the RKI in its paper [1] to a study from Hong Kong that appeared in spring 2020 and has since been widely cited internationally in the SARS-CoV-2 literature [30]. Therefore, it will be presented here in detail.

In its article, the RKI referred to a '*recent*' study in which it was possible to show the differences between medical masks (mouth-nose protection = MNS) and FFP masks,

> '*that also* (an) *MNS leads to a relevant reduction of exhaled airborne respiratory virus excretion (...)*' [1].

By 'current' study, reference was made to the study from Hong Kong. However, as stated by the authors in their article, this study was already conducted between 2013 and 2016, and was therefore no longer up to date when the RKI article appeared: The study was published after the appearance of the new coronavirus only '*up to date*', and the RKI therefore knew that.

Medical masks (professional surgical masks) were used in this study. Selected for the study were primarily 246 patients who came to the outpatient department of a clinic in Hong Kong because of respiratory symptoms of various causes. However, the study ultimately focused on only 111 patients with evidence of influenza viruses (N = 43), rhinoviruses (N = 54), or seasonal human coronaviruses (N = 17), with three times two of the viruses detected (all RNA viruses). Patients were asked to participate as volunteers in a study designed to assess the extent of release of (1) respiratory droplets and (2) aerosol containing viral RNA in exhaled air. RNA detection was performed by RT-PCR (= real-time polymerase chain reaction).

Randomized (= randomly assigned), the subjects were given either a surgical mask (which the study directors ensured was correctly fitted) or no mask during the first examination, in order to determine the extent to which the mask had an influence on the release of the (respective) viruses, i.e. would reduce the release of viruses into the environment. In principle, it was planned to examine all subjects once with and once without a mask, but most of them (80%) refused a second examination for reasons of time: for the examination the exhaled air was collected for 30 (!) minutes. The particles obtained were divided into two fractions (1) > 5 µm (= droplets) and (2) < 5 µm (= aerosol particles). The results must therefore take into account that in the two groups 'with mask' and 'without mask' in most cases the same subjects were not examined, although this was in itself the intention of the investigators.

A remarkable result of the study, but not picked up by the RKI, is the following: Although all participants had an acute upper respiratory viral infection (with concentrations of $^{107-8}$ RNA copies per sample in nasal secretions and of approximately ^{104} RNA copies per sample in pharyngeal secretions), droplets with evidence of viral RNA were found without a mask in only 6 of 23 (with infection by influenza viruses), 9 of 32 (with infection by rhinoviruses), and 3 of 10 (with infection by coronaviruses) of the samples taken, respectively. Virus RNA-containing aerosol particles were detected under the same conditions, i.e., also without a mask, in only 8 of 23 (influenza viruses), 19 of 34 (rhinoviruses), and 4 of 10 (coronaviruses) of the samples.

Thus, even without a mask, despite acute upper respiratory tract viral infection (with high viral concentrations in the respiratory secretions), only a few samples yielded any viral RNA detection at all. This result shows that - contrary to common belief - a person with acute upper respiratory viral infection apparently does not necessarily release a high number of viruses.

And with mask, the results were as follows: Viral RNA detection in droplets was possible in 1 of 27 (with infection by influenza viruses), in 6 of 27 (with infection by rhinoviruses), and in 0 of 11 (with infection by coronaviruses) of the samples taken, respectively. In aerosol particles, viral RNA detection was possible in 6 of 27 (influenza viruses), in 12 of 32 (rhinoviruses), and in 0 of 11 (coronaviruses) of the samples.

The RKI makes in its article from these partial results a '*relevant reduction*' *of* the excretion '*of respiratory viruses via the excretory air*' by masks [1]. However, the RKI does not indicate how low the virus concentrations in droplets and aerosol particles were even without a mask (see below). Moreover, the RKI only singled out the result in subjects infected with one of the seasonal coronaviruses, as if it could be shown that masks 'work' with coronaviruses and thus also with SARS-CoV-2. In the subjects with the influenza or rhinovirus infections, there was little difference in the groups with or without masks.

The RKI also did not take into account that such an effect can only be achieved if masks are worn correctly, which was taken care of by the study leaders for each individual test person. No one, however, is available to show people (completely untrained in this) in public how masks are (have to be) worn correctly so that they could be effective in principle. However, whether they would be effective even then in the given epidemiological context (e.g. shopping, public transport, schools, offices) would have to be shown by appropriate studies, which, however, do not exist.

However, the results are also special in that in the samples in which virus RNA was detected at all (both with and without mask), the RNA concentration in droplets and in aerosol particles was consistently extremely low (mostly only ^{100}, i.e. 1 RNA copy per sample, and only occasionally somewhat higher values, which were also found in the samples with mask; the detection limit was 0.3 RNA copies per sample), so that only the few higher values ('outliers') could be compensated by the mask - very low values in view of the high values in the respiratory secretion.

Given the efficient collection technique and the (long) collection time of 30 minutes, the authors concluded from their results that prolonged close contact was probably required for pathogen transmission to occur at all.

However, when considering the results of the study from Hong Kong, the question arises as to what practical relevance a mask should actually have: Namely, if (1) a large proportion of infected individuals did not release viral RNA even without a mask, and if then
(2) moreover, in those with viral RNA release, RNA concentrations are extremely low despite high viral concentrations in nasopharyngeal secretions, there is little overall to suggest a benefit of masks. However, despite their own clear analysis, the authors note that their results suggest that masks (as surgical masks as used in the study) could be used by sick individuals. However, they also speak only of sick, i.e., symptomatic, individuals and by no means of every citizen in public spaces.

However, this question, i.e. whether the widespread use of masks in public spaces, even if only in certain situations, is useful for every citizen, was not the subject of this study either - contrary to the impression one may get when reading the RKI article [1]. The authors are quite critical of their own results (this is, however, one 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 be perfect), namely because no viral RNA release could be detected in a large proportion of the test subjects - regardless of the type of their viral infection - even without a mask, and this despite the (long) measurement duration of 30 minutes. They see a further deficit in the fact that only in individual cases and only in the case of influenza virus was it investigated whether the viral RNA released (in low concentration) 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 precisely this is cited as evidence in the RKI article, the study does not provide any indication that the general wearing of masks (whether professional surgical masks or so-called community masks) in public spaces (e.g. stores, public transport, schools, offices) can reduce the risk of infection for people encountered during this time - albeit with contact times that are generally much shorter than the measurement duration in the study of 30 min. The study results, on the other hand, show that the risk of coming into contact with excreted viruses from other people, even if they are acutely infected and have corresponding clinical symptoms, is once again much lower and probably negligible if one is not directly coughed on, a situation that most people in public will hardly ever have actually experienced, even if just a

such situation is cited as a risk and thus as (*one*) justification for masks. Finally, it is incomprehensible that the RKI, on the basis of a study in which a maximum of 11 subjects with evidence of seasonal coronaviruses were examined and in which the study directors also checked or, if necessary, corrected the correct fit of the masks, speaks of masks causing a '*relevant reduction*' *in* virus release. Only then was this partial result of the study, which was not very meaningful, declared to be a justification for the fact that masks 'work'. But how the RKI can conclude from a result of only 11 test persons (moreover with acute respiratory infection) to a similar effect when wearing masks by a population of almost 80 million (without symptoms), should not be questioned here.

Brief contacts. In terms of life experience, encounters in public spaces are only in a few cases close (< 1 m) and prolonged (≥ 15 min) face-to-face contacts, which, however, (in contrast to patient care in hospitals) do not generally extend over 15 min or more. In most cases, people pass each other only briefly in public (e.g., aisle in supermarket) or stand behind each other (e.g., checkout in supermarket) or next to each other (e.g., public transport). And even if the journey by public transport takes more than a few minutes, experience has shown that you can almost always position yourself in such a way that you do not have face-to-face contact with other passengers, even if it should be crowded (for the possibility of pathogen transmission by aerosol particles, see **Part C.**). Keeping a distance during conversations, e.g. during banking transactions or during a consultation, e.g. in a bookstore, is always possible - and makes masks superfluous.

Distance. The fact that face-to-face contact, which is crucial for droplet transmission, was virtually 'lost' at some point during the course of the pandemic (at the beginning, at any rate, the RKI and 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) is an important factor in the numerous misunderstandings and misinterpretations (see **evidence question 4.**): it is not uncommon for some people to react fearfully when someone comes 'too close' from any side. Since the discussion about the role of 'aerosols' arose only later, the RKI could not yet consider this aspect in its contribution, which cannot be reconciled with the required 1.5 m distance and the 'everyday masks' [1].

2. WHO assessment of 2019

As a further source, the RKI has referred to the WHO (World Health Organization) in its 'reassessment'. Therefore, their statements on the question of what role masks could play in the containment of the pandemic will now follow.

In 2019, in a review paper on so-called non-pharmaceutical measures (i.e., without medication or vaccination) to contain epidemic and pandemic influenza, the WHO had recommended non-medical masks only with reservations to protect the general population during severe epidemics and pandemics, and surgical masks for symptomatic persons in contact with other people [31]. At the same time, however, WHO has stated that there is no scientific evidence for this, i.e., based on the scientific data, it is not known whether this measure is effective in reducing pathogen transmission; rather, the potential effectiveness is based on plausibility.

If a measure is only plausible, no scientifically based effectiveness can be derived from it. Something can be called plausible if it is somehow plausible and comprehensible to most people who think about it - and therefore a plausible measure could perhaps be effective. Thus, such a theory would be able to give reason to test it in a scientific investigation. But plausibility cannot replace such an investigation. This is also comprehensible for scientific laymen, otherwise one could immediately do without any scientific investigation, because many things are plausible. Plausibility cannot be sufficient to impose a mask obligation for (almost) the entire population in Germany.

Two updates have since been published by WHO and will be presented later (see below).

3. ECDC assessment

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

ECDC provided only vague information on the potential effectiveness of masks against transmission of the new coronavirus in April 2020 [32], citing, among other sources, the 2019 WHO statement [31]. According to ECDC, there is limited indirect evidence that nonmedical masks (made of different materials) can reduce the release of respiratory droplets into the environment during coughing, but the available data suggest that nonmedical masks are less effective than medical masks in controlling the source of the pathogen ('source control' = foreign protection).

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

The use of (non-medical) masks in public could primarily serve as a means of 'source control', but should only be considered as an additional measure, but not as a substitute for the central prevention measures, which include careful hand hygiene as well as the avoidance of own hand-face contacts (eyes, nose, mouth). In its publication, the ECDC listed numerous arguments for and against the use of masks.

In summary, the ECDC says in the April 2020 publication that the recommendation for the use of masks in public should carefully consider the gaps in the scientific data and the potential adverse effects. They should only be considered as a complementary measure, but should not be allowed to compromise established measures, particularly of careful hand hygiene and avoidance of own hand-face contact (eyes, nose, mouth). So here, too, there is no question of a

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

In February 2021, the ECDC published a first update on this, expressing the same assessment as in spring 2020 [33]. The very 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.* ‘

The ECDC goes on to say in the summary:

1. The evidence for the effectiveness of medical masks in the population to prevent COVID-19 was consistent with a small to moderate protective effect, but there were still significant uncertainties about the size of the effect.
2. With respect to nonmedical masks, face visors, and FFP2 masks used by the public, the effectiveness was sparse and associated with very low safety, he said. High-quality studies are needed to assess the relevance of medical mask use in the COVID-19 pandemic, he said.

Ultimately, the ECDC nevertheless recommends wearing masks in certain situations in public, for example: when there are transmissions in the general public and in this situation when staying in closed public areas or also in households for symptomatic persons and then also for the other persons of the household.

However, ECDC also states that due to the given (i.e.: lack of) scientific evidence, it cannot make a recommendation on whether medical or non-medical masks should rather be used in public.

ECDC further states that the very limited scientific evidence regarding the use of FFP2 masks does not support their mandatory use in public instead of other mask types. Although FFP2 masks are not expected to be inferior to other types of masks, the difficulties in achieving their proper fit and use in public should be considered, as well as the potential disadvantages of difficult breathing.

Further, as in the April 2020 report, it states that masks should not replace the other preventive measures: (1) physical distance, (2) staying home when sick, (3) working via telecommunications if possible, (4) respiratory etiquette,
(5) careful hand hygiene, (6) avoid contact of hands with face (eyes, nose, mouth).

Finally, appropriate use of masks and improving compliance with their use, when recommended as a public health preventive measure, are key to the effectiveness of this measure and can be improved through education campaigns, he said.

4. CDC recommendations

The RKI cites the U.S. Centers for Disease Control and Prevention (CDC) as another health authority of international importance, but does not cite any publication in this regard. The CDC's comments are similar to those of the WHO and ECDC, but at that time they did not even refer to scientific evidence, except with regard to the early excretion of the pathogen at the end of the incubation period [34]: Thus, there was no scientific support for the RKI's mask recommendation from this side either.

A scientific update was published by the CDC in November 2020, but both the information contained therein and the scientific basis are very limited because there are no meaningful data for '*real-world effectiveness*' [35]. Nevertheless, at the end of the paper, the CDC recommends mask use and even goes so far as to state that mask use in public may prevent future lockdowns, especially when combined with other non-pharmaceutical interventions, such as spacing, hand hygiene, and adequate ventilation.

Thus, the CDC recommends a 'bundle' of measures without comprehensible evidence of the effectiveness of the individual measures in the bundle, as is equally true for ventilation (see **Part C.**) and spacing (see **Evidence Question 4**) in addition to masks. The importance of hand hygiene is very likely high, although it must also be noted that one can never wash (or disinfect) one's hands frequently enough in public for it to be effective, i.e., protective, so avoiding one's own hand-face contacts when out and about must be considered significantly more important than hand washing or disinfection.

Like all other international health authorities, the CDC adheres to the mask recommendation even though, on the one hand, the necessary scientific data are lacking and, on the other hand, masks are not (or cannot) be used correctly by citizens who are not trained in them, so that they become a contamination risk (see **Part B.**). In view of these considerable limitations, the CDC does not even begin to weigh the measure with its potential disadvantages for all people and in particular for children of all ages.

5. Updated Cochrane Review

Cochrane reviews are current (or updated, if the original work was published earlier) systematic reviews (usually with meta-analysis, i.e. a statistical evaluation of different studies on the same topic) and are therefore important for every author when it comes to the scientific basis of a question. Thus, the RKI also consults the corresponding Cochrane review for its mask recommendation.

A Cochrane review updated in 2020 evaluates, among other things, studies on the effectiveness of masks in reducing the spread of respiratory viruses [36, 37]. As a preprint, this review was available to the RKI for its publication [36]; the final publication did not appear until the end of 2020 [37]. However, the studies evaluated therein did not address the wearing of masks in public, as made mandatory in Germany for all citizens in certain situations (stores, public transport, sometimes even outdoors).

Rather, studies in completely different settings were evaluated, and thus it is misleading when the text of the RKI article, which explicitly discusses the use of masks in public, states [1]:

> '*In an update to their 2003 Cochrane review, the authors, based on observational studies during the SARS outbreak, recommend the use of masks also in combination with other measures.*'

Included in the current 2020 review, for example, was an investigation at a large religious gathering in Australia to examine whether the wearing of

masks (professional surgical masks) in participants with respiratory infection could reduce pathogen transmission within such mass events with close contact (e.g., staying in tents) between participants.

In another study, general practitioners in France included households with influenza cases during home visits. The ill persons were to wear a (professional surgical) mask, the remaining members of the household were not. The rate of transmission to other members of the household was to be determined. Similarly, another study from Australia looked at the effect of masks in households with ill members. In addition, there were other studies in which the effect of hand hygiene was investigated together with masks, for example in two studies in student dormitories, i.e. in a somewhat large residential community.

All of them were studies that have nothing to do with the wearing of masks in public (stores, public transport, schools, etc.), not even in a broader sense. Moreover, most of the studies cited in the Cochrane review were conducted among medical personnel and therefore play no role in the question of whether masks make sense in public.

Summary assessment of the scientific basis cited by the RKI for the mask recommendation in public spaces.

Masks not evidence-based. There is no scientific evidence from the literature cited in the RKI article that masks (of any type) worn by the normal population in public spaces (stores, public transport, schools, etc.) can reduce pathogen transmission in respiratory infections. So whether it is possible to use

> '*achieve a sustained reduction in the rate of spread of COVID-19 in the population and decreasing new cases*',

as stated in the RKI article, is unproven, and scientific evidence is equally lacking that the additional use of masks in the population could cause '*several components (...) to complement each other*' [1].

For this, too, i.e. the alleged interaction of various measures (in a so-called 'bundle'), must be proven and cannot simply be assumed or considered plausible. The so-called AHA formula was only developed later (by an advertising agency).
- similar to the 'baby elephant' interval introduced in Austria).

Consequentially, the RKI article states, among other things, very

cautiously [1]:

> '*Partial reduction of this unnoticed transmission of infectious droplets by wearing MNB could* (emphasis in this opinion) *contribute to a further slowing of the spread at the population level*',

a formulation that is not adequate in scientific discourse due to the obvious lack of evidence for the RKI's momentous mask recommendation.

Unnoticed transmissions. The RKI cites no evidence for the statement at the beginning of the article that there is increasing evidence that '*a high proportion of transmissions occur unnoticed'*. It should be noted: It was precisely this alleged possibility of unnoticed transmission that was the reason for the RKI's '*reassessment*' of masks in the public domain. Even then, however, there was no evidence for this.

Normally, science develops, and the measures derived from it are oriented to these developmental steps. On the subject of unnoticed transmission, however, the RKI persists with the presentation established almost a year ago, but even then not exhaustive: the scientific basis was not included in the spring of 2020 and continues not to be included.

Epidemiological connection is decisive. Although the RKI states in the article that

> '*Outbreak investigations and modeling studies*' (showed) that '*the rapid spread of SARS-CoV-2 is due to a high proportion of illnesses that initially start with only mild symptoms, without restricting the sufferers in their daily activity. Excretion of high amounts of virus can occur as early as 1 - 3 days before the onset of symptoms. Partial reduction of this unnoticed transmission of infectious droplets by wearing MNB could* (emphasis added for this review) *contribute to a further slowing of the spread at the population level*." [1].

But, 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.

Furthermore, outbreaks in circumscribed settings, e.g. in nursing homes or in accommodations for asylum seekers or for employees in slaughterhouses or farms, reflect a completely different epidemiological situation than the stay of people in public spaces (they should therefore also not be included in the calculation of incidence figures with the total number of persons tested positive in each case, but only one case of each outbreak, the so-called index case, should be counted, but that is a different problem). Modeling studies, as outlined at the outset, cannot provide insights into the expected reality [38].

Despite all these obvious limitations in the informative value of the alleged evidence cited, the RKI article ends with the statement [1]:

> '*In the system of various measures,* (emphasis for this report) *situational general carry of MNB (or MNS if production capacity permits) in the population is another building block to reduce carryover*'.

The RKI changes from 'can' and 'could' to 'is' or: from the possible to the actual - with considerable impact. After the RKI has only rather cautiously commented on the possible positive effects on the first two pages ('*could*', '*may*'), it speaks in this last sentence with '*is', however,* as if the wearing of masks was actually, i.e. confirmed by the results of scientific studies, such a building block, this, however, without citing a scientific basis for this (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 (or paragraph) of an article, because an (easily readable) brief summary is often given there. Readers are thus left with the impression that a positive effect of the mask recommendation for the public space represents a 'fact' - which, however, is precisely not the case, as has been shown and will be further demonstrated on the basis of specialist literature published later. For the policy was

However, this statement is essential in order to be able to impose the mask obligation, because the RKI, as the decisive scientific authority in Germany for the prevention of infections, to which at least the administrative courts generally attach great importance, has thus provided the decisive justification for the mask obligation.

Conclusion

At the time of the RKI's publication, scientific data for a positive effect of masks in public (in the sense of a reduced '*rate of spread of COVID-19 in the population*' [1]) were not provided by the RKI, WHO (2019), ECDC or CDC, because - and this is still true at present, i.e. about one year later (see below) - such data do not exist [1, 31 - 35]. Similarly, the update of the Cochrane review also does not support the use of masks in public spaces [36, 37]. This has already been confirmed by two other reviews of the relevant literature from April 2020 [39, 40]. The same is even more true for the Hong Kong study conducted several years ago [30].

Other publications on the effectiveness of masks

Only after the '*reassessment*' by the RKI [1] did a number of publications appear, most of which were also picked up by the media. They are discussed in the following.

1. the WHO's 2020 assessment

The WHO recommendation of June 2020 on masks in public (as in a previous recommendation in April) states that there are no scientific data that the wearing of masks (medical masks to so-called community masks) by (apparently) healthy persons, i.e. people without symptoms of an upper respiratory tract infection, in public settings can protect against infections with respiratory viruses, including those caused by the coronavirus [41]. Thus, with this new recommendation, the WHO has once again not advocated the general wearing of masks in public, even if this has been interpreted differently in the media.

In the recommendation of June 2020, however, the WHO (in addition to the use of masks in the medical field) for the first time deals in detail with the use of masks 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 - thus not intended by the WHO as a 'regulation' or 'obligation'. It is important to note, however, that WHO makes this recommendation only for areas (e.g., counties) with (1) known or suspected widespread transmission outside of localizable outbreaks, so to speak, many infections in the area, not at individual hotspots, and in such an epidemiological situation (2) on occasions (e.g., public transport) where spacing is difficult. In that case, it could be an additional measure and part of a comprehensive approach to suppress coronavirus transmission. At the same time, however, WHO notes that there is no direct scientific evidence for this (so, as in the earlier 2019 recommendation [31], it is merely plausibility) and that disadvantages must be considered in addition to potential benefits.

An update to the June 2020 publication appeared in December 2020 [42]. However, it is not fundamentally different from the June guideline. For the normal population

only non-medical masks are recommended. Medical masks should be used by persons at increased risk for serious complications if a distance of at least 1 m cannot be maintained. Anyone caring for persons 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, the WHO comments 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: Child's ability to use the mask correctly and availability of adults for supervision, local social and cultural environment, special settings such as households with elderly relatives or schools.
- From the age of 12, the same principles apply as for adults
- Special decisions are needed for immunocompromised children, for children with cystic fibrosis or with certain other conditions (e.g., carcinoma), and likewise for children of any age with developmental delays, disabilities, or other specific health conditions that interfere with mask use.

WHO, like ECDC, points out that the use of masks alone, even if used correctly, is not sufficient to ensure an adequate level of protection for uninfected persons or to prevent transmission starting from an infected person (stranger protection). Hand hygiene, physical distance of at least 1 m, respiratory etiquette, adequate ventilation of enclosed spaces, testing, contact tracing, quarantine, isolation, and other infection control measures and infection control measures, whether masks are used or not, are critical to preventing person-to-person transmission of pathogens, he said.

WHO gives very detailed guidance on what to look for in the correct use of masks:

- Perform hand hygiene before putting on the mask (no indication of what exactly is meant by this, i.e. hand washing or hand disinfection).
- Inspect masks for damage and do not use damaged masks
- Carefully put on mask, making sure that nose and mouth are completely covered, adjust nose clip and straps to minimize gaps between face and mask. If ear straps are used, ensure that they do not cross as this will increase the gap between the face (cheek) and mask.
- While wearing the mask, avoid touching it. However, if it is accidentally touched, hand hygiene should be performed.
- Remove the mask using appropriate technique, i.e. do not touch the front, but instead loosen the straps from behind
- Replace mask with a new, dry mask as soon as it has become moist
- Either discard the mask or place it in a clean, resealable plastic bag where it can remain until washed and cleaned. Do not wear the mask by the straps around the arm or wrist or push it under the chin or down the neck.
- Perform hand hygiene immediately after disposing of the mask
- Do not reuse masks for 1x use
- Dispose of disposable masks correctly after each use

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

On the scientific evidence related to the protective effect of masks in public, WHO says:

> *'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 review no. 88 - 93].

Despite the limited and conflicting scientific evidence cited by WHO for mask effectiveness in healthy people in the general public, the **use of** masks in the general public is advised in addition to all other measures (see above) in cases of known or suspected transmission in the general population or outbreaks. When decision makers consider the use of masks for the general population, they should base their decision on the given risk.

1. **Inside closed rooms (indoor settings)**

- If ventilation is poor regardless of physical distance; limited or no opening of windows or doors for natural ventilation; ventilation system is not functioning properly or cannot be assessed
- With adequate ventilation, if the physical distance of at least 1 m cannot be maintained
- In households, if there is a visitor who is not part of the household and if ventilation is poor, limited opening of windows and doors for natural ventilation or if the ventilation system is not working properly regardless of whether the physical distance of at least 1 m can be maintained
- In households with adequate ventilation, if the physical distance of at least 1m cannot be kept

2. **Outside closed rooms (outdoor settings)**

- If the physical distance of at least 1 m cannot be maintained
- Individuals at increased risk for serious complications of COVID-19 should wear a medical mask in any setting where physical clearance cannot be maintained

3. **For sports activities**

- People who exercise should not wear a mask while doing so because masks interfere with the ability to breathe easily
- In indoor areas, care should be taken to ensure good ventilation and, in addition, careful disinfectant cleaning of the environment, especially of surfaces with frequent hand contact.

Decision makers should consider the following points when recommending masks for the public in public spaces:

- The purpose of the mask should be clearly communicated, i.e. where, when, how and what type of mask should be worn. It should be explained what is achieved with masks.

could be used and what not. Furthermore, it should be made clear that the mask is only one part of a package of measures together with hand hygiene, physical distance, etc., all of which are necessary and should reinforce each other.

- People should be informed and trained in when and how to use masks safely, i.e., to put them on, wear them, take them off, clean them, and dispose of them.
- The feasibility of use, supply and replenishment issues, social and psychological acceptability (both of wearing and not wearing different types of masks under different conditions) should be considered.
- Scientific data and evidence on the effectiveness of mask use (including different types of masks or other face coverings such as scarves) should be collected on an ongoing basis.
- The impact (positive, neutral, or negative) of mask use in the general population will be evaluated (incl. behavioral and social science).

Potential benefits of masks in healthy people in public

- Release of respiratory droplets containing infectious viral particles reduced, including from infected individuals before they develop symptoms
- Reduced potential for stigma and greater acceptance of mask-wearing to prevent infection of others or among individuals caring for patients with COVID-19 in nonmedical settings
- People are made to feel that they can help stop the spread of the virus
- Promote concurrent behaviors to prevent transmission, such as hand hygiene and avoiding touching the eyes, nose, and mouth
- Prevent transmission of other respiratory diseases, such as tuberculosis and influenza, and reduce the burden of these diseases during the pandemic

Potential disadvantages of masks in healthy people in public

- Headache and difficulty breathing depending on the type of mask
- Development of skin lesions on the face, non-allergic contact dermatitis or worsening of acne with frequent use for many hours
- Difficulty communicating clearly, especially with people who are deaf, hard of hearing, or lip-reading
- Discomfort
- False sense of security that may lead to less adherence to other critical prevention measures, such as physical distance and hand hygiene
- Poor compliance with mask wearing, especially in younger children
- Waste management issues, inappropriate mask disposal resulting in increased public waste and environmental hazards
- Harm and difficulty in wearing masks, especially for children, persons with developmental delays, with intellectual disabilities, with cognitive limitations, with asthma or chronic respiratory or breathing problems, persons who have had facial injuries or recent oral surgery for and persons who live in hot and humid climates.

Summary of WHO pronouncements

Although WHO also explicitly states in the most recent statement of December 2020 (incidentally, as previously in June 2020) that the scientific evidence supporting the effectiveness of masks in the general public in preventing respiratory infections (including from SARS-CoV-2) is limited at this time, and contradictory at that, it nevertheless makes a recommendation for masks in certain epidemiological situations for the general population.

The WHO's mask recommendation is therefore not a scientifically based recommendation. Whether political lobbying was actually behind it does not need to be discussed here, but it must be stated that the WHO, as the scientific health authority of the UN for the entire world, did not make its mask recommendation precisely on a scientific basis. This is shown by the results of the scientific literature evaluated in this report:

According to this study, there is no scientific evidence that masks, which must be worn by healthy people in public, e.g. when shopping, in public transport, in offices and schools, make a traceable and quantifiable contribution to even reducing the spread of the new coronavirus.

The potential benefits cited by the WHO in connection with the wearing of masks are therefore, on the one hand, the more or less evidential (in the German sense, i.e.: obvious) finding that the spread of respiratory droplets containing viruses can be reduced as a result. On the other hand, the potential benefits cited are merely possible effects at the psychological level.

The WHO recommends exclusively non-medical masks for the population and still only in special epidemiological situations and thus only in circumscribed regions with high infection numbers in the area as well as locally in outbreaks, but without giving any indication of the extent of the case numbers, but in any case not as a general (nationwide) mask obligation, as Germany has been experiencing since spring 2020. Therefore, the WHO recommendation cannot be used as a basis for general compulsory masking either.

2. Lancet Review

The systematic review with meta-analysis published in the prestigious medical journal 'The Lancet' at the beginning of June 2020 also provides no evidence for the effectiveness of masks in public spaces [43]. However, this very publication has been and continues to be cited as evidence when it comes to whether masks are effective in public. However, 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 promoted by the WHO). In addition to physical distance and eye protection, it also deals with masks, but not with the wearing of masks in public spaces for the protection of others. In most of the 44 comparative studies discussed there, which could be included in the meta-analysis, it is rather about SARS or MERS, in 7 of them about COVID-19, but - and this is decisive here (not the pathogens) - in no case about a study that would allow conclusions about the wearing of masks in public spaces for reasons of external protection.

If you read the abstract of the Lancet review and then look at Figure 4 with the meta-analysis of the studies in which mask use was evaluated, you might say at first glance: masks are well proven in their efficacy. However, if one delves a little deeper into the figure, one sees that almost all of the individual studies were conducted in the hospital setting and only three in the non-healthcare setting (all on SARS-1) [44 - 46], but this was also not, as with the mandatory wearing of masks in Germany, for the protection of others in public, but for self-protection in the family (1 x) [44] or when leaving the home (1 x) [45]. Incidentally, visiting farmers' markets and owning pets were also identified as protective factors in this study, factors that could rather be considered as risk-increasing or, in other words, for whose protective effect there is no rational explanation. From this it can be concluded that so-called confounders were present, which incidentally calls into question the other results of the study. The third study [46] could not show any effect of masks at all, because 95% of the participants stated that they had never worn a mask when in contact with SARS patients. Thus, how this study could have been included in the Lancet review's evaluation of mask effectiveness at all is unclear. At this point, it should be reiterated that these three studies were the only ones in the Lancet review that even addressed mask wearing in the general population outside of hospitals. Thus, this review is not suitable for making a statement about the effectiveness of masks for people in public spaces.

All other studies included in the review come from the field of medical facilities. However, it is not possible to assume the opposite effectiveness (protection of others) of masks in fleeting encounters in public spaces from patient care in hospitals, where the wearing of masks by staff in certain situations has always been recommended for occupational safety reasons in the case of close and prolonged patient contact (self-protection = no contact with blood and body fluids of patients regardless of whether an infection is known in the patients and, if so, which). This is because patient care involves very different potential pathogen contacts than encounters between people when, for example, shopping, on public transport, in schools or among colleagues in the office. Medical personnel who have to care for patients with respiratory infections or other potentially infectious pathogens in the nasopharynx are in close contact (< 1 m) and also have face-to-face contact.

Another important criterion is that contacts in patient care typically last longer and take place repeatedly, and thus for many years and also by the RKI, a duration of at least 15 min of such close vis-à-vis contact has been cited as a prerequisite for *possible* pathogen exposure of the staff. Such a duration does not occur in public spaces with the usual short contacts there, 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, and then there can be no contact with the respiratory secretion of the other person. The same thing happens with patient care: If you don't have to care for the patient with close contact, but just want to discuss something with him, you stay a bit away from his bed, don't need to put on a mask, and can talk to him normally, even if he's currently having an acute respiratory viral infection.

Mankind has always lived this way even in seasonal influenza times, and the question arises whether everything should be different now with the new coronavirus and moreover: whether only with this virus or with all other respiratory viruses. However, this new virus is not even remotely comparable to a dangerous pathogen such as smallpox or Ebola virus, but according to current studies is comparable to a more severe influenza, as we have experienced several times in recent years (eg, 2016 / 2017 and 2018 / 2019) [47].

The '*Lancet-Review*' does not contribute anything to the effectiveness of masks as external protection in public (just as little as self-protection), because also this systematic review has not brought to light any studies that would allow any or even a supporting statement on the wearing of masks in public spaces for reasons of external protection - nevertheless, this publication is cited in the media and by numerous physicians for this. This may also be due to the fact that the authors have not really expressed themselves clearly and unambiguously in the summary of their results and their assessment of them, if that was read at all and not just looked at Figure 4. Thus it says there:

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

So, in plain language, the summary of the authors of this review is: There is no scientific evidence for an effectiveness of masks in the public, if necessary their use could be made dependent on the epidemiological context, but in any case there is a lack of scientific evidence, and this lack must be made clear.

The WHO does not exclude the use of masks in public (this also applies to children [48]). This was already the principle statement of the WHO in 2019. It has also remained the same that the WHO explicitly states that there is no scientific evidence for the wearing of masks in public. Therefore, only plausibility remains (see above).

3. German Society for Pneumology (DGP)

In a statement of May 2020 on the effect of masks on self-protection and protection of others, the DGP comes to a positive assessment [49]. In this statement, the DGP provides an overview of various experimental studies on the theoretical effectiveness of masks. It also cites some individual studies from the Cochrane review [36]. As explained above, however, studies showing the effectiveness of masks in public spaces for the protection of others are not included, because there are no such studies. In all, therefore, we are not dealing with scenarios that are even remotely comparable with the encounter of people in public spaces. In the end, however, the DGP draws the conclusion, which is incomprehensible from a scientific point of view, that

> '*non-medical masks made of fabrics (...) (have) a foreign protection effect*'.

However, this conclusion is not supported by any of the studies cited in the DGP statement.

4. So-called 'Jena Study

A modeling study published for the first time at the beginning of June 2020 reports on the effect of mandatory masking using the example of the city of Jena and other cities and regions in Germany [50]. In August 2020, the study was published again in a slightly modified version [51] and appeared for the third time in the second, already modified version in December 2020 [52]. The third publication was submitted to the journal in July, i.e., only shortly after the appearance of the first (and shortly before the appearance of the second), was ultimately accepted in November, and published in December 2020. It was presented by the media in December as a new study, which it is not in terms of the subject matter.

The so-called Jena study is - besides the 'Lancet review' - often cited in the media as clear evidence for the efficacy of masks, by the way also - indeed - together with a study on golden hamsters ('hamster' study; see below), i.e. an animal experimental work.

The authors of the 'Jena Study' are all macroeconomists who use the same methodology ('synthetic control method') to conduct studies commissioned by policymakers to mathematically 'model' the effects of political decisions (so-called 'reforms'). In the study, the development of corona case numbers after the introduction of mandatory masking in Jena was compared with that in comparable cities (= synthetic Jena) without mandatory masking. The authors conclude that the mask requirement led to an approx. 40% reduction in the daily increase rate of corona infections.

However, the study does not take into account the epidemiologically decisive aspect that already from March 1, 2020 (i.e., about 5 weeks before the introduction of a mask obligation in public spaces in the city of Jena), the spread rate of the new coronavirus decreased and that on March 10, 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 that the introduction of compulsory masking (from April 6, initially in Jena, and about three weeks later throughout Germany) occurred during a phase of the Corona epidemic in which there had already been a continuous and significant decline in the number of infections, a development that subsequently continued. It is therefore not possible to infer an effect of the mask requirement on the decline in the number of infections, because both overlap, but this was not taken into account in the modeling study.

It is particularly important for the evaluation of the 'Jena Study' that, according to the RKI data, the infection events in Jena were concentrated on only a few days in March and that the majority occurred before mid-March: there were (1) approx. 3 - 5 positive cases at the end of February, (2) between 43 and 53 positive cases on the weekend around March 7 - 9, and (3) between 59 and 73 positive cases in the period from March 11 to 14,
(4) followed by a marked decrease in the number of positive cases on individual days before the end of March, and (5) another 3 - 5 positive cases at the end of March. The close temporal relationship of events (2) and (3) indicates that these were outbreak situations and not a successive spread of infection 'in the area'. At any rate, by the end of March, the incidence of infection in Jena had already subsided to such an extent that it was no longer possible to expect an effect from the mandatory use of masks from 6 April, because there was no longer any incidence of infection that could in principle be influenced by it.

In addition, it must be taken into account that the reporting date of the cases used in the study does not allow an even approximately reliable statement about the time of infection, which can only be determined precisely enough by the date of illness (= onset of clinical symptoms), as practiced by the RKI in its modeling studies [54]. Indeed, according to RKI, the time between infection and reporting date is 14-21 days, and this period is composed of: (1) the incubation period, (2) the delay until the patient goes to the doctor because of increasing symptoms, (3) the time for performing the test (incl. transport to the laboratory and evaluation in the laboratory), (4) the administrative delays in reporting the test results to the RKI, and (5) the publication by the RKI [55]. However, the 'Jena Study' assumes a delay of only about 8 days [50] or about 10 days [51, 52].

In other words, the effect attributed to the mask requirement in this study in terms of the decline in the number of infections is, on the one hand, overshadowed by the significant decline in positive tests that had begun everywhere in Germany a few weeks before the introduction of the mask requirement in Jena and elsewhere. On the other hand, it must be taken into account that the infections reported to the RKI in each case occurred 14 - 21 days previously, so that the mask obligation could not have had any influence on the infection figures for at least the first 2 - 3 weeks.

Another important aspect for assessing the effect of mandatory masking is that the reported infection figures may always include infections that originate from outbreaks, e.g., in homes, hospitals, or community shelters. Institutional outbreaks, however, are not influenced by mandatory masking in public spaces, so that a decrease in infection figures in a locality or region may be due to the fact that outbreak events had previously increased the number of infection cases, but afterwards the case numbers were lower than before the introduction of mandatory masking due to the absence of further outbreaks. This is precisely what seems to have played an important role in Jena, considering events (2) and (3), as shown above: These were most likely time-limited outbreaks, each with high numbers of persons 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 concrete epidemiological context, but cannot be influenced by a mask requirement when shopping or using public transport. Thus, without taking into account from which epidemiological context the infection figures reported from the different locations originate (i.e. whether outbreaks were among them or not), the effect of masks in public on the occurrence of 'new infections' (= positive test results) necessarily remains unclear.

Overall, this modeling study also does not produce results that would support a masking requirement because, in addition to the introduction of the masking requirement, the listed potential influencing factors (probable outbreaks), especially from the period before, were not taken into account. With these limitations of the study, circular reasoning can easily occur because the authors, as economists, do not have medical/epidemiological expertise and therefore did not include important potential influencing factors, such as the issue of outbreaks and their possible causes, in their considerations.

There are numerous examples from other countries where, for example in Spain, despite the strictest masking requirement, the number of cases testing positive increased extremely between July and the end of October 2020, while in Sweden, without masking requirement, it increased in the same

period were significantly lower [55]. There are further examples of this from other countries: despite mandatory masking, the numbers of positive test results rose sharply [56, 57]. However, one can see something similar for Germany from the RKI data (introduction of mandatory masking on April 28) (e.g., in the daily situation reports). Similarly, the head of the Austrian AGES (Agency for Public Health) said that neither the introduction of mandatory masking nor its repeal has had any measurable impact on the incidence of infection in Austria [58]. In the last two months of 2020, the number of people testing positive also increased significantly in Sweden, but not to the same extent as in Austria, where the mask requirement has been in place almost universally since the spring of 2020 [58]. Influencing factors may also have remained undetected in all of these empirical data from numerous countries, but it is striking that there was no effect of mandatory masking on case numbers in any of the countries.

5. Mathematical estimation: Wuhan, New York and Italy

This was another modeling study that aimed to show for Wuhan (China), but mainly for Italy and for New York City, that with the introduction of mandatory masks in the public, the number of new infections decreased significantly [59]. This study was apparently quickly criticized for poor statistical methods (and the journal was asked to retract the article, which did not happen) [60]. A critical letter to the editor regarding this study was accepted and published by the journal [61].

From an epidemiological point of view, there are fundamental objections against this study, which make its results not meaningful, no matter how well they might have been calculated. As in the 'Jena study', these authors (also not physicians or infection epidemiologists, but chemists, including a co-chemistry Nobel Prize winner from 1995, as well as physicists or geologists) have overlooked the fact that the effects of a measure could not be seen immediately, but because of the interval between the time of infection and the reporting date at the earliest approx. 2 - 3 weeks later.

Moreover, the authors believe that they have not only shown that the mask requirement had the greatest effect of all measures, but are also convinced that their study has proven that aerosol transmission of the new coronavirus is the dominant mode of transmission. From what specifically they conclude this, they do not elaborate, but possibly from the fact that masks mechanically arrest respiratory droplets and thus prevent them (i.e., the smaller ones that do not immediately sediment) from forming aerosol particles that are capable of suspension and may contain viruses. They further claim that the aerogenic route of transmission is the most efficient because aerosol particles already reach deep into the lungs during normal inhalation, and also that this route of transmission typically requires a low 'infectious dose'. In addition, free-floating viruses have a high mobility and a sufficiently long 'survival time' for their spread.

However, on the one hand, these are consistently unsubstantiated assumptions and no scientific evidence and, moreover, assumptions that are not compatible with the findings as to which anatomical regions the new coronavirus must reach: because it replicates in the upper respiratory tract and mainly in the nasal mucosa, but not in the lungs [62] (see **part C.**). Furthermore, until then nothing was known about the so-called 'infectious dose' (i.e., with how many pathogens must a principally susceptible person come into contact for an infection to occur), and thus there was no evidence that a

low virus number is sufficient for an infection (in the meantime, a little more is known about this; see **part C.**). Finally, coronaviruses, as viruses with a lipid envelope, are among the most sensitive viruses to environmental influences, all in all not good prerequisites for 'surviving' unprotected in the air for even a slightly longer time capable of infection or
- In more scientific terms: to remain capable of infection and replication. The authors are natural scientists and obviously did not ask themselves such questions or could not ask them as non-medical scientists.

Also, the authors have not shown, for example, as stated in the critical letter to the editor [61], (1) from which epidemiological context the infections originated, i.e. whether they were acquired in the private sphere or during patient care and, if the latter, whether the personnel had sufficient protective equipment available. And they have (2) furthermore not considered that other factors besides the mask obligation may also have played a role (so-called confounders), and (3) furthermore also not considered how the masks were accepted by the population in the first place, because even if they are compulsory to wear, one cannot assume that all people also use them and - also important - wear them correctly.

6. Mathematical-theoretical study

Another paper is a purely mathematical-theoretical modeling study published at the end of April 2020 [63]. The authors (all mathematicians and statisticians) are - similar to the RKI in [1] - very cautious about the effectiveness of masks, but ultimately claim that masks together with other interventions (so-called 'social distancing' and especially hygiene measures) could reduce mortality and the burden on the medical system. While masks are not a '*panacea,*' the authors say, they could have a synergistic effect along with other non-pharmaceutical interventions. They go on to write that masks alone, if not very effective and 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. The relative benefits of general mask use could interact with other public health measures. Masks, therefore, should not be considered as an alternative but as a complement to other public health measures. They 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 - value of even low-effectiveness masks if used widely.

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 mask use, uncertainty regarding their (intrinsic) effectiveness (especially for self-sewn masks) in capturing respiratory droplets and/or aerosol particles, and finally because of, as they actually write, even surprising levels of uncertainty regarding the basic transmission mechanisms of respiratory infections. Nevertheless, they conclude their paper by stating that - despite uncertainty - (1) the potential benefits, (2) the lack of obvious harms, and (3) the precautionary principle lead them to strongly recommend the most universal possible use of masks in public (and indeed everyday masks, except when

medical masks could be used without affecting the medical system). Thus, the authors make surprising claims: (1) without evidence, a potential benefit of masks is simply assumed, (2) that masks are quasi side-effect free is among the other unproven assumptions, and finally, (3) the precautionary principle cannot be invoked to justify measures based on plausibility alone.

In contrast to aftercare, precaution means not only recognizing potential hazards or risks before they occur and assessing their significance, but also reacting to potential risks at this point in time - despite possibly incomplete knowledge - so that they either do not occur at all or, if they do, then only in a weakened form. The so-called precautionary principle originates primarily from environmental policy and was concretized as follows at the UN Conference on Environment and Development in Rio de Janeiro in 1992:

> 'In the *face of the threat of irreversible environmental damage, a lack of complete scientific certainty should not be used as an excuse to delay action that is inherently justified. …*'.

The idea behind the precautionary principle is that measures to protect against potential risks should be taken even if it is not yet known exactly what these risks are based on and whether they will materialize at all and, if so, to what extent [64, 65]. The precautionary principle has also been extended to health and safety policy. It is always a matter of

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

Acting in accordance with the precautionary principle requires a strict risk-benefit assessment, so that the means or measures used to reduce or eliminate the potential threat do not lead to a burden on society that is possibly more harmful than the realization of the potential threat. Thus, when acting according to the precautionary principle, not only the negative consequences of the potential 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. To this end, a sound scientific basis must be established on the basis of which both the benefits and risks of one aspect and the other can be assessed, even if not conclusively.

Acting according to the precautionary principle therefore requires some preliminary work with a description of the potential risk and as much scientific basis as possible in order to be able to prove an effect of the intended measures on the impending risk. Plausible considerations as justification for the chosen measures are not sufficient if one wants to justify one's actions with the precautionary principle. This is exactly what happens when one refers to the precautionary principle without further scientific justification and declares the wearing of masks as a measure that can protect against the spread of the coronavirus [63].

It is not quite that simple, otherwise one could enforce any measure with reference to the precautionary principle. The federal government suddenly started at the beginning of 2021 to justify the Corona measures because of the new virus variants with the precautionary principle, after there was no talk of this in 2020. However, there were

there are no further explanations on the part of the politicians, as if the term 'precautionary principle' for itself and made any justification superfluous.

This modeling study looks somewhat similar to the contribution of the RKI [1]: At the end there is a statement which cannot be reconciled with the considerations of the authors before, namely that the validity of their theoretical results for reality is completely open. If one reads only the last paragraph of the publication, one learns nothing 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 effectiveness of masks in public spaces and should therefore be mentioned here.

Without going into the details of the methodology, the procedure was as follows: One group consisted of hamsters artificially infected with the new coronavirus, and the other group of hamsters was without infection. The respective cages were close to each other and either separated by a wall made of surgical mask material or not. The mask material was intended to simulate an infected individual wearing a surgical mask. Thus, there was no direct or indirect contact between the animals in either group, so that pathogen transmission, if it occurred, must have resulted from droplets of respiratory secretions or aerosol particles. As a result, when the surgical mask material was used, there were significantly fewer corona infections in the exposed, i.e., primarily uninfected, animals, from which the investigators concluded that this protection was effective.

However, the question arises whether one can conclude from the result of such an animal study on the effectiveness of (surgical) masks in humans, even more so when they are worn by millions of people in public, because the two settings are quite obviously not comparable with each other in any way. In 2020, when the study was conducted, no surgical masks were worn in public either, but anything one liked, up to some cloth, was allowed. Second, the principle effectiveness of masks depends not only on their material, but significantly on how they are worn, i.e., how well they fit all over the face. In public places, it is easy to see that there are very different ways of wearing masks and, as a rule, none that are even close to correct. So even if a clear effect is observed under the controlled conditions in the animal study, this does not mean that the result could be extrapolated to the general population. Surprisingly, however, the authors themselves come to this conclusion - and that is why journalists have also reported in this way, even though they too could recognize that the conditions are very different and not comparable with each other.

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

The RKI named to the question about the background of the '*first scientific indications*' of 19.07.2020 in its answer of 21.07.2020 on the one hand two experimental

Laboratory studies (from 2008 and 2013, so known for quite a long time) in which the principal ability of textile MNB to retain droplets was shown, albeit with a large influence on efficacy by the material used [67, 68]. For evidence of the '*infection-preventive effect at the population level*', the RKI has given the three modeling studies discussed here [50 - 52, 59, 63] (where [50 - 52], as stated above, are three publications on the same investigation).

Thus, with experimental and modeling studies, the RKI (at the time of the inquiry in July 2020) wanted to substantiate its then new statement, still present in the FAQ today, of the '*first scientific evidence*' for the effect of masks as foreign protection.

At the beginning of 2021, a request from the public was submitted to the RKI according to the Freedom of Information Act. The RKI was asked to provide the scientific basis (1) for the statement that asymptomatic persons infected with SARS-CoV-2 cause a relevant proportion of transmissions and (2) for the mask requirement. The RKI responded by listing a total of 8 citations: 2 for asymptomatic transmission and 6 for mask effectiveness. Of these, the following literature citations are included in this advisory. (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 various substances is included in the review [29]). One of the literature citations was not addressed here because it was a study from the hospital setting in medical personnel (fabric masks versus medical masks). All 6 citations on the effectiveness of masks were obviously copied by the RKI from the BfArM's statement on the use of masks (the same citation errors are present, and the order of the citations also corresponds to the BfArM's information). The contribution of the BfArM is discussed in **part B.**

A little more than half a year after the July question (see above) on the effectiveness of masks for external protection, the RKI's current information shows that there is no scientific evidence for the effectiveness of masks for healthy people in the public for external protection and that there is also no scientific evidence that pathogen transmissions from asymptomatic persons play a relevant role in the spread of SARS-CoV-2.

Additional publications on the effect of masks

After having discussed publications up to this point, which have always been mentioned especially in the media, but also by scientists, when it came to the allegedly assured effectiveness of masks in the public, and which have thus achieved relative popularity, lesser-known publications will be presented in the following.

The publications were mainly found via the bibliographies of other publications, e.g. also the current ones of the international health authorities, in order to check the publications cited by the respective authors as evidence for their assessments. They are each briefly discussed in the chronological order in which they were submitted to or published in the journals (as indicated).

a) Publications 'per masks

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

1. **Narrative** review (letter to the editor, and therefore without peer review = expert opinion from the same field, submitted April 2020) [69]: This is a small literature review, with most of the studies discussed coming from the clinical field, if they are mask studies at all and not other issues or general pronouncements from international health authorities without citing literature. Ultimately, masks are advocated by the authors even though they have cited no scientific data for them.
2. **Mathematical estimation** (submitted April 2020) [70]: The purpose of this mathematical modeling study was to determine the potential effectiveness of masks in combination with lockdown periods on the infection dynamics of the new coronavirus. The authors concluded the following: (1) The baseline R0 can be reduced below 1 if masks are always worn in public, not just when there are signs of respiratory infection. (2) If lockdown periods with 100% mask use are introduced, there is no more spread of infection, secondary and tertiary 'waves' are 'smoothed out'. Thus, the epidemic is under control. This effect is also given if the masks used are only 50% effective in stopping the exhaled virus (with an equal or lesser 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 was: '*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 scarce in many places and not even sufficiently available for medical personnel or personnel in homes. The authors wanted to contribute to the study of the epidemiological significance of masks in the general public. According to the calculations they made, masks can reduce both infections and deaths even with only a limited effect and can delay the peak of the epidemic. They conclude that masks are an effective intervention strategy, especially for a pathogen that is often present asymptomatically. It is important, they say, to distribute masks optimally so that they are available in the first place. Obviously, the authors assumed different levels of mask effectiveness in their calculations, without making it clear what levels of effectiveness they relied on 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 version 4 without completed peer review, finally published in January 2021 [72]: 'Narrative' means it was not searched for *all* studies on the topic for the evaluation. This publication, whose title suggests the efficacy of masks, is very frequently cited, but it is not readily available due to the selective

Literature selection no '*evidence review*' as stated in the title. Scientifically sound conclusions cannot be drawn from it.

5. **Mathematical estimation** (submitted May 2020) [73]: the authors highlight that they took a different approach than most modeling studies, which focused mainly on the dynamics of transmission of the virus and on the resulting reproductive number (R0). Rather, they wanted to include affected people by looking at different groups of people (e.g., susceptible, symptomatic, hospitalized) to represent optimal control of infection with different non-pharmaceutical interventions. As a result, the following measures were most effective in their model: staying home, hand washing, early case detection (using PCR), and masks. Introducing all strategies at the same time for at least 50 days could greatly reduce the number of new cases, they said.
6. **Narrative review** (submitted May 2020) under the 'Viewpoint' section in the respected scientific journal '*Science*' [74]: Repeatedly, this publication has been referred to as a '*study*' with evidence for the effectiveness of the masks. However, it is not a study, but a simple opinion piece. It is a small review paper (of 2 ½ printed pages), in which mainly hypotheses are raised as well as some questions and only a few studies (among them an animal experimental one with golden hamsters; see above) are mentioned, but not and certainly not exhaustively discussed. The aim of this publication was obviously (this is legitimate in a scientific context) to initiate some question, but the authors do not try to give fixed answers. Thus, this publication is not suitable to prove an effectiveness of masks in the public.
7. **Narrative review** (submitted May 2020) [75]: the authors (who are very numerous) did a very limited literature review, but it does not allow any conclusions to be drawn about the effectiveness of masks in the public, as many experimental mask studies and mask studies from the hospital setting were among them. Studies on mask wearing in public were not among them, but neither are there any such studies. Nevertheless, the authors conclude that masks should be worn whenever spacing is not possible (e.g., on public transportation) because it is very likely to reduce the spread of virus-containing droplets and thus the transmission of SARS-CoV-2. Furthermore, the authors say it is undisputed that infected individuals can transmit the pathogen days before symptoms appear. Although this was the prevailing view in mid-May 2020, when the article was submitted, even then it lacked scientific evidence and was based on assumptions and misleading publications [16], but even then it was questioned or corrected [17 - 19]. This article does not contribute to support the effectiveness of masks for healthy people in the public (but is cited for this by RKI and BfArM; see above).
8. **Mathematical estimation** (letter to the editor, i.e., no peer review, submitted June 2020) [76]: 42 geographic regions on six continents were included. The purpose was to examine whether there was a relationship between the frequent use of masks in some countries, particularly Asian countries, as opposed to others, such as European countries, where the use of masks was not established or yet mandated during the early phase of the pandemic (from January 21 to March 11). The question of this study was whether the early use of masks in the Corona pandemic might have helped contain the pandemic. The authors' finding was that the number of cases in some

Asian countries (masks were used earlier) was lower than in other countries (masks were used later). According to the authors, masks were an independent factor in controlling the pandemic. Still, they conclude only that it is reasonable to assume that mask use could mitigate the pandemic because it could reduce the release of aerosol particles and droplets. They believe, they write, that wider use of masks is key to controlling the pandemic, independent of hand hygiene, so-called social distancing and other measures.

9. **Mathematical estimate** (submitted July 2020) [77]: The use of masks was investigated for employees in stores with regular customer contact, but the use of masks in public, as is mandatory in Germany, is not comparable with this setting. Thus, the results cannot be applied to the question of the effectiveness of masks in public spaces for almost every citizen. Moreover, the authors themselves say that their results should be interpreted with great caution.
10. **Mathematical estimate** (submitted August 2020) [78]: base was US states with and without mandatory masks between April 8 and May 15, 2020, but compliance with mask use could not be determined, as the authors elaborate, so it is unclear how often masks were worn at all (and certainly not whether they were worn correctly). In addition, only the 5 days prior to the imposition of the mask requirement were taken as the reference period, which is far too few for a before-and-after comparison, because it takes much longer for the effect of a new measure to become apparent (about 10 - 14 days). For this reason alone, the study would therefore not be meaningful. However, the authors only conclude that their results suggest that mandatory masks in the public could help to mitigate the spread of COVID-19, so they are cautious about the validity of their study.
11. **Mathematical estimate** (submitted August 2020) [79]: All authors come from ophthalmology backgrounds and included and compared a wide variety of countries around the world for their study. Countries such as Africa, Latin America, Asia, and Eastern Europe with very different infection rates, population structures, and climates were included in the study. However, effects based on regional geographic observations and associated characteristics (e.g., climatic) are not suitable for comparison with or among each other. The appropriate limitations apply to this modeling study: There are different causes for increases in case numbers (e.g., outbreaks), different compliance with masks, which is not retrospectively verifiable, and other factors (so-called confounders, i.e., variables that influence both the occurrence of risk factors and the outcome of an observation) that cannot be detected in such a study.
12. **Mathematical estimation** (submitted September 2020) [80]: Compliance with mask wearing in 24 countries was evaluated to determine the possible influence on case numbers. 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 variables that could not be accounted for in the model. As a result, the authors conclude very cautiously that because of such confounding factors and also because of variations in mask types as well as in their use, randomized controlled trials of mask use in public places are needed to determine the true effect of mask wearing on attenuating respiratory pathogen transmission.

13. **Mathematical estimation** (preprint, submitted to *Science in* September) [81]: According to the authors, this study was intended to avoid the problem with the use of assumptions in complex mathematical modeling by simply plotting the disease cases, hospital admissions and deaths and the respective date against each other. However, again, possible other (confounding) factors were disregarded and only policy measures, such as school closures, etc., were included. Furthermore, it is not stated where the respective case numbers originate, and one does not learn in which epidemiological context the cases occurred, e.g., in public or in hospitals or nursing homes and, if the latter, whether the staff there had adequate protective measures, such as protective clothing, available during the typically close and prolonged care of patients, or what proportion of the cases originated from outbreaks. Furthermore, the authors assume that the virus was new to the population, which is immunologically incorrect, as we know that more than 80% only get sick mildly or not at all, so we have background immunity through contact with similar viruses or through our natural immunity. There was no exponential growth anywhere, because such infections always spread in the form of a Gompertz curve (and exponential growth always has a natural end, even e.g. bacterial growth in a nutrient solution). By the way, this paper is one of the numerous pre-publications (preprints: as of early January 2021), i.e. the authors' manuscripts submitted to the journal, which have not yet gone through a so-called peer review, which means that things can still change, because very few manuscripts simply go through the review process and are published without the authors having to make changes.
14. **Systematic review** (summary of a so-called '*rapid review*' by authors of the RKI, published in September 2020 on the internet pages of the RKI) [82]: In this work, a total of 27 mathematical modeling studies were evaluated with regard to the effectiveness of non-pharmaceutical interventions in controlling the COVID-19 pandemic.

    On the one hand, this work from the RKI has not yet been published in a journal, but the entire manuscript has also not yet been published as a preprint; there is only a summary of it on the RKI website. Secondly, numerous papers are cited in this review as preprints, which in turn have also not yet been published in peer-reviewed journals. Nevertheless, the RKI writes the following under the link on the corresponding website (last viewed on 03.04.2021):

    > '*As part of a rapid review, the Robert Koch Institute (RKI) reviewed studies published in peer-reviewed journals on the effectiveness of nonpharmaceutical interventions (NPIs) in curbing ...*' (emphasis added for this review).

    The RKI thus claims that the studies discussed have already been published in scientific journals. However, of the 6 citations in which, among other things, the effectiveness of masks was investigated, this is not true for 4 citations because they are (also) still in the preprint stage. This preliminary publication also lacks citations of papers that are critical of the Corona measures. In addition, a conspicuously large number of preprints are cited. However, this only becomes apparent when one looks at the bibliography. Working with such manuscripts, which have not yet been peer-reviewed and thus not yet accepted by the journals, in a literature review is not unproblematic, because until the final

publication may well change essential aspects of a paper (if the paper is ultimately accepted for publication at all).

In the media, for example, reference has already been made to this work, which is not yet available as a complete manuscript, i.e. not verifiable in detail, in such a way that the recommendations of the RKI are based, on the one hand, on a comprehensive evaluation of the currently available scientific findings and, on the other hand, that the recommendation to wear masks as a protective measure against SARS-CoV-2 is therefore definitely evidence-based. However, these conclusions are neither possible nor scientifically admissible on the basis of the '*Rapid Review*' from the RKI.

15. **Mathematical estimation** (abstract, authors from the RKI, published on the RKI website in September 2020) [83]: This RKI article also contains selective citations. Although it has not yet been independently peer-reviewed by the journal '*Lancet Public Health*', to which it was submitted, it has already been published in an abstract, like [82], also on the RKI pages. In it, a modeling study using publicly available databases aims to examine the impact of each of the non-pharmaceutical infection control measures used within the 37 OECD member countries from January - July 2020. The authors conclude that restrictions on gatherings and assemblies are most effective. In addition, mask-wearing, school and work closure policies, and testing volume could curb the number of positive cases. However, the literature list lacks publications in which Corona measures were critically evaluated as having no impact on infection incidence. Upon inquiry to the RKI with the request to send the complete manuscript, it was informed that there are numerous
The author is of the opinion that there have been '*suggestions from the professional public*' regarding the manuscript, which is why it is being revised and resubmitted. It remains to be seen whether the literature list will be completed after the revision.

    These two RKI publications by Pozo-Martin et al [82, 83] help the federal government to justify the Corona measures taken. Presumably for this reason, they have already been posted as an abridged version on the RKI pages, but without also publishing the full manuscripts. Readers who are not familiar with the rules of publication may not realize the problems associated with such pre-publications, which are even more incomplete as summaries (so
    e.g. journalists treating them as if they were closed publications).

16. **Mathematical estimation** (preprint, submitted October 2020) [84]: All authors are from economics. The subject of this mathematical estimation was, first, the effect of the indoor mask requirement in Ontario, Canada's most populous province, between March and mid-August 2020, where the mask requirement was phased in over approximately two months in the total of 34 regions, so that regions with earlier mask requirements could be compared with those where the mask requirement came later. In a second approach, the impact of all non-pharmaceutical interventions (NPI) including masks was calculated for all 10 provinces in Canada. Differences between provinces in both mask effectiveness and the effectiveness of the other NPIs were analyzed. Estimation of differences between regions with or (still) without masks in the province of Ontario showed (already) two weeks after the introduction of mandatory masks a reduction in weekly new positive

Corona Falls by 25 - 30%. At the level of all provinces, this result was confirmed and was even higher at 36 - 46%. This time lag before the mask requirement is very narrow, because after about two weeks the first effects of a measure begin to show, if there should be any. Apparently, however, there was no further reduction in positive cases in the period thereafter, otherwise the authors would have reported it, and this makes the result even more questionable from an epidemiological point of view. As usual in mathematical modeling studies, possible other (confounding) effects could - by necessity - be excluded.
)factors are not included, but only the policy measures, i.e. in this case the mask requirement.

17. **Narrative review** (first submitted October, revised November, published December 2020) [85]: It is a review paper that looks at mainly recent (rather than all) publications on masks. For this reason, the authors refer to the work as a 'narrative update'. It is a text that strings together one claim after another and also fails to come up with any new work because there are no relevant studies.

b) Publications 'contra masks

In the following, 7 publications are presented that have not demonstrated a positive effect of masks in the public, even if they partially recommend the use of masks in the result (again, in the chronological order in which they were submitted or published, depending on the information in the publication).

1. **Systematic review** (submitted May 2020) [86]: 9 randomized controlled trials conducted outside medical facilities (households, student dormitories) were evaluated. No efficacy of masks as a sole measure for prevention of influenza-like illness (ILI) was found. In each of 6 of these studies, 3 groups were compared: (1) hand hygiene alone, (2) masks and hand hygiene, and (3) no measure. A significant reduction in ILI was found only with the use of masks along with hand hygiene, but not with masks alone. However, the authors note that the exact protection of masks over and above other measures, such as hand hygiene, remains unclear.
2. **Systematic review with meta-analysis** (commissioned and funded by WHO in 2019, published in May 2020) [87]: The work was intended to prepare for the development of a guideline on the use of so-called non-pharmaceutical interventions in the general population for pandemic influenza. In it, 10 randomized controlled trials of masks were evaluated to determine their effect on transmission of laboratory-confirmed influenza infections. No evidence of mask effectiveness in reducing influenza transmission emerged, either when worn by infected persons to protect contacts (third-party protection) or when used by noninfected persons for their own protection. The authors also note that correct use of masks is essential because otherwise the risk of transmission may be increased.
3. **Living Rapid Review'** (first part published in June 2020) [88]: Subsequently, a total of five updates have been published (last in March 2021) [89 - 93]. The aim of this continuously updated review is to examine the effectiveness of masks in reducing respiratory viral infections, including SARS-CoV-2, on the one hand in the context of patient care in medical facilities and on the other hand in the

population. So far, no evidence for the effectiveness of masks outside the medical field has been found.

4. **Umbrella Review** (published July 2020) [94]: In this work, all available systematic reviews of randomized controlled trials were evaluated together (in contrast, in usual systematic reviews, the original studies are evaluated). In each case, the subject of the study was the use of masks to protect against respiratory infections in medical personnel and normal members of the public. No evidence was found for masks as external protection, and even for the wearers themselves there was only a possible reduction in the risk of infection (self-protection).

5. **Mathematical estimation** (preprint, submitted October 2020) [95]: eight different so-called non-pharmaceutical measures (in addition to wearing masks
e.g. limiting gatherings, closing stores, closing schools) in 41 countries were investigated for their effect on the reduction of the R-value. However, it was found that when masks were included in the evaluation (together with the other measures), no further reduction in R-value resulted, i.e. masks had no effect.

   In December 2020, the study was published in *Science,* but since then the evaluation of the masks is no longer available [96]. The article does not explain this. Thus, if one has not read the preprint, one does not notice that the measure listed there in the first place is missing in the final publication. The only mention at the end is that it was difficult to estimate the effect of masks in public spaces because there was limited public life due to the other measures that were enacted. In the preprint it was said about masks [95]:

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

6. **Randomized controlled trial** (conducted in April and May, published in November 2020) [97]: In Denmark, this study investigated whether the recommendation to wear a surgical mask whenever leaving the home, in addition to other known protective measures (keeping at a distance, etc.), could reduce the risk of infection with the new coronavirus in a population with moderately high infection rates. At the time of the study, wearing masks in public was rare in Denmark and was not publicly recommended. Participation in the study was open to those whose occupation did not require them to wear masks and to spend at least three hours per day away from home and among people. By randomization, a total of 3,030 study participants were assigned to the mask group

and 2,994 participants in the control group. Infection with SARS-CoV-2 was detected by antibody detection, PCR testing, or hospital diagnosis. In the mask group, infection by the new coronavirus was detected in 42 participants (1.8%) and in the control group in 53 participants (2.1%), so the difference was small (and not statistically significant) at 0.3%. The study was aimed at self-protection and was therefore - in contrast to the mandatory wearing of masks in Germany until January 2021 - not aimed at the protection of others, so that this study cannot contribute to answering the question of whether the wearing of masks by healthy people has an effect on the protection of others, i.e. whether other people can be protected from contact with the pathogen. However, the study is just as unsuitable to support the self-protection by medical masks, on which the policy in Germany under the impression of the new variants ('mutants') since January also sets. There is also no scientific basis for this decision that since then OP or FFP2 masks (in Bavaria only FFP2) must be used when shopping and in public transport.

7. **Experimental study** (published in December 2020) [98]: The Deutsche Bahn AG (DB) and the German Aerospace Center (DLR) carried out the project '*Air Quality in Rail Vehicles*' on the occasion of the Corona pandemic. In this project, the dispersion paths of particles in the order of aerosol particles (simulated by the release of CO_2 as tracer gas or artificial saliva particles with a diameter between approx. 3 - 4 µm from a source at the head height of a seated person in the train carriages) were to be investigated with an experimental procedure in a stationary test car (type ICE 2). The measurements were carried out in each case without and with (surgical) mask. The result (already) without mask was that the spreading takes place mainly directly and immediately at the source. There was no spreading in the whole wagon or indirectly via the ventilation system. Interesting is (1) the result that a passenger sitting at a table directly opposite the source of the pathogen (i.e. close face-to-face contact at a distance of approx. 1 - 2 m) comes into contact with only 0.2% of the released particles, whereas at the seats in front and next to it on the other side of the aisle only 0.01% arrived. In other words, even for the person sitting directly opposite, there would be practically no risk of coming into contact with a released pathogen. Another important point is that (2) the ventilation system operates with a very high air exchange rate and also with a high proportion of fresh air, so that all the air in the wagon is exchanged once every 5 min or so (i.e. 12 air changes per h). This in turn means that there could be no relevant pathogen contact for the passengers, given the constant dilution by the supplied air, also because the contact time is much too short to lead to infection if the particles were infectious, given the low spread of particles away from the pathogen source, as the results show.

   DB and DLR should have concluded per se from their results (which were very good for the ICE 1/2 fleet, but also well transferable to many other types of rail vehicles) that masks are not necessary in trains because (1) there is hardly any aerosol dispersion and (2) the entire air of the wagon is exchanged within a few minutes by the ventilation system, so that potentially infectious 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 with fresh air supply, i.e. a dilution of the particles in the air of the wagon takes place, which reduces the potential risk of transmission continuously, very quickly and to a high degree.

reduced to a certain extent. The mask reduces this risk only insignificantly and only for the immediate seat neighbor. For these reasons, this study was included here in the group of contra-mask studies, contrary to the interpretation of DB and DLR, because the results speak against masks having an effect in terms of protection against infection. However, whether 'aerosol' transmission, which was taken as a given in the study, plays any role at all in the transmission of coronavirus is the crucial question 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 public spaces, although, as with WHO [41, 42], limited to specific epidemiological situations, but by all with clear
'warnings' are provided, with the consequence that policy-makers refer to these very assessments, made however without scientific basis, but limit the 'warnings' to the need to nevertheless keep their distance.

It must be stated that all national and international health authorities, albeit reservedly, have given an assessment on the wearing of masks in the public space with great implications, contrary to the scientifically established standards of Evidence- based Medicine, which is based only on so-called plausible considerations, which, however, cannot be sufficient to provide policy-makers with a scientifically sound basis for decision-making in such a situation, i.e. for the use on millions of people. A clear scientific opinion, as one can expect from these authorities, looks different.

Not surprisingly, therefore, the literature published since the spring of 2020 has shown no evidence of mask-wearing by the general public, even if the authors of mathematical estimates claim so and the authors of opinion pieces in e.g. narrative reviews do not (cannot) present data for this. Numerous physicians of various specialties and scientists from other disciplines like to refer to such 'positive' publications, and in particular often to modeling studies, which are anyway not comprehensible to people with not particularly sound mathematical foundations (not quite rare among physicians) and thus have a deterrent effect, but perhaps just by this 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 reviews are missing. In contrast, the quality of 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 has been and continues to be cited by countless physicians as evidence. They think they are on the safe side, probably because this journal (together with the NEJM) is one of the two highest-ranking medical journals in the world. This means that physicians can be sure that what is published there has a sound basis, has been thoroughly examined by a relentless peer review, and can be

be taken on trust. This assessment is clearly not appropriate for this article. What's more, it's easy to see without having to know how meta-analyses work mathematically. The WHO had this
WHO commissioned (and funded) an '*urgent review*' because it apparently needed the results urgently (hence an '*urgent*' review) for a new evaluation of the mask issue for the new coronavirus. Already in 2019, WHO had commissioned a similar review related to influenza pandemics [87]. However, because influenza was apparently 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, an 'urgent review' was requested by WHO in which only publications on the three particular, because non-seasonal, coronaviruses SARS, MERS, and SARS-CoV-2 should be evaluated (with SARS-CoV-2 likely to become a seasonal one).

To do this, WHO needed a publication in a journal that was beyond reproach. The more recognized a journal, the easier it is for readers to accept and disseminate the messages of the articles published in it. However, it is not known to what extent the results of the literature search met the expectations of the WHO. To put it charitably, both the authors of the Lancet review and the WHO with its mask recommendation of June 5, 2020, have at least tried to get out of the affair with scientific decency, so to speak. What remains, however, is that the WHO has probably bowed to the political pressure, as has been reported, but then makes the clear statement that the scientific evidence for the 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 measures incl. masks in autumn 2019, which did not show any effectiveness of masks [87]. In addition, a systematic review with meta-analysis had already been published in 2017, which investigated the effectiveness of hand hygiene and masks [99]. This meta-analysis indicates a significant protective effect only for hand hygiene, but not for masks. The studies evaluated in it from the so-called community setting were conducted in families with persons suffering from influenza. And also the 'Lancet review'
[43] has not been able to show any effectiveness. Studies or opinion pieces published in the period thereafter also failed to show evidence of the effectiveness of masks in public (see above). Thus, according to the scientifically accepted criteria, there is no evidence that masks worn by healthy people in public have a positive effect on the incidence of infection (but possibly a negative effect; see **Part B.**)

The fact that the mask requirement was nevertheless imposed in Germany cannot be reconciled with the requirements of the IfSG in § 1 (2), according to which infection protection measures should be evidence-based. Political decisions are not provided for in the IfSG, 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 worldwide shortage of professional masks (of which there were by far not enough in clinics and nursing homes in the spring of 2020, so that they were out of the question for use by the population in Germany anyway), the general mask requirement could only be introduced in Germany with the indication that self-sewn masks or even just a cloth in front of the mouth and nose were also sufficient.

Naturally, no statements can be made about the quality of non-medical masks, because every citizen could use what he wanted. For this reason alone, as stated in the RKI article, no data can be available [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, however, the last sentence of the RKI article [1], as everywhere else in the text, should only have mentioned that masks could be a building block to reduce transmissions, but not to formulate this as a fact.

All extensions of the mask requirement, such as in schools, in parliaments and on hiking trails (e.g. like through the Höllentalklamm in the Zugspitz area because of narrow places on the way), in pedestrian zones of city centers or on parking lots in front of stores because of possible crowds or also in some communities when riding a bicycle in the city are based not least on the unscientifically led 'aerosol'-discussion, which was propagated by bio-scientists and taken up by aerosol-physicists as well as by 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 school children 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 and weeks would have been approved by an ethics committee in Germany. However, even pediatricians have advocated that school children should wear masks, or can wear them without harm, even during lessons [101]. In an '*open letter*', a pharmacist has commented on this and expressed his lack of understanding that the statement of the pediatric societies lacks any scientific and ethical quality [102]. He questions whether the mask is not rather a political instrument than a useful medical measure and whether the authors and signatories fulfilled a political mandate less as physicians but more as political functionaries. If so, the author continues,

> '*however, it would be appropriate to present this mandate transparently and explain that the wearing of masks for children is politically desired and the risks that may exist in doing so are accepted*'.

A few months earlier, this author had already published an article in the *Deutsche Apotheker Zeitung, in* which he criticized, among other things, the fact that all standards previously important for the effectiveness of masks have been invalidated, and that only some piece of cloth in front of the mouth and nose is important, without paying attention to filter effectiveness (in view of different particle sizes), and without attaching importance to the correct handling of the masks, or that the actual risk of transmission plays a role [103].

Since the introduction of the obligation to wear masks, they have been held up as the only visible measure by politicians and the scientists advising them, and most of them have been strictly demanded, although they have clearly had no effect over the months. Instead of abolishing them - as obviously useless, potentially harmful and just not confirmed by data that can be called scientific - the mask obligation was successively extended to e.g. the irrational obligation to wear masks outdoors in crowded places or in pedestrian zones (against which also virologists and aerosol physicists speak out), to the obligation to wear masks for pupils even during the whole school day and the FFP2 mask obligation in stores and in public transport in Bavaria.

The fact that schoolchildren are now forced to wear masks for hours on end, and sometimes even during recess in the schoolyard and in physical education classes, is already incomprehensible in view of the complete lack of medical evidence. In addition, there are no systematic studies on possible harmful side effects and such studies are not even required by the professional societies of pediatricians. That the side effects are by no means harmless or rare is shown by a study (already published in December 2020 as a preprint and in the meantime final) of the University of Witten-Herdecke, in which preliminary results from an online register, in which e.g. parents, teachers or physicians can enter the complaints of children in connection with wearing masks, are presented [104]. At that time (within 1 week after the start of the registry), approximately 18,000 participating parents reported the following complaints about nearly 26,000 children, with an average wearing time of 4.5 h per day (with the respective percentage frequencies): irritability (60%), headaches (53%), concentration difficulties
(50%), dejection (49%), dislike of school or kindergarten (44%),
Discomfort (42%), learning difficulties (38%), and drowsiness or fatigue (37%).

S3 guideline of the AWMF. Despite the lack of confirmation of the effectiveness of masks in the general public from scientific studies, an S3 guideline of the AWMF was published on February 1, 2021, with the participation of numerous professional societies, in which the wearing of masks was pronounced as an 'evidence-based recommendation' with the recommendation grade 'Strong recommendation A', although the quality of the evidence was classified as '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 consensual recommendations for action.*
>
> *The guideline recommends adaptable and appropriate packages of measures to reduce the risk of infection and enable schools to operate as safely, regularly, and continuously as possible during pandemic periods.* (…)
>
> *These recommendations were developed by a representative group of experts from scientific societies, school stakeholders, and policy makers using a structured approach. They are based on currently available studies on the effectiveness of measures to control and prevent transmission of SARS-CoV-2 in schools.*
>
> (…)‘

Among the notes it further states:

> '***Standard Package of Measures.*** *A package of measures is always necessary for the prevention and control of SARS-CoV-2 transmission in schools: Measures must be implemented in a coordinated manner to be effective. The starting point is a standard package of measures based on the AHA+L rules that apply to the general population and that specifically include spacing, hygiene, wearing an appropriate mask, and ventilation.*
>
> (…)‘
>
> ***'Evidence base.*** *Evidence on the effects of interventions with respect to SARS-CoV-2 transmission was systematically collected using a Cochrane Rapid Review [Ref]. The evidence obtained is largely based*

on modeling studies with quality deficiencies [Ref]. For the potential effects of specific interventions, particularly strong individual studies from the Cochrane Rapid Review were used [Ref]. For all effects considered, the confidence level of the evidence is very low or low."

The recommendation on '*Ventilate and reduce aerosol concentrations in classrooms*' shows very low evidence, but the level of recommendation is 'Strong Recommendation A' as for the mask recommendation.

The claim to the scientific basis of the guideline formulated in the 'preamble' is - as is usual for scientifically based guidelines - high. The concrete recommendations of the guideline stand in stark contrast to this, because despite the lack of meaningful scientific evidence (quality of evidence: 'very low' or
'low'), both masks and ventilation are recommended with the recommendation grade 'Strong recommendation A' with simultaneously high consensus strength (100% for masks and 93% for ventilation). Contrary to the presentation in the 'Preamble', both recommendations are not '*scientifically based* (...) *recommendations for action*', only the consensus level of the participants was high, but this cannot compensate for the lack of scientificity of the recommended measures. Otherwise, one would be back to the time before evidence-based medicine (around the beginning of the 1990s, i.e., about 30 years ago), where experts presented their opinions and were then voted on, if necessary, if there was no consensus anyway. At that time, scientific principles hardly played a role, but rather the 'experience' of the individual experts and their prestige in the group of their respective colleagues mattered. However, the S3 guideline follows this old pattern almost exactly. The only difference is that the underlying scientific evidence has been taken note of and its informative value has been classified. Surprisingly, the level of recommendation was not influenced by this in any way (possibly in the discussions, but not in the outcome, and that is the only thing that counts for a guideline).

As a result, the S3 guideline of the AWMF is not compatible with the requirements for such guidelines, but rather represents a perversion of what constitutes a scientifically based guideline. Ultimately, it is a misdirection of those who are not familiar with the meaning of (high-quality) guidelines (S3). It is thus very much in line with political decisions and may have come about as a result of subjectively perceived political pressure.

In July 2020, a study by the University of Leipzig on cardiopulmonary side effects caused by masks in adults was published [106]. The authors concluded that in healthy individuals, breathing, cardiopulmonary performance and well-being were reduced when wearing surgical masks. However, significant limitations were observed in this regard in the context of FFP2 masks. These negative effects would need to be weighed against the potential protective effect of masks against viral transmission and should influence medical recommendations and policy decisions.

Another study (conducted in the first half of June 2020, i.e. within the first approx. six weeks of the mandatory mask use in Germany) dealt with the psychological, psychosocial and psychovegetative effects of mask wearing [107]. The author comes to the following conclusion: The very fact that approx. 60% of the (approx. 1,000) study participants already suffered from severe (psychosocial) consequences at this early stage of mask wearing, e.g. strongly reduced participation in life in society (due to the effort to avoid mask wearing), social withdrawal,

reduced health self-care (to the point of avoiding medical appointments) or the exacerbation of pre-existing health problems (post-traumatic stress disorder, recurrent herpes simplex, migraine), indicate that the results of the study urgently required an examination of the risk-benefit ratio of the mask prescription.

The use of masks by politicians as an important measure to contain the pandemic and the observations that can be made in the media among politicians and the (normal) public on the handling of masks show that it is probably neither a matter of masks having to be scientifically proven to be effective, nor of 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 is meant by correct handling of masks for reasons of infection control, but there is only an occasional brief reference to this. This aspect also shows that the mask obligation is less about the claimed benefit in terms of infection protection, but about its (psycho)social function, as it was very clearly expressed 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.* '

Even today, the mask seems to have the crucial function of showing the population that the government is doing something to protect them from the presumed danger of infection. On the other hand, it is supposed to be a kind of reassurance to the population that by wearing the mask they can contribute to their own well-being and that of others. The mask is thus needed both by politicians and by the population, which trusts the measures taken by politicians, in order to stabilize their mental and emotional state - including, of course, that of the politicians, who would be left virtually naked, i.e. without a 'protective measure' for the population in times of pandemic, if they did not have the mask and therefore cling to it, even though experience since the spring of 2020 shows that it cannot have the desired effect, because the number of people tested positive has, unaffectedly, been high or The number of people tested positive has risen and continues to rise from time to time, even to unprecedented heights - despite the maximum extended masking requirement. The fact that the mask obligation is important for psychological reasons and because of its symbolic meaning was already expressed in July 2020 on the reintroduction of the strict mask obligation in Austria independently of each other by both the Federal Chancellor and the Minister of Health of Austria in ZIB 2 on ORF 2 and at a press conference [109].

B. Hygiene

At the beginning of June, the German government published the AHA rules [110]. The 'H' stands for 'hygiene', and this means (1) coughing or sneezing into the crook of the arm and (2) washing hands frequently and thoroughly for at least 20-30 seconds. It lacks (3) the proper use of masks. By the time the AHA rules were introduced, about six weeks had passed after the mask requirement was imposed, and by then enough was known about the inadequate and thus potentially infectious handling of masks by the general public. This section therefore discusses the risks from an infection control perspective associated with the mandatory use of masks for almost the entire population, when the policy is already in place to do so.

Use of masks not self-explanatory

The population never learned to use masks correctly and was not trained to do so even after the masks were made compulsory. The RKI never made any concrete statements on this, e.g. in press conferences. It always remained with the rather meaningless formulations for the population, they must be used '*correctly*'. Instead of the constantly repeated request to stay at home, people should have been offered continuous training in the use of masks and it should have been made clear to them that and why certain rules must be observed when using masks. Thus, in addition to the lack of a scientific basis for mandatory masks (see **Part A.**), this aspect is important: if masks are to be used, then proper handling must be given a central role so that the masks themselves do not increase the risk of spreading the pathogen. It is difficult enough to communicate the necessary rules to medical staff or to anchor these rules in their minds in such a way that hospital hygiene staff do not have to be reminded of them repeatedly (but they do have to be). Why this is important will be explained below.

In two places in the (short) article justifying masks to the public, the RKI makes urgent reference to the problems associated with the use of masks (MNB) [1]:

1. ... that '*the use of MNB will not affect the central protective measures, such as the (self)Isolation of sick persons, maintaining a physical distance of 1.5 m, coughing rules and hand hygiene to protect against infection cannot be replaced. These central protective measures must therefore continue to be strictly observed*'.
2. '*Hygienic handling and care of MNB must also be observed. For this reason, care must be taken not to touch* (emphasis added for this expert opinion) the *MNB - especially when putting it on and taking it off - to prevent contamination by hands. In general, a longer wearing time is also associated with an increased risk of contamination*.' (here the RKI refers to the advice of the BfArM = Federal Institute for Drugs and Medical Devices; see below [111]).

However, the correct handling of masks is not self-evident for the population. It is rather confusing when the RKI writes that one should not touch the masks, either - 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 detailed information (see below). The citizen would therefore have to gather the important information from the announcements of various higher federal authorities.

Proper handling of masks important

The mask obligation exists according to the RKI, which made the obligation to use masks in public possible by its publication [1], because every citizen can carry the new coronavirus in the nasopharynx undetected and because it allegedly leads to
'*unnoticed*' transmission of the pathogen to fellow humans can occur during encounters in public spaces (see **Part A.**). Almost all people in Germany therefore have to wear masks because we cannot know whether we currently have the virus in our nasopharynx, even if we do not have any symptoms of an upper respiratory tract infection.

and therefore, i.e. because of this ignorance, cannot stay at home to protect other people from 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 may be present in us from being released into the environment.

What all types of masks have in common is that they must be used correctly so as not to become a quasi risk of infection themselves. Because if we harbor the virus undetected, or if it multiplies or has multiplied in our nasopharyngeal mucosa without causing symptoms, then according to the theory of the
'unnoticed' transmission with our nasopharyngeal secretions a potential source of pathogen, from which it could come to a spread of the virus from our body to other people. So, in order to prevent just that, the mask cannot be the only protection, and that is because human beings - for whatever reason - very often touch their faces with their hands, being a universally known fact that everyone can check at any time on themselves and on 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 disturbs. For example, you sweat underneath it, it itches, your glasses fog up, the mask gets pulled out of place, or you can't get enough air (this is already the case with everyday masks, not just FFP2 masks). People are therefore constantly with their hands on the mask, which one should not touch, however, according to RKI - correctly.

Either way, you yourself or your fellow human beings can come into contact with infectious agents via the mostly unnoticed hand-face contacts precisely where the pathogens of respiratory infections must reach in order to be able to produce an infection, namely to the mucous membranes of the upper respiratory tract, including the eyes (or where they are located if you are already infected). Moreover, it has been known for decades that respiratory viruses (whether envelope-free, such as rhinoviruses, or enveloped, such as influenza and coronaviruses) can remain growable in cell cultures outside the body for a certain time (depending on the extent to which they are embedded in residual respiratory secretions) and thus remain potentially infectious [113 - 115].

Because one can therefore contaminate one's hands almost constantly on various occasions (in one's own household, at work as well as in public) and inevitably has frequent own hand-face contacts, hand washing is one of the recognized indispensable measures to reduce the transmission of respiratory infectious agents according to all health authorities in the world as well as, for example, according to the results of the Cochrane Review Update [1, 33, 35, 37, 42, 111]. However, this is precisely what people cannot do when they are out shopping or using public transportation, for example. Likewise, hand disinfectant is not always available.

Hand hygiene: hand washing

When all health authorities in the world point out the importance of hand washing, this always means thorough hand washing with water and soap for 20 - 30 sec. For the general education of the population about individual protection against infections - in addition to emphasizing the general necessity of frequent hand washing - it is also necessary to point out that, if possible, one should not touch one's face with one's hands as long as one has not been able to wash one's 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 to

but you can train it: If you know it's important, you can watch yourself and reduce your own hand-face contacts.

That is why information campaigns for the general public should not only point out the need for frequent hand washing, but also explicitly point out why hand washing is so sensible and important: so that people do not touch their eyes, nose and mouth with contaminated hands. Only then can the call to wash hands really be understood and not (so easily) dismissed as an annoying hygiene rule. For this reason, all health authorities in the world point out the great importance of hand hygiene in reducing the transmission of respiratory viruses through indirect contact or through one's own hand-face contact (the same applies, incidentally, to the prevention of gastrointestinal infections, whose pathogens, e.g. noroviruses, can also be acquired through contaminated hands and subsequent mouth contact).

For the prevention of the transmission of respiratory pathogens, this means that you should not touch or go under the mask, because you can contaminate your hands and thus expose your fellow human beings to the risk of coming into contact with their own pathogens through surface contact and thus get an infection, 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 repeatedly trained with the medical staff, e.g. also by using a UV lamp, in order to be able to see under the UV light after using a fluorescent hand disinfectant whether the entire skin of the hands and in particular the finger syringes incl. thumb were really included in the disinfection). The agents used for hand disinfection are alcoholic solutions with mostly 60 - 80 % alcohol, which contain refatting agents so that the skin does not become too dry, because alcohol otherwise dries out the skin (hand washing as well). They are generally very well tolerated (alcohol is non-toxic), but despite the addition of refatting substances, adequate skin care is important if hands have to be disinfected frequently, as is the case with medical staff. Properly performed, hand disinfection is more effective than hand washing (eliminates or reduces more potential infectious agents in less time), but in normal life, hand washing is the method of choice, while in the medical field when caring for patients (for skin protection reasons, among others), hands should only be washed if they are visibly soiled.

When you are out in public, e.g. shopping, you usually don't have the opportunity to wash your hands. That is why, for example, grocery stores have provided hand disinfectants at the entrances to the stores since about the early summer of 2020, in addition to other disinfectants intended for surfaces (i.e., especially to wipe the handle of the shopping cart with it), but which do not contain re-fatting agents if they are also alcohol-based, because that is not necessary for this purpose. Therefore, one must not confuse hand disinfectants with surface disinfectants, especially if these agents contain other active ingredients and not alcohol, because other active ingredients must not be used on the skin because they are toxic to humans or perhaps 'only' have an allergenic effect. In this respect, already the provision of

disinfectants lead to incorrect use by the public, who do not know (and usually do not need to know) the difference between hand and surface disinfectants. The shelves on which the disinfectants are offered for self-application also tend to look untidy 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 used, there is another difficulty for the untrained hand disinfection population: It is not enough to simply take any amount of disinfectant solution, but it must be a sufficient amount to wet the entire skin of the hands. This varies somewhat depending on the size of the hand, but usually it is about 3 mL, which is necessary even for smaller hands (for larger ones correspondingly more). With this amount you have a puddle in the palm, and this also means that a smaller amount or even just a little spray cannot lead to an effective disinfection of the hands. This puddle must then be distributed over both hands - not unlike hand washing, i.e. literally according to the principle: 'One hand washes the other' - so that, on the one hand, the entire skin of both hands is wetted with the agent. On the other hand, however, the agent must be rubbed in everywhere until the hands are dry again. This takes a total of 20
- 30 sec, which sounds only seemingly short, and only then can one speak of effective hand disinfection. Spreading the agent everywhere, however, must also be done quite deliberately, because it is not enough to just rub the palms together. Rather, care must be taken to ensure that the fingertips and thumbs in particular are involved, because this is where the decisive contact with objects or surfaces takes place. Of course, for effective hand disinfection, the spaces between the fingers and the folds of the palm of the hand are also included, but in normal life (as, incidentally, also in the medical care of patients), the really important contacts are with the fingertips (which is why long fingernails are also an obstacle to effective hand disinfection, because, unlike when washing your hands, if you do not use a nail brush, you cannot get the product under your fingernails). Contact with the flat of the hand or the spaces between the fingers is much less frequent.

The general public knows nothing about this (they do not have to), but it has not been explained to them either. 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, are reprimanded by other people who tell them not to take so much of the product and to hurry, because others also want to disinfect their hands.

In summary, it can be said that with some certainty the possibility of hand disinfection cannot replace the washing of hands with soap and water, where you at least have a certain mechanical wash-off effect by the water, even if you may not really spread the soap all over the skin of the hands. In addition, no matter what you did before, that is, hand washing or hand disinfection, your hands are immediately re-contaminated when you touch the mask or other objects again. The general public is not aware of this either, because they have not learned it (and did not have to learn it, or do not have to learn it), namely that even proper hand disinfection does not protect against the hands coming into contact with potential infectious agents again the next moment, i.e. the next time they come into contact with an object or a surface, i.e. they are contaminated. But that is what medical personnel learn. In this respect, the hand sanitizer provided in front of the stores helps

Hand sanitizer does not, but only leads to more deception and provides (once again, so 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 provide clear guidance on the use of masks or the required handling of masks and the hand hygiene that is essential in this process to prevent the spread of SARS-CoV-2 through their use [1, 33, 35, 37, 42, 111].

Contamination. Masks are contaminated from the inside by the wearer when exhaling and speaking and can also be contaminated from the outside by hand contact and respiratory droplets from other persons. Masks worn in public spaces should serve as 'foreign protection' or 'source control', according to the theory, i.e. in the case of wearers of masks who are (still) undetected infected, the pathogens released into pots when speaking etc. should be caught by the mask so that they do not (or at least not in large numbers) enter the environment as far as possible.

With this assumption, the inside of the mask is therefore potentially contaminated (because one does not know whether one is already infected) with the pathogen. This means that, at the very least, contact with the inside of the mask can contaminate one's own hands with the pathogens released from one's own nasopharynx (NRR) in the event of (as yet) unnoticed infection, similar to what happens when one touches one's own mucous membranes of the eyes, nose or mouth. The potentially contaminated hands are then used to touch public surfaces (e.g. the handle of a shopping cart or the handrail of an escalator). Subsequently, these surfaces are also touched by other persons, which can lead to a spread of the pathogens from the NRR of the mask wearer.

Moisture penetration. Sooner or later, every mask (even the professional medical mask) becomes soaked through by the exhaled air when worn for a longer period of time and thus becomes permeable and then no longer represents a barrier. Rather, the potential infectious agents from the NRR (which, incidentally, can also be bacteria, such as, in particular, Staphylococcus aureus, one of the most common pathogens of purulent infections of e.g. random wounds) can be found not only on the inside of a soaked mask, but also on the outside.

As a member of the hospital hygiene staff, this is pointed out to the clinically active staff, just as the medical staff is reminded again and again of the correct use of masks, e.g. in order not to contaminate their hands with the potential infectious agents from their own NRR if, against the rules, the mask is nevertheless worn hanging around the neck in order to put it on again later.

RKI, ECDC, CDC and WHO strongly emphasize that extremely careful hand hygiene and avoidance of hand-face contact are essential and must not be neglected by the use of masks in public.

The BfArM has also issued corresponding warnings and precautionary measures for the public when using masks (MNB, MNS or OP mask, FFP mask). The BfArM explicitly stated as late as spring 2020 that wearers of community masks cannot rely on the masks to protect them or others from transmission of the new coronavirus, as no corresponding protective effect has been demonstrated for these masks. As of November 2020, this (correct) representation is

no longer available on the BfArM website. Instead, it said there with date of 12.11.2020:

> '*Independently of normatively defined proofs of performance, as required for medical face masks and particle-filtering half masks, the effectiveness of the mouth-nose coverings in terms of general population protection has meanwhile been confirmed in numerous scientific publications on the basis of the broad experience gained internationally (Ref.). In this context, the protective effect of the masks depends on the tightness and quality of the material used, the adaptation to the shape of the face and the number of layers. Tightly woven fabrics, for example, are more suitable than lightly woven fabrics in this context. Thus, according to current knowledge, the risk from droplets containing pathogens can be significantly reduced by the correct wearing of good 'everyday masks.* ‘

However, after it was decided in the federal government in January 2021 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 face masks and particle-filtering half masks. Thus, they generally provide less protection than these regulated and tested mask types. However, this does not mean that they have no protective effect. Internationally, there are numerous scientific publications that confirm the experience gained about the effectiveness of the mouth-nose coverings in terms of general population protection (Ref.). In this regard, the protective effect of the masks depends on the tightness and quality of the material used, the adaptation to the shape of the face and the number of layers of fabric. For example, tightly woven fabrics are more suitable than lightly woven fabrics in this context. Thus, according to current knowledge, the proper wearing of good everyday masks can significantly reduce the risk of exposure to droplets containing pathogens.* ‘
>
> (The references given do not confirm the effectiveness of masks; see above under the heading RKI: 'First scientific indications' for third-party protection, p. 32 of the expert report).

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

- The masks should be used for private use only.
- The tips on hygiene as given in the recommendations of the Robert Koch Institute (RKI, www.rki.de) and the Federal Center for Health Education (BzgA, www.infektionsschutz.de) should be followed. This is the only way to protect ourselves and others from the spread of the coronavirus.
- Even with a mask, the safety distance of at least 1.5 m from other people recommended by the RKI should be maintained.
- **MNB.** The mask must fit well and sit over the mouth, nose and cheeks. The edges of the mask should fit snugly so that as little air as possible is breathed past the mask. It is best to try different mask shapes until you find one that fits.

- **MNS.** The mask must fit well and sit over the mouth, nose and cheeks. The edges of the mask should fit snugly so that as little air as possible is inhaled past the mask. Adjusting the length of the ear loops (e.g. knots) can improve the tight fit.
- **FFP2.** The mask must fit snugly and fit over the mouth, nose and cheeks. The edges of the mask should fit snugly and not allow airflow past the mask. An FFP mask can only provide its full filtering performance if it fits tightly.
- The first time the mask is used, it should be tested to see if it allows enough air to pass through to minimize interference with normal breathing.
- A soaked mask should be removed and changed.
- When putting on and taking off the mask, it should only be touched by the straps of the mask if possible.
- After removing the mask, hands should be washed thoroughly (at least 20 to 30 seconds with soap) in compliance with general hygiene rules.
- The mask should be stored in an airtight bag or similar after removal or washed immediately. Storage should only be for as short a time as possible, especially to avoid mold growth.
- **MNB.** Masks should ideally be washed at high temperatures. Preferably at 95 °C, but at least at 60 °C. Do not use short wash programs and then allow to dry completely. Be sure to follow all other manufacturer's instructions, such as 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 in dealing with masks in public

Correct handling of masks is not always easy to achieve among medical personnel, as already mentioned. Among the general public, however, all these requirements, which are considered indispensable, are not even remotely achievable. Thus, when shopping
e.g. to observe:

- 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 glasses fog up, because unlike a professional surgical MNS, the community mask usually lacks a slightly bendable temple that you can adjust well to the anatomy of your nose. So you have to take off and put on the goggles 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 also repeatedly go with your hands to the mask or even under it.
- Outside the stores, the mask is often only partially removed and then hangs with a loop over an ear, is pushed under the chin, is worn on the wrist or forearm, or it is removed and simply put in the handbag, trouser pocket or jacket pocket. Furthermore, it can be observed that the mask (sometimes several at the same time), in order to be always ready to hand for the next use, hangs in the car on the rear-view mirror.

However, you also have to ask yourself how you are supposed to do it differently when you are on the road, even if you make an effort to avoid contaminating your hands on the mask as much as possible:

- You can't wash your hands when you get out of the car and put on your mask before entering the store, and you can't wash your hands after

Leaving the store when the mask has been removed again, do not wash your hands.
- Hand sanitizers are also not always available.

The next question is how to manage contamination-free to take care of the masks after each use when you have to go to several stores:

- One possibility would be to simply leave the mask on after leaving a store, as has been observed with some people. Then all errands (and the paths in between, if they are footpaths) could be done with a single mask. People then walk around outside with a mask where it is usually not mandatory.
- It is likely that the mask material will soak during several purchases.

In everyday life this is an unsolvable task, one wants to bring zig million citizens to keep these necessary precautions with the use of masks, if that is already not completely simple with the medical personnel, where however with the hygiene specialized personnel (hygiene specialists, hospital hygienists) always persons can remind locally of the correct handling: It is out of touch with reality. Therefore, the mask recommendation of the RKI cannot be justified by pointing out the necessary precautions, namely because they are unfulfillable requirements that inevitably and for all professionals recognizably cannot (be) implemented.

A mask obligation 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 frequent hand-face contacts of people would become even more frequent due to the mask obligation, but hand washing on the way is only possible in exceptional cases, and for a correspondingly frequent hand disinfection, every citizen would have to carry hand disinfectant. There is the risk that the - already inevitable - improper handling of the mask and the increased tendency to touch oneself in the face while wearing the mask actually increases the risk of pathogen spread and thus pathogen transmission even further, a risk which, however, is precisely what the mask is intended to reduce. The increase in positive test results since the start of the mask requirement can therefore also be attributed to the mask requirement 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. The question of aerosol transmission is of great importance in connection with the potential effectiveness of masks and also under the aspect of so-called unnoticed transmission as well as for the distance requirements.

Almost all 'hygiene measures' used by politics have the aerosol transmission as a basis, even if they are not (always) explicitly justified with it: However, there is no other explanation for measures such as the all-around 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.

The increasing importance of aerosol transmission in Germany

A mixture of airborne particles is called an aerosol. However, from media reporting to technical articles, the term 'aerosol' is often reduced to the particles in suspension. Correctly one must speak of aerosol particles. It does not have to be infectious agents, because all airborne particles can form an aerosol.

Meanwhile, many consider the route of transmission via aerosol (i.e., airborne or aerogenic transmission) relevant for SARS-CoV-2. According to the most recent presentation of transmission routes by WHO (dated 01.12.2020), the new coronavirus (like all other respiratory viruses) is transmitted via (large) pots of respiratory secretions and via direct and indirect contacts with respiratory secretions of infected people [42, 116]. Aerosol transmission outside medical care (where aerosol-producing measures may be used, such as open endotracheal suctioning of intubated patients) cannot be ruled out, but detailed examination of all published clusters where the respective authors postulated or at least considered aerosol transmission likely suggested, according to WHO, that transmission via so-called large droplets and/or contaminated objects (i.e., contact) could also explain pathogen transmission within these clusters [116].

The other international health authorities (ECDC, CDC) also agree that the COVID-19 pathogen - like other viral respiratory pathogens - is mainly transmitted via large droplets and contact [117, 118]. The RKI does not commit itself and considers aerosol transmission possible in principle, but does not emphasize this route of transmission [119]. Thus, the role of aerogenic transmission in SARS-CoV-2 is scientifically unclear, to say the least.

Nevertheless, already shortly after the beginning of the pandemic in spring 2020, aerosol transmission was brought to the fore by different scientists (especially virologists, but soon also aerosol physicists) (this also with regard to the claimed asymptomatic / presymptomatic transmission) and subsequently presented in the public by the media as at least as important transmission route as the transmission by (large) droplets (> 5 µm). In the meantime, transmission by aerosol particles is considered so important by politicians and the public that in September 2020 the federal government issued the
ventilation' in its AHA rule. For the same reason, the use of FFP2 masks was made compulsory for staff in numerous hospitals on the initiative of the respective hospital managements - but this was done without the RKI recommending it, because there the recommendation remains unchanged - so far at least - to use FFP2 masks only for close patient contact (= occupational health and safety requirement) 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 respiratory viruses) could be detected from the air, it cannot be concluded that these were viruses capable of replication and infection [42]. Similarly, the release of droplets already capable of suspension when speaking, sneezing, coughing, or singing is no proof of transmission by aerosol particles, because the occurrence of an infection depends not only on (1) the immune status of the contact persons and any predisposing chronic diseases, (2) the type and duration of contact, (3) the stability of the virus in the

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

The result of the constant mention of 'aerosols' is, on the one hand, that indoor rooms are now to be ventilated frequently and, despite the cold, not even briefly, so that schoolchildren had to sit warmly dressed in class during the cold season, or, for example, one starts to freeze during a longer dental treatment because the windows are permanently open. Furthermore, it is seriously considered (or demanded by politicians and aerosol researchers) to install expensive high-performance air purification devices with particulate filters (so-called HEPA filters of class F 14, i.e. a filter material which is able to separate even such tiny particles as viruses, which are many times smaller than bacteria, for the elimination of which, e.g. in operating rooms, 'only' filters of class F 13 are used), e.g. for schools or restaurants, but this without solid scientific evidence. The WHO also calls for high-quality scientific studies to clarify or verify the transmission routes, the infectious dose and the settings in which transmission with SARS-CoV-2 occurs more frequently [42].

Behavior of aerosol particles in the air

Respiratory droplets consist of glycoproteins and salts in aqueous solution, and infectious agents may be distributed in them. Potentially infectious aerosols are formed on the one hand outside the body when the water content of small respiratory droplets in the dry (compared to the respiratory tract) ambient air is reduced by evaporation and in this way particles capable of suspension are formed [120 - 128]. However, such tiny droplets are also already exhaled from the deep airways [123, 124]. If, for example, a cloud of larger and smaller droplets (droplets) is released during coughing, the large ones sediment close to the site of release, and the smaller ones rapidly become progressively smaller by evaporation and in some cases disappear completely if they did not have a pathogen trapped within them, i.e. if they did not have a 'core'. For this reason, the international infectious disease literature has been referring to so-called droplet nuclei (aerosol particles) for decades. Moreover, the initially released cloud does not simply remain in the air in front of the person, but in addition to reduction by sedimentation and evaporation, is also broken up by the air movements, thus 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 have disappeared from the air shortly after their release, having sedimented onto some surface. What remains are the smaller droplets, which sediment much more slowly and in the process usually evaporate very quickly, i.e. rapidly become successively smaller, and in addition the tiny droplets, which are already capable of suspension in the exhaled air, i.e. are already released from the (deep) respiratory tract as aerosol particles [123, 124]. The extent and speed of evaporation depend (1) on the relative humidity: the lower, the faster, (2) on the air temperature: the higher, the faster, and last but not least (3) on its initial size: the smaller, the faster up to lightning-like [127].

Coughing and sneezing release a particularly large number of droplets, which are moreover virtually hurled into the air due to the force of the cough or sneeze and can therefore travel greater distances (several meters) [120, 121]: most have a diameter of < 100 µm (for comparison: 1 mm = 1,000 µm). This is the size of approx. 80 - 95% of the droplets released during coughing and approx. 99% of those released during sneezing.

When coughing, just under 50% of these droplets are smaller than 4 µm, and when sneezing, just under 20%, and thus they are already initially capable of floating, but also immediately become even smaller due to evaporation, until they may have disappeared (if no 'core' was present). The remaining somewhat larger droplets also dry out quickly and can thus also become particles capable of floating, but again only if solid components remain after evaporation of the water content, e.g. salt crystals or dried protein, or if the droplet contained an infectious agent as a 'core'. However, if such a core was not present, consequently no potentially infectious aerosol particles can be formed from such droplets after evaporation.

Even though aerosol physicists can impressively visualize droplet clouds, e.g. when coughing, or with artificial aerosol particles, most droplets released by humans disappear from the air within a very short time (due to rapid evaporation and sedimentation). Only that part of the droplets can lead to the formation of infectious aerosol particles that contained a nucleus of infectious agents when released, which remain in the air as suspended particles after evaporation.

Aerosol physicists also always emphasize that an aerosol can in principle 'stand in the air' for hours if it is not broken up by air movements and removed by ventilation - natural ventilation through windows or mechanical ventilation through room air conditioning (RLT) systems (so-called air conditioning systems). In principle, this also applies to droplet nuclei that have formed, for example, after a coughing fit. If droplet nuclei consist of infectious agents, their potential infectivity depends largely on three factors (see below): (1) How long can the pathogens remain infectious while freely suspended in the air? (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 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 occur?

Aerosol particles which, for example, are formed by evaporation from the respiratory secretion released after coughing or are released as particles already capable of suspension, do not all contain the pathogen which may be detected from the respiratory secretion. This is true even if a person has an acute respiratory infection, i.e. a correspondingly high pathogen concentration in the respiratory secretion. Accordingly, one is not necessarily a so-called 'viral shedder' in the case of a viral infection of the upper respiratory tract, for example (this is also shown, for example, by the results of the Hong Kong study [30]). A large part of the released larger and smaller droplets up to tiny droplets is therefore not infectious even if one has just an acute cold, but this concerns only a small part of the droplets of all sizes [122, 125].

For example, one article shows that at a virus concentration of 7×10^{6} copies per mL, the probability is only 0.01% that a 1 µm droplet (still 3 µm in size when released with a water envelope) contains a virus particle [129]. For a 50 µm droplet, the probability before evaporation is about 37%, but for a 10 µm droplet it is already 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].

In the meantime, it is known to a broad public through the countless media reports that airborne particles can move with the air movements (with or without mechanical

ventilation, so-called air-conditioning) can spread over many meters in the room air, but the fact that they are also massively diluted by this, the further they move away from the source, is usually not mentioned, although this aspect is decisive for the risk of infection. Also with the mask obligation in the free one, which - unspoken - just like the all around distance (see **proof question 4**) is to be led back on the aerosol theory, the aspect of the dilution in the air, which is very effective at the outside air, is considered much too little, whereby this factor is essential and would contribute to the reassurance of humans, who are afraid of the virus. It follows that making masks compulsory outdoors, whether in pedestrian areas or at a farmers' market, for example, is an irrational measure with no infection-protection effect.

Behavior of aerosol particles in the respiratory tract

Since so-called large droplets (> 5 µm) sediment shortly after release, they can only reach the mucous membranes of the eyes, nose or mouth in close face-to-face contact (< 1 - 2 m) and only possibly (because not all of them land there, but e.g. also only on the skin of the face), i.e. they can only reach the upper respiratory tract, if at all. The smaller the particles, the further they penetrate into the deep respiratory tract. Aerosol therapies take advantage of these properties [122]: (1) Particles > 5 µm in diameter are used for diseases in the area of the nose,
(2) in diseases of the trachea and large bronchi, particles of 2 - 5 µm and (3) in pulmonary diseases, particles of 2 - 0.5 µm, which can penetrate into the smallest bronchi and alveoli. The deposition rate for aerosol particles in the respiratory tract is known from simulation models [123]: according to these, particles of 1 µm are deposited 94% in the lungs and only 6% in the upper respiratory tract including the trachea. Particles with a diameter of 2.5 µm are deposited in the nose in only 4%.

However, very small aerosol particles can not only be inhaled into the lungs from the ambient air, but they are also produced and exhaled there, i.e. in the lungs [123]. By means of laser technology, these particles were measured in test subjects [124]: It was shown that no particles > 5 µm were released during quiet breathing, but that very many tiny particles of about 0.4 µm in diameter were exhaled, i.e. that the lungs were a kind of 'aerosol generator′ (by means of special breathing maneuvers, it could be shown that these tiny particles are produced in the lungs and not only in the upper respiratory tract).

From this, one can conclude that these aerosol particles can only be infectious if a person has pneumonia (= lung inflammation), and as is known, this is not the case with an infection with SARS-CoV-2 in most people - and if one would have pneumonia after all, one is (1) seriously ill and can therefore (2) under no circumstances go among people (restaurant, public transport, stores, etc.). Thus, for these reasons, one cannot be considered as a source of pathogen transmission in public spaces. As a 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 the particles must originate at the site of infection [128].

In indoor air, for aerosol physical reasons, just the very small particles (produced in the lungs) of about 0.4 µm size accumulate and can remain in the air for a very long time, while the larger and even smaller ones disappear [124]. A

Particles of this size could presumably hold at least one virus particle, and thus the author (an aerosol physicist) concludes that persons infected by SARS-CoV-2 already release airborne particles containing the virus when breathing, and that these infectious particles remain in the room air for a long time - and thus could be inhaled by other people [124]. However, for this to happen (see above), an infected person would have to have pneumonia, because these tiny particles are formed in the lungs.

Most (70%) of the respirable particles between 0.1 and 0.5 µm inhaled are exhaled again, i.e. only about 30% of these smallest particles are deposited somewhere in the deep respiratory tract (= lung), the larger part penetrates only briefly during inhalation, but then leaves the respiratory tract again during the next exhalation [123, 124].

In order for respiratory viruses to cause an infection of the respiratory tract, infectious particles must land (impact) on the special cells of the mucosa where the pathogens find their specific binding sites, i.e. not simply anywhere in the respiratory tract on any cells. In the case of SARS-CoV-2, these are primarily the cells with so-called ACE-2 receptors, which are particularly pronounced on the ciliated cells of the nasal mucosa [62]. Cells with ACE-2 receptors become successively much rarer in the area of the deeper airways [125]. Thus, for the new coronavirus to cause infection, it must reach the ciliated cells of the nasal mucosa and bind to the specific receptors. If the motility of the ciliated cells is reduced (= reduced so-called mucociliary clearance, e.g. in heavy smokers or in 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, patients infected with the new coronavirus develop primarily an upper respiratory tract infection, if they develop symptoms at all. Pneumonia, i.e., infection of the deep airways, develops secondarily, if at all, with a delay of about 7 days after the onset of initial symptoms in the upper airways. Thus, even in those patients who develop pneumonia during the course of the disease, the disease does not already primarily affect the lungs. This probably only occurs via microaspiration (which incidentally also occurs in healthy people in deep sleep), whereby infectious secretion from the nasopharynx reaches the lungs and, particularly in the case of old age and chronic diseases, can lead to secondary infection there, whereby the course of the disease only becomes severe and life-threatening [122].

The new coronavirus must therefore settle primarily in the upper respiratory tract in order to cause an infection [62] and therefore initially only ever causes an upper respiratory tract infection and only secondarily (after a latency period of about one week), in persons with certain risk factors, possibly also pneumonia due to descent of the pathogens. In most people, it remains with rather harmless symptoms of the upper respiratory tract with or without cough.

For the theory of aerosol transmission, this means: Since aerosol particles in far predominance immediately penetrate into the deep respiratory tract, but an infection there, if it would occur at all, cannot lead to the symptoms of an upper 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), aerosol transmission of SARS-CoV-2 can de facto play no role from a medical point of view.

Significance of virus RNA detection from the air

Whether, in the case of respiratory viruses, the detection of viral nucleic acid (in the case of coronaviruses: RNA) by means of PCR outside the body, i.e., e.g., from air samples, means that the nucleic acid found originates from an intact (and thus, in principle, capable of infection) virus particle cannot be answered by pure RNA detection - and is rather rarely investigated because it is relatively costly. However, even the confirmation of an intact (i.e. capable of reproducing) virus by means of cell culture cannot be equated with proof of the infectivity of these viruses under normal living conditions. This is because the so-called inoculation of a cell culture is a process under laboratory conditions in which the virus is artificially and ideally brought into contact with its target cells because it is (1) directly and (2) moreover, in unchanged concentration, given to the cells. In the case of a virus contact in normal life, on the other hand, potentially infectious droplets or aerosol particles released by an infected person must first find their way - quasi 'by themselves' - to the mucous membranes of the upper respiratory tract of another (and moreover) non-immune person. Once there, if this occurs at all, the number of potentially infectious viruses must be sufficiently high for at least some of them to make it through the protective respiratory secretion to the surface of the mucosal cells and also to adhere there, so that they can then penetrate the cells and multiply.

In addition, there is the following: Coronaviruses have a lipid envelope, thus belong to the so-called enveloped viruses and as such are sensitive to environmental influences (e.g. UV light). Certain aerosols (approx. 0.4 µm) can in principle remain airborne for several hours, but from a medical point of view the most important question is whether such viruses in an aerosol, i.e. floating unprotected in the air, can remain infectious for any length of time at all. The detection of viral RNA is neither proof that this RNA originates from viruses capable of replication (in a cell culture), nor that it originates (which is by no means directly comparable with cultivation in a cell culture) from viruses capable of infection for humans, i.e. intact viruses [42, 116].

The detection of viral RNA in air samples is not sufficient to confirm aerogenic transmission, nor are the results of studies in which aerosols are experimentally generated, counted and measured, and their residence time in experimental situations is determined. All in all, this is a complex issue, which primarily concerns infectiological and epidemiological factors and must include the various environmental conditions (indoor, outdoor air) as well as aerosol physical characteristics (see above). For example, from an infectiological point of view, it would have to be clarified whether infectious aerosols can 'land', i.e. adhere, in sufficient numbers at all at the decisive points in the upper respiratory tract where SARS-CoV-2 has to reach, because it primarily multiplies in the epithelial cells of the nasal mucosa, i.e. also: in the upper respiratory tract.
[62] - and not in the deep respiratory tract, where aerosol particles almost exclusively reach.

Number of pathogens required for infection

For any infection to occur, contact with a certain (and often unknown) minimum number of pathogens is required, and this contact, in order for an infection to be successful, must occur at the sites in the body where the pathogens must enter in order to multiply. This is, as already mentioned above

In the case of the new coronavirus, mainly the nasal mucosa [62], and to a lesser extent the pharyngeal mucosa, but not the lungs (otherwise pneumonia would already occur primarily in SARS CoV-2 infected persons, which is known not to be the case). The approximate number of coronaviruses with which a person must have contact for an infection to occur is not (yet) precisely known, although a study published in December 2020 indicates that, according to a mathematical estimate based on 39 transmission events, a number of more than 1,000 virus particles on average must be transmitted from one person to another in order to cause an infection [130].

If contact with the pathogen were to take place primarily or at least to a relevant extent through the air, i.e. via inhalation, a relatively high number of secondary infections (triggered by an infected person) would have to be assumed, because the air surrounds all people and no one can escape it [116, 131]. However, the basic reproduction number (R0) of about 3 (i.e., about 3 subsequent infections by an infected person in the absence of immunity of the population to the pathogen) would be low for the new virus; one would expect many more subsequent cases because of the unavoidable exposure of all people to airborne transmission of the pathogen. However, R0 could also be so low for the new coronavirus because the number of pathogens required for infection (so-called 'infectious dose') is rather high for this virus, so that there are relatively few subsequent infections despite airborne transmission because mucosal contact with sufficiently high numbers of pathogens rarely occurs [131].

Outbreaks as evidence of transmission by aerosol particles

In 2020, there were various publications about outbreaks that allegedly proved aerosol transmission of the new coronavirus, but in all these outbreaks it was not or only marginally considered that instead of aerosol transmission, the other transmission routes via (large) droplets and / or (direct and indirect) contact also come into question and would first have to be evaluated in their significance in order to attribute a significant role to aerosol transmission. In the media it is spread that contact transmission (mostly called by the unscientific term 'smear infection') does not play a role in SARS-CoV-2. Instead, however, one would have to say: This transmission route was not investigated or not sufficiently considered, because it is not sufficient for such a statement that the virus was not or rarely found in environmental tests.

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 lies in the special working conditions of the workers in this (and other) meat (and fish) processing factories, where low temperatures (10°C) and hard physical work (with heavy exhalation) on the one hand and air conditioning without fresh air supply on the other (low air exchange rate and constant re-circulation of the air in the working hall) suggest efficient pathogen transmission via aerosol.

According to the authors of the study, the shared (close) housing of workers in their living quarters and dormitories and the shared trucks - and thus the multiple direct and indirect contact opportunities associated with them, including droplet contact - did not play a major role in the occurrence of the infections. As limitations of their study the

authors then state, however, that (1) all information about worker housing and truck sharing came from the contractor (and not from their own inspection of housing conditions) and that (2) all air testing was qualitative (i.e., detection of viral RNA in air only) but not quantitative (i.e., number of RNA copies per m³ of air). Finally, the authors themselves state that their study should not be considered an *epidemiological study.* The authoritative authors of the study are mainly virologists and geneticists, but not population-based epidemiologists, the so-called senior author (last named in the list of authors) is a biologist. Thus, the authors are predominantly bioscientists, not epidemiologists with medical-infectious disease training.

There have been other publications about outbreaks that are always cited for proving aerosol transmission, e.g., a restaurant-associated outbreak in China
[133] and a choir sample in the USA [134]. However, a mode of transmission cannot be proven with outbreak investigations, because there is always the important question of whether all possible modes of transmission were actually adequately tested in the investigation of an outbreak (or could be tested retrospectively in the reappraisal of events) before concluding that aerosol transmission was the most likely mode of transmission. The restaurant-associated outbreak was attributed by the authors to an air conditioning system that had faulty airflow [133]. However, if this had been substantiated as a cause of airborne transmission in this specific case, then it would be open to question whether, for example, there would also have been airborne transmission in a room without air conditioning, so one could not speak of the new coronavirus being airborne quasi-naturally, but perhaps only when there was faulty airflow through an air conditioning system.

In the report on the choir test in the USA [134] it is noticeable that 9 of the 10 authors were not medical doctors, but e.g. (heating-ventilation) technicians, engineers, chemists, only one co-author was a medical microbiologist. The article was (logically) published in a technical journal ('Indoor Air') and not in a medical one. From the peer reviewers' reports, all of which can be viewed, it is clear that critical comments were made in terms of infection epidemiology: Thus
e.g., 3 choir members became symptomatic already 24 h after the choir rehearsal and 7 others within 48 h thereafter [135]. This suggests that not only the so-called index case from the article could have been infected, but also up to 10 other choir singers who, however, only developed symptoms later (and possibly already had very minor symptoms at the choir rehearsal, which they did not perceive, however, or which they did not remember when they were later interviewed as part of the work-up of the outbreak, a frequent problem in the clarification of outbreaks, which must always be done retrospectively). Another question is whether there was actually no indirect contact via contaminated items, because after all, the singers were together for 2.5 h and also had a break together. The original CDC report also indicates that the singers had very close contact, as they were only seated at a maximum distance of about 15 - 25 cm, so that contact with large droplets (< 1 - 2 m) also seems possible in addition to direct and indirect contact [135]. However, this was not addressed accordingly in the outbreak investigation [134].

Masks as protection against the generation or release of aerosols

As so-called community masks, i.e. everything from the purchased mask similar to the medical mouth-nose protection to the (self-made) cloth mask to the cloth in front of the mouth and nose, everything was possible and 'allowed' from the end of April 2020 (beginning of the mask obligation) to the end of January 2021, the main thing was that something was in front of the mouth and nose [103]. However, such masks and cloths do not offer any protection against the formation of aerosol particles in the air or their release from the deep respiratory tract, but can only reduce the formation of aerosol particles somewhat (but how much is unknown), because the larger droplets are caught by the fabric and therefore no longer reach the outside air, where they - the smaller, the faster - can dry up within seconds to so-called droplet nuclei, if they contain a 'nucleus' at all (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 submissions on this are also inconclusive, but in public discourse masks are '*effective*' because they can retain droplets. However, this is unscientific. However, what is presumably true for (large) droplets is not true for the smaller droplets and certainly not for aerosol particles. Humans normally emit aerosol particles in addition to the larger droplets (see above), but these not only penetrate the mask material directly, but can also escape laterally or above and below, i.e. everywhere where the mask is not close to the face (but of course even there, although not as numerous). This applies not only to the so-called community masks (made of cotton or other materials), but also to the medical mouth-nose protection (surgical mask), whose function is 'only' to protect from droplet contact (i.e. to act as personnel or self-protection during patient care with close vis-à-vis contact) or to prevent the release of droplets (i.e. to be there as protection of the open surgical wound against droplets from the nasopharynx of the surgical team during surgery = protection of the patient).

So if the aerosol transmission was really as important as it has been presented in Germany for months, all people would have had to wear respirators long ago, so-called FFP masks (at least FFP2), because only these masks are in principle suitable by their material and design to separate free-floating particles, so that the wearer can neither inhale nor release them. However, this could also only apply if such masks are worn correctly, i.e. fit tightly against the skin everywhere and have no exhalation valve, and then it is difficult to breathe through them because the mask material is very dense. FFP masks (almost only FFP2, very rarely FFP3) are worn in the medical field only for self-protection of personnel from inhalation of potentially airborne infectious agents (in the case of open tuberculosis of the respiratory tract) and, if necessary, by very immunocompromised patients also for self-protection from inhalation from mold spores always present in the air (for both indications they can have exhalation valves). However, FFP masks are never worn 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 for reasons of external protection (but they are not allowed to have exhalation valves). Since then, there is the FFP2 mask obligation in Bavaria (and in the federal government the obligation to wear a medical mouth-nose protection, so called OP mask or FFP2 mask).

The ability of different types of masks to reduce aerosol concentrations in room air (i.e., for extraneous protection) has been investigated several times in experimental studies. One of these studies used volunteers, almost all of whom (N = 208) had laboratory-confirmed acute influenza infection and 6 of whom had suspected acute COVID-19 [136]. It was tested whether there was a difference in medical and self-sewn cotton masks in how many aerosol particles (20 - 1,000 nm) were released during coughing and sneezing and thus measurable in room air. The test subjects were given a medical mask and then a 3-layer cotton mask or no mask at all. Two measurements each (during one hour) of aerosol particles in the close environment of the test subjects, i.e. in each case with one of the masks or completely without mask, were carried out in a mechanically ventilated (= with so-called air conditioning) room (with closed windows) and in a car (also with air conditioning). The aerosol concentration in the air in the room and in the car was also determined without the test subjects wearing any of the masks. All subjects had an acute upper respiratory tract infection with typical symptoms (coughing, sneezing). According to the results of this study, there were no significant differences in aerosol concentration between medical mask and cotton mask. The authors' conclusion was that cotton masks could be a substitute for medical masks in rooms with air-conditioning in infected (i.e. symptomatic) individuals (with air-conditioning because that is how the studies were conducted and therefore it is not known what the results would have been without air-conditioning).

In another experimental study, a result was found that speaks rather against so-called community masks, which are mostly made of cotton fabric [137]: namely, with cotton masks (compared to without a mask), there was an increased release of (smallest) aerosol particles (< 0.5 µm), which are tiny cotton fibers. These cotton fibers, according to the authors' interpretation, could be contaminated with the virus in case of an asymptomatic or pre-symptomatic infection of the wearer and thus even increase the release of potentially contaminated aerosols.

Another experimental study showed that all mask types (surgical, FFP2/N95, and cotton masks), did provide some protection against transmission of infectious aerosol particles [138]. However, it was shown in this simulation model that viral RNA was released even with optimally fitting FFP2 masks. Especially FFP2 masks are rarely worn correctly even by medical personnel because these masks are hardly tolerable when worn for hours (as it has been common practice in numerous clinics for months). Therefore, it can be deduced from these study results that in real life in clinics, and of course even more so when FFP masks are worn by persons untrained in this in public, which has become more and more frequent over time, the virus RNA is released despite the masks - and possibly to a not insignificant extent. However, FFP masks in particular suggest increased safety, which they do not offer if worn inadequately,
i.e. all masks (types), but FFP masks in particular convey a deceptive feeling of safety, thereby tempting to wear them carelessly (and incidentally to particularly frequent hand-face contacts) and are thus overall more counterproductive than protective.

In a September 2020 article (an opinion piece) in the prestigious NEJM, it was hypothesized that by allowing the wearing of masks to reduce the release of

aerosol particles, limited contact of other people with the virus takes place, i.e. contact with low virus counts [139]. This could lead to mild forms of progression, which would be equivalent to a kind of 'vaccination'. The authors used the historical term '*variolation*' for this, a method long used in East Asia to immunize children against smallpox by taking secretions from smallpox vesicles of a sick person and applying them to the nasal mucosa of the 'vaccinees' [140].

The theory of variolation associated 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 evidence that the possibly lower number of released and potentially infectious aerosol particles due to masks leads to the fact that the severity of the infection of contact persons is mitigated with the result that the so allegedly (mildly) infected persons have a protective immunity afterwards.

Duty medical masks

In January 2021, an FFP2 mask requirement was initially introduced in Bavaria for stores and public transport. Shortly thereafter, it was decided in the federal government (federal government and minister presidents) that only 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 reasoning behind this is medically incomprehensible, because both types of masks are designed for different purposes, but have now become interchangeable due to the policy decision, which means that any medical basis has been lost.

From the end of April 2020 (start of the mask obligation) until mid / end of January 2021 (in Bavaria somewhat earlier than in the federal government), the so-called everyday mask made of cloth (or even just a cloth in front of the mouth and nose) was considered adequate for the implementation of the mask obligation. It should be used as
'foreign protection' serve (see above) to prevent the release of larger droplets from which smaller inhalable aerosol particles could arise. So, for about nine months, the everyday mask was correct because, in the view of the federal government and the RKI, it was suitable for preventing so-called unnoticed transmission or at least limiting it to such an extent that the obligation to wear it seemed justified to policymakers. In the new year 2021, the transmissibility of the new virus had not changed. In particular, there was no new knowledge about the modes of transmission, since the aerosol theory had been around almost since the beginning of the pandemic in the spring of 2020. A crucial change for policy makers came with the increasing reports of viral mutations from the UK, South Africa and Brazil, which were supposed to be (and possibly actually are) more 'contagious', i.e. more easily transmissible.

The reason given in Bavaria for the FFP2 mask requirement was that, in view of the virus mutations, 'self-protection' was now also important. The protection principle of the FFP2 masks must therefore mean protection against the inhalation of aerosol particles, while the FFP2 mask also guarantees 'external protection'. Since then, the remaining federal states have thus been able to decide whether to also make the FFP2 mask mandatory or to 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 just as little better protection against inhalation

of aerosol particles than the everyday fabric mask, so can provide an improved
'Self-protection' cannot ensure, because the MNS has other functions: (1) it can act as
(1) MNS can provide 'external protection' against the release of larger respiratory droplets, but it is not intrinsically better suited for this purpose for the public than the fabric masks have been up to now, especially since it is not worn better, i.e. 'correctly', as the RKI always says, and (2) MNS can provide 'self-protection' against respiratory droplets from another person in close face-to-face contact (< 1 - 2 m). In principle, the previously used fabric mask can also do both.

Accordingly, there is no medical sense to the new obligation to wear an MNS or an FFP2 mask. According to press reports, both the ECDC and the 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

Letting plenty of fresh air into rooms used by several (e.g. offices) or even numerous people (e.g. classrooms) is always a good idea, because we are constantly breathing out carbon dioxide and need to breathe in oxygen, and we give off body odors and heat, so rooms where several people are present at the same time and for hours on end, such as classrooms in particular, undoubtedly benefit from ventilation. However, the fact that ventilation of rooms has come to be seen as a
This '*hygiene measure*' is, as it were, a step backward to the time of earlier centuries, when the development of diseases was attributed to '*disease-causing air*' (miasma theory [142]), because no infectious agents were yet known. At that time, therefore, hospitals were built in such a way that the bed halls were not only large in area but also high, i.e. had a very large air volume, and there were large windows everywhere through which the 'disease-causing' air could be discharged and fresh air introduced (but sophisticated supply and exhaust air ducts were also used as early as the 18th century) [143]. However, these times, with their ideas about the origin of communicable diseases corresponding to the state of medical science, are long gone. Today, we know much more about the origin of infections, and there is the principle of evidence-based medicine.

Summary: Aerosol transmission and scientific evidence.

The public and the media say that aerosol transmission is now
'recognized', 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 must be considered when schools open concerns the now-recognized possibility of aerosol transmission, that is, airborne transmission, particularly indoors when air circulation is inadequate.*'

The WHO publication of July 2020 is cited for this statement [116]. However, 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*

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 (e.g., superspreading event), especially if hand hygiene was not performed and masks were not used when physical distancing was not maintained.(Ref) (Where 'Ref' is used, literature references are given in the WHO article).

The WHO article, which explicitly deals with the transmission of the virus and the resulting preventive measures, does not mention that aerosol transmission is a recognized possibility of transmission of the new coronavirus, so that one must assume that the authors of the GfV statement have not read the WHO article they cite. This also applies to the WHO contribution of December 2020 [42].

In itself, this would also immediately raise the question of what is actually to become of the distance rule if aerosol transmission should actually play an important role (see **evidence question 4**). Would then 1.5 m or 2 m still be sufficient or 1 m, as recommended by the WHO and prescribed in Austria ('baby elephant') until the beginning of 2021 (since then 2 m)? How much distance would we need to protect ourselves from the aerosol particles of fellow humans? And: Does the aerosol theory only apply to the new coronavirus or also to the other respiratory viruses? If one thinks it consequently to the end, the aerosol theory, i.e. the transmission of respiratory infectious agents by air (because this way of transmission could not be valid only for one respiratory virus or would have to have meaning at least for all coronaviruses), would have the consequence that mankind would have to change its living together radically, and therefore it would have to be clarified with the necessary scientific accuracy, to which extent, if at all relevant, the pathogen transmission via aerosol plays a role with 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, however, does not exist so far in the aerosol theory for the new coronavirus. Thus, among other things, the question would have to be addressed which role masks (see above) and the distance (see below) would play, if the aerogenic transmission were to be considered a relevant fact, i.e. whether the mask would continue to be about external protection or perhaps self-protection would have to be placed in the foreground. For this, however, only FFP2 masks (but then only correctly worn masks) would be suitable (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 preferably always, because respiratory viruses are on the move all year round) to protect others from the release of their own (= 'foreign protection') and themselves from the inhalation of aerosol particles (= 'self-protection').

All these crucial questions are so far completely unresolved (perhaps because it is not understood what the dimension of the aerosol theory is, so what the consequences would be) and are not even discussed. Especially the media

and influential scientists have long left no doubt about the importance of 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 that almost half of the transmission is aerosol, almost half is droplet, and maybe ten percent of the transmission is smear infection or contact infection.* ‘

First, '*gut feeling*' has nothing to do with science, and second, the aerosol transmission was made a (but only apparent) fact also by such statements of a scientist recognized in his field. Just as little scientific is his admission about 'bad breath' and 'aerosols' [146]:

> '*This bad breath, these are aerosols. There's gases in there too - it's not just vapors, it's not just little liquid droplets - but now for our simplified discussion, it's enough to think of it like this. Can you imagine, the same situation, you're standing at the same cake buffet talking to someone at the same distance, but they both have masks on. Can you imagine still noticing that this conversation partner has bad breath? (...) Exactly, you will no longer notice. And this "not noticing anymore", we can also translate it as "There I will rather not get infected so quickly anymore". And this is something that those who have doubts about the effectiveness of everyday masks should perhaps also take home as an everyday example.* ‘

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

> '*Bad breath is caused by volatile sulfur compounds (sulfides) mixed in with the exhaled air. They are formed by gram-negative anaerobic bacteria decomposing organic material, e.g. food residues, proteins, in the oral cavity. Hydrogen sulfide is the best-known representative of sulfides. It smells like "rotten eggs." Another group of sulfur compounds are the methyl mercaptans. They are considered to be the main causes of bad breath. They produce an odor of rotting cabbage or even a musty, rancid smell. If the breath smells of fish, rotten meat or feces, biogenic amines are responsible. They are formed from amino acids by bacterial breakdown of carbon dioxide.* ‘

So 'aerosols' have nothing to do with halitosis. Similar to WHO (see above and [116]), other scientists [131] comment: based on the quite low baseline reproduction number of SARS-CoV-2 (compared to measles with 12 - 18) with about 3, such situations seem to be the exception rather than the rule. Furthermore, it would be difficult retrospectively to determine the potential interactions between individuals that occurred before, during, and immediately after the event. The potential for viruses to spread rapidly and widely-but not necessarily through the air, but primarily through direct and indirect contacts-in premises with large numbers of people should not be underestimated, he said. Experimental studies with labeled bacteriophages (= special viruses pathogenic only to bacteria but not to humans) had shown that viruses can be transmitted within hours from a single contaminated door handle or the contaminated hands of one person to other people and objects. Again, these were speculative considerations that could not rule out the possibility of transmission via aerosols, but they were

possible alternative explanations for the occurrence of such clusters - and must therefore also be considered [131].

The CDC also cite that the epidemiology of COVID-19 indicates that most of these infections occur through close contact - 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.* '

Transmission of SARS-CoV-2 via aerosols currently remains a hypothesis. This statement is consistent with the WHO assessment and CDC statements [42, 116, 118]. Transmission via aerosols is merely a rather unlikely possibility, as shown above. Therefore, no necessary protective measures can be derived from this on an approximately scientific basis, such as a FFP2 mask obligation or special 'air purification devices' or RLT systems with HEPA filters or even frequent ventilation. Nor is there currently sufficient evidence from careful studies that, for example, choral singing poses a risk of transmission by aerosols, or that contacts between people over distances greater than 1.5 m (WHO: 1 m) can pose a risk of infection due to the aerosol particles released during speech, etc. One cannot infer a risk of infection from aerosol-physical studies of the dispersion of artificially generated aerosols. Whether aerosol transmission actually plays a relevant role in the acquisition of this pathogen could only be shown by carefully planned epidemiological studies in different settings, including randomized controlled trials.

In general, on the question of aerogenic transmission of infectious agents, it can be stated that whenever the possibility of airborne transmission is considered, transmission by large droplets and / or by direct or indirect contact is almost regularly equally considered.

In line with this, an aerosol physicist (who, incidentally, considers outdoor transmission to be virtually impossible) recently stated that even indoors, the greatest risk of transmission is in the vicinity of an infected person because one is then in the still undivided cloud of aerosol particles 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, but this is for other reasons, namely because on the one hand one is thus exposed to possible droplet contact, but on the other hand one is also much more likely to have direct and indirect contact possibilities than when one is standing a few meters away in another place in the room.

The aerosol theory has nowhere near sufficient scientific basis, and therefore lacks evidence that this mode of transmission is relevant to the natural course of SARS CoV-2 infection. At the same time, this theory is exceedingly harmful to human coexistence as a whole and has a destructive effect on contacts 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 safely excluded in order to consider aerogenic transmission.

Summary assessment of the scientific data on masks

The effectiveness of masks for healthy persons in public is not supported by scientific evidence. Likewise, 'third-party protection' and 'unnoticed transmission', which the RKI used to justify its 'reassessment', are not supported by scientific facts. Plausibility, mathematical estimates and subjective assessments in opinion pieces cannot replace population-based clinical epidemiological investigations. Experimental studies on the filtering performance of masks and mathematical estimates are not suitable to prove efficacy in real life. While international health authorities advocate the wearing of masks in public spaces, they also say that there is no evidence for this from scientific studies. On the contrary, all currently available scientific results suggest that masks have no effect on the incidence of infection. Consistently, all publications cited as evidence for the effectiveness of masks in public spaces do not support this conclusion.

Any mask, to be effective in principle, must be worn properly. Masks can become a contamination risk if they are touched. However, on the one hand, they are not worn properly by the general public and, on the other hand, they are very often touched with the hands. This can also be observed with politicians who are seen on television. The population was not taught to use masks properly, it was not explained how to wash hands on the way or how to perform effective hand disinfection. It was also not explained why hand hygiene is important and that care must be taken not to touch the eyes, nose and mouth with the hands. The population was virtually left alone with the masks.

The transmission of SARS-CoV-2 through 'aerosols', i.e. through the air, is medically implausible and scientifically unproven. It is a hypothesis that is mainly based on aerosol physicists, who understandably cannot judge medical correlations from their field of expertise. The 'aerosol' theory is extremely harmful to human coexistence and leads to the fact that people can no longer feel safe in any indoor space, and some even fear infection by 'aerosols' outside buildings. Together with the
'unnoticed' transmission, the 'aerosol' theory leads to seeing a risk of infection in every fellow human being.

The changed statements of the policy on masks, first fabric masks in 2020, then since the beginning of 2021 either OP masks or FFP2 masks, lack any clear line. Even though OP masks and FFP masks are both medical masks, they have different functions and are therefore not interchangeable. Either has the policy,

who made these decisions, has not understood itself what which mask type is suitable for in principle, or it is not important to it, but only the symbolic value of the mask. From my professional point of view, the mask decisions of the politicians are not comprehensible and, to put it mildly, can be described as implausible.

Short digression about masks in Japan

Already in the spring of 2020, media reports in this country repeatedly pointed out that people in Japan and other Asian countries have known for a long time what benefits masks have in public. Therefore, I would like to give some information at this point about why actually especially Japanese wear masks so often and how the wearing of masks has developed there. This question was discussed in detail in two articles (long before the current Corona pandemic) [108, 149].

According to this, 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 then quickly abandoned masks in the 1920s, in Japan they persisted to some extent (but nowhere near to the extent seen in the last 10-20 years) over the decades, but less for protection against infection, and more under the aspect of the traditional symbolic order of 'purity' and 'impurity' and a notion of 'miasmas' (see above [142]) rather than viruses or other infectious agents. In the 1970s, hay fever emerged (as a medical problem new to Japan to the extent observed) associated with cedars, which had only been planted there after World War II. Masks were then worn during the pollen season in spring. Then it became rather quiet about masks again until the 1990s, when mask-wearing gradually became a socially accepted general protective measure in Japan through a combination of influences from (massive) advertising by the leading mask manufacturer and from social and political pressures due to the increasingly widespread neoliberal ideology according to which, among other things, everyone is responsible for their own health protection ('self-healthcare'). In the 2000s, several epidemics came in quick succession with SARS (2003), avian flu (2004), MERS (2006), and swine flu (2009), and swine flu in particular again promoted the use of masks, resulting in a huge increase in mask sales. However, mask-wearing also became a social norm, especially on commuter trains, so those who did not wear masks stood out. In addition, sneezing and coughing in public has always been considered rude in Japan.

Retrospectively, the authors see 2009 as a kind of turning point: On the one hand, masks maintained a certain level of fear among the population, and on the other hand, they established themselves among people as the front line of protection. Added to this was the probably very crucial aspect, given the insecurity of jobs, that employers could require their employees to wear masks, and henceforth one was under pressure to comply or, if necessary, endanger one's job. Mask-wearing was revived once again after the 2011 Fukushima nuclear disaster, as masks were also relied upon to protect against radioactive radiation. In the spring of 2013, air pollution coming from China was reported to have reached southwestern Japan, and the public was advised in the media to wear masks that could filter microscopic particles (i.e., FFP masks). All in all, the whole development led to the consolidation of masks as a general-purpose means of personal protection.

According to the authors [108, 149], the mask ('safety blanket') in Japan is to be seen as *one* aspect of a broadly based type of risk culture: It is, however, rather a ritual of self-protection than a selfless community practice and thus has nothing to do with the 'protection of others' that is put in the foreground for the mask obligation in this country, and finally it is apparently not only supposed to serve the protection against infectious agents, but is supposed to include, besides the (still comprehensible) protection against pollen exposure and air pollution, even the protection against radioactive radiation, which can only be described as irrational.

After all, women allegedly like to use masks so that they do not have to put on makeup when they leave the house or so that they can hide skin blemishes underneath, and men do so when they have been unable to shave [150]. Further motives were that one could withdraw behind the mask and thus signal that one did not want to be addressed, and that one could remain unrecognized in public with a mask.

Thus, there is a conglomerate of very different reasons for the mask in Japan (and presumably in other East Asian countries), of which infection control is only one among several, but perhaps not even the leading one.

Evidence question 4

Can compliance with spacing requirements reduce the risk of infection, especially in children?

Keeping a distance is particularly emphasized in the government's Corona rules and is therefore probably also at the beginning of the so-called AHA rule (distance - hygiene - everyday masks or, since the beginning of 2021: everyday with mask). It has always been emphasized that, despite masks, it is most important to maintain a minimum distance of 1.5 m from other people. According to the original AHA rule, masks should also only be worn if the minimum distance could not be maintained (in the meantime, this restriction no longer exists). In reality, however, masks seem to be more important because their use has been expanded 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, it has been necessary to maintain an all-round distance of 1.5 m in public. However, there is no international agreement on how great the distance to other people should be. For example, the WHO speaks of 1 m, as did Austria in 2020 ('baby elephant'), but since the beginning of 2021 it should now be 2 m there. The CDC speaks of
'six feet', and that is about 2 m. In Germany, therefore, 1.5 m is a kind of middle ground. The differences between these definitions alone indicate that there is no scientific basis for them.

For decades, the rule practiced in the medical care of patients in hospitals has been to keep a distance of at least 1 m during vis-à-vis contacts, if this is possible (e.g., if there is only something to discuss), but only if the patient has respiratory symptoms. However, if it is necessary to get closer to the patient - as is often the case when caring for inpatients - medical staff should put on a medical mask (surgical mask) to protect themselves from direct

Protect contact with droplets of respiratory secretion on the mucous membranes of the face (eyes, nose, mouth).

This distance rule, which has been known for a long time, is based on the transmission of respiratory pathogens by so-called large droplets (> 5 µm) from the nasopharynx of 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. Once sedimented, they no longer pose a risk of infection. If one remains appropriately distant from a person with respiratory infection, one has no contact with the droplets. That, at least, is the rule. Particularly when sneezing vigorously, but also when coughing, the droplets can also be propelled through the air over a further distance. If another person were standing there, he or she could possibly be hit by such far-flying droplets on the mucous membranes of the face.

Such a situation, i.e., that one would have to regard other people as a potential risk of infection even without respiratory symptoms, was never problematized in infection protection measures in hospitals before 2020, not even during the influenza season; after all, patients with respiratory infections do not cough and sneeze constantly. The fact that it is appropriate to keep a certain distance from other people when one has a respiratory infection was also known in the normal population (not working in the medical field), when it was then explicitly said to the interlocutors that they preferred to stand a little further away so as not to bring the other person into contact with the pathogen (and also did not want to shake hands in greeting).

However, these precautions only ever applied when dealing with symptomatic persons, even in hospital. In the influenza season, for example, non-symptomatic patients or colleagues were never regarded as potentially infected simply because it was the influenza season, and therefore no prophylactic distance was maintained even if there was no obvious respiratory illness. In recent years, there have repeatedly been very severe influenza seasons in which hospitals were overcrowded and patients 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 yourself or a person you want to talk to has a respiratory infection, even if it is in all likelihood just a banal cold. A cold is also unpleasant, and one would like to spare others or even oneself (if the other person has the symptoms) and therefore keeps some distance.

For about a year, however, people are supposed to keep their distance from each other all the time, even if no one has respiratory symptoms. This was justified with the so-called unnoticed transmission in case of asymptomatic or presymptomatic transmission by the SARS- CoV-2 virus. The fact that this risk hardly plays a role in reality - in contrast to mathematical modeling - 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 only a vis-à-vis distance makes sense, if at all. Droplets fly forward, but not to the side and to the rear, so to require this distance to the side and to the rear can have nothing to do with droplet transmission. But if it was already about the 'aerosol' theory, a distance of 1.5 m would not be sufficient. At that time

but in Germany, 'aerosol' transmission was not yet an issue. Perhaps it seemed easier for politicians to talk about an all-round distance than to restrict the distance requirement to vis-à-vis contacts. One can only conjecture about this, because the policy has not been explained.

There is no scientific research on spacing outside of medical patient care.

To summarize:

1. Keeping a distance of about 1.5 m (1 - 2 m) during vis-à-vis contacts when one of the two persons has symptoms of a cold can be described as a sensible measure. However, it is not proven in a scientific sense, but there is only evidence or can be called plausible that it is an effective measure to protect against pathogen contact by droplets of respiratory secretion when the person in contact has signs of a cold. An all-around distance, on the other hand, is not useful for protecting oneself when the contact person has a cold.
2. Keeping 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. However, this greatly impairs people's ability to live together and, in particular, carefree contact among children, without any discernible benefit in terms of protection against infection.
3. However, close contacts, i.e. under 1.5 m (1-2 m), among pupils or between teachers and pupils or among colleagues at work, etc., do not pose a risk even if one of the two contacts has signs of a cold, because the duration of such contacts at school or even among adults somewhere in public is far too short for droplet transmission to occur. This is also shown by studies from households where, despite living in close quarters with numerous skin and mucous membrane contacts, few members of the household become ill when one has a respiratory infection.

Summary answer to the evidence questions

Based on the foregoing representations of the scientific literature, the evidentiary questions posed by the court can be answered as follows:

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

There is no evidence that face masks of various types can reduce the risk of infection by SARS-CoV-2 at all, or even appreciably. This statement applies to people of all ages, including children and adolescents, as well as asymptomatic, presymptomatic, and symptomatic individuals.

On the contrary, the even more frequent hand-face contact when wearing masks increases the risk of coming into contact with the pathogen oneself or bringing fellow humans into contact with it.

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

For the normal population, there is no risk of infection in either the public or private sector that could be reduced by wearing face masks (or other measures).

4. **Can compliance with spacing requirements reduce the risk of infection, especially in children?**

   There is no evidence that compliance with distance regulations can reduce the risk of infection. This applies to people of all ages, including children and adolescents.

The reviewer added the following bibliography to her review:

Expert opinion - Literature

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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 appraiser rendered his opinion, which is incorporated herein in its entirety, as follows:

In the following, as a professor of psychology, chair of the Department of Educational Psychology at the University of Regensburg, and expert in the field of scientific methods and diagnostics, I would like to present my professional assessment of the questions raised. I will address the individual questions and describe the state of the art, with reference to the underlying scientific sources.

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

To answer this question, an assessment scheme for ranking the quality of evidence from studies with different methodological approaches is first presented. Then, the recommendations of the Robert Koch Institute (RKI) on measures in schools, the recommendations in the S3 guideline "Measures to prevent and control SARS-CoV-2 transmission in schools" and the WHO recommendations on mask-wearing, especially in children, and the scientific studies underlying these recommendations are discussed. Next, the state of the science with respect to studies of high quality from an evidence-based perspective is summarized. In particular, the special features of mask-wearing in children are discussed. Based on this, the extent to which the risk of infection can be reduced by wearing masks in schools is presented.

Finally, in light of recent events, the observed increase in reported positive SARS-CoV-2 test results in children and the relevance of the viral variant
B.1.1.7. has been received.

Evaluation scheme for ranking the quality of evidence from studies

Various methodological approaches can be found in research on the effect of masks. Many studies are so-called observational studies in which, for example, people are asked whether they wear masks in everyday life or not, and the incidence of infection is compared. The methodological problem is that it is not possible to conclude a causal effect of the mask from such studies, because mask-wearing persons can also behave differently in terms of hygiene in other respects. For example, it is very likely that mask-wearing persons also wash their hands more frequently, so that an observed effect may also 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 draw conclusions about virus spread in real life from such laboratory findings. The reason is that in such studies only one transmission pathway is experimentally tested. In real life, however, there are other transmission routes on which the wearing of a mask may have a negative effect, so that in total masks may even have a negative effect on the spread of the virus, although a positive effect on transmission via the air stream can be demonstrated experimentally. For example, studies show that while masks reduce the viral load in exhaled air, more viruses accumulate on the outside of the mask [1]. Thus, while a mask reduces the airborne route of transmission, it increases the route of transmission by touching the mask with the hands. From the perspective of application research, drawing conclusions about the spread of viruses in real life from the investigation of a single transmission pathway in the laboratory is a well-known misconception, because in practice it is the interaction of all transmission pathways that counts.

Finally, there are studies that attempt to estimate the effect of prescribing mandatory masks on the basis of modeling the spread of the virus in the population. However, the outcome of modeling studies depends fundamentally on the parameters built into the model. For example, many modeling studies ignore the fact that virus spread is strongly influenced by seasonal effects, which can then be incorrectly attributed to an effect of prescribed measures [2]. Furthermore, some parameters cannot be estimated from empirical data, but must be fixed with certain theoretical assumptions. For example, the time between infection and reporting a test result to the public health department varies substantially from person to person, which is not adequately represented in several modeling studies [3]

In order to really scientifically investigate the effect of mask-wearing, studies are actually necessary in which people in everyday life are randomly assigned to a group with or without a mask and the infection incidence in both groups is observed over a longer period of time (so-called randomized controlled trials), which can be considered the gold standard of efficacy research.

Recommendations of the RKI on measures in the school sector

On October 12, the RKI published a recommendation on preventive measures in schools [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 class - for elementary schools from a 7-day incidence in the population of 50 per 100,000 and for secondary schools already from a 7-day incidence in the population of 35 per 100,000.

From an evidence-based perspective, it should be noted negatively that these recommendations of the RKI do not refer to any studies on the effectiveness of mask-wearing. The corresponding paper merely states - without referring to a single supporting empirical study (p. 3):

> "The recognized infection control measures are also effective in childhood and adolescence, are readily implementable, at least for older children, and are an important component in managing the pandemic."

Furthermore, it is explicitly pointed out that these recommendations completely disregard the possible harm of mask-wearing in children. Thus, the RKI explicitly writes in the corresponding paper (p. 4):

> "Psychosocial and other aspects such as avoiding stigma are not part of this recommendation; the focus is on infection prevention."

From the perspective of evidence-based medicine, in which it is important to weigh both the benefits and the costs of a measure against the background of existing empirical studies, this paper by the RKI on the recommendations for preventive measures in schools must be classified as questionable: The claimed benefit of mask-wearing in children is not supported by empirical studies, and possible harms were even explicitly ignored in the drafting 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 SARS-CoV-2 transmission in schools" was presented by the Scientific Medical Societies [5]. The recommendations formulated in the guideline were developed by a representative group of experts from the scientific societies - led by the German Society for Epidemiology, the German Society for Public Health, the German Society for Pediatrics and Adolescent Medicine, and the German Society for Pediatric Infectious Diseases - as well as those involved in school activities and decision-makers. With regard to the wearing of masks, the recommendation is as follows (p. 5):

> **2.2 Evidence-based recommendation**
>
> Proper wearing of masks by schoolchildren, teachers and other school personnel should be implemented in schools.
>
> **Quality of evidence**: Low ⊕⊕⊙⊙
> **Degree 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).

2.2 Evidence-based recommendation

From high levels of infection, a medical mouth-nose protection should be used.

Quality of evidence: Low ⊕⊕⊙⊙
Degree of recommendation: Strong recommendation A
Consensus strength: consensus (86%); votes in favor 18, votes against 3, abstentions 4
Literature: Chu et al. (2020); Krishnaratne et al. (2021); Li et al. (2020).

With regard to the evidence underlying the recommendations, the guideline specifically states (p. 6; emphasis added by the author of the expert report):

Evidence base

- Evidence on the effects of the intervention with respect to SARS-CoV-2 transmission was systematically collected using a Cochrane Rapid Review [1]. The evidence obtained is largely based on modeling studies with quality deficiencies. The **confidence level of this evidence is very low or low**.
- Indirect evidence of SARS-CoV-2 transmission during mask use in the general population has **low confidence levels.**
- Health outcomes beyond COVID-19 **have not been systematically screened** and are based on indirect evidence, individual studies, and/or expert consensus.
- Evidence on other criteria (acceptability, health equity, social and environmental consequences, financial and economic consequences, feasibility) was not reviewed, i.e. **no systematic search and evaluation of scientific studies was performed**. All assessments of these criteria are based on expert consensus. A restriction of fundamental rights by the measure was considered, also with regard to the proportionality of the measure. A legal review was not carried out.

As the highlights show, the evidence base on which the recommendations to wear masks in children were based is consistently low to very low, and a systematic search and evaluation of scientific studies has not taken place in some cases. Nevertheless, the following claims are subsequently made with regard to the benefit - without at this point citing concrete empirical evidence for the claims made (p. 6):

> "Mask-wearing reduces transmission of SARS-CoV-2. Mask-wearing in schools reduces incidence of infection as part of a package of measures."

It should also be critically noted that the meta-analyses cited under "Literature" - Chu et al. (2020), Krishnaratne et al. (2021), and Li et al. (2020) - are also exclusively meta-analyses of observational studies. Thus, Li et al. explicitly write in the conclusion in the abstract:

> "Robust randomized trials are needed in the future to better provide evidence for these interventions."

This is exactly how 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 analyzed in the meta-analyses are mostly hospital-based studies, which cannot simply be transferred to the school setting in terms of infection incidence. For example, only one of the six studies included in the meta-analysis by Li et al. was not in the hospital setting, but in the normal population, and in this study, interestingly, there was no significant effect of mask-wearing for persons outside hospitals.

In fact, there are now relatively extensive observational studies on the occurrence of infections outside hospitals, which are not yet included in the meta-analyses mentioned, but which point in a similar direction. For example, a large study from Spain has recently appeared in the Lancet [6], in which 282 clusters of infections in households were examined with respect to factors that influenced the incidence of infection. One factor was whether or not masks were worn. There was no significant difference in infection incidence between the "never wore mask" and "always wore mask" groups, 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 substantiated with convincing scientific evidence, as should actually be the case with high-quality S3 guidelines.

It is particularly noteworthy that potential harms are almost completely ignored. As 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 potential harm from mask-wearing, the guideline states - mind you, although the evidence was not systematically reviewed (p. 6):

> "There are few health side effects associated with mask-wearing. There is no evidence of potential harm from wearing a mask."

Overall, the S3 guideline does not meet the actual expectations 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 provide only very low to low evidence and are also questioned by more recent studies. With regard to harm, it is claimed that there is no evidence for possible harm, although the studies have not been systematically reviewed. As will be described in more detail in a moment, a look at the official recommendation of the WHO alone would have sufficed in this respect.

possible damages are at least partially listed with corresponding references. Particularly with regard to harm, the S3 guideline thus almost borders on misleading the users of such guidelines.

WHO recommendations for wearing masks

The WHO general recommendations on mask use were last updated on December 1, 2020 [7]. On the one hand, it explicitly differentiates between settings inside and outside hospitals. On the other hand, it explicitly 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 base, the wearing of masks is recommended in cases of high virus spread when a distance of 1 m cannot be maintained. However, explicit reference is made to the numerous possible harms, with reference to corresponding scientific evidence, which should be included in decisions on mask wearing (p. 10; the references given refer to the numbering in the 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 August 21, 2020, the WHO also published a recommendation on mask-wearing 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."

Furthermore, studies are cited which indicate that masks are less effective in children than in adults. So it says (p. 2):

> "One study, conducted under laboratory conditions and using non-betacoronaviruses, suggested that children between five and 11 years old were significantly less protected by mask wearing compared to adults, possibly related to inferior fit of the mask."

With regard to the recommendation whether children should wear masks, it is then explicitly stated that the potential harms should be given priority consideration. This is stated in the *Main Conclusions* (p. 2):

> "The benefits of wearing masks in children for COVID-19 control should be weighed against potential harm associated with wearing masks, including feasibility and discomfort, as well as social and communication concerns."

And in the *Overarching Guiding Principles,* the first two points are:

- Do no harm: the best interest, health and well-being of the child should be prioritized.
- The guidance should not negatively impact development and learning outcomes.

Nonetheless, surprisingly, the wearing of masks is then recommended for children six years of age and older, but only if (among other things) there is a higher viral spread in the population and a higher risk of infection in the relevant age group, and possible negative influences on learning and psychosocial development are weighed.

In summary, the WHO recommendations explicitly point to the lack of high-quality scientific evidence on the effectiveness of mask-wearing overall and in particular with respect to children. At the same time, many of the potential harms are mentioned, and it is explicitly recommended that potential physical, psychological, and social harms in children be considered and prioritized as appropriate.

Randomized controlled trials of the effect of masking on viral spread.

As mentioned at the outset, randomized controlled trials are actually required for a high-quality scientific investigation of the effect of masks on virus spread. Since such studies are very costly, until relatively recently such studies were not available with respect to 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 randomized controlled trials, the results are consistent:

- *Cochrane Review of* 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)."

- *Policy Review of* the U.S. 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 stated at a press conference on February 28, 2020, that the RKI explicitly does not recommend wearing masks in everyday life. Verbatim, he clarified when asked [11]:

> "This has been studied multiple times: There's just no scientific evidence that that [wearing masks] makes any sense."

Thus, at the onset of the SARS-CoV-2 pandemic, there was no scientific evidence from randomized controlled trials that mask-wearing could contain the spread of respiratory viruses in any relevant way. This has since been confirmed in the first major randomized controlled trial of the effect of mask-wearing on SARS-CoV-2 infections. In a Danish study [12], 4,862 people were randomly assigned to either a group that was to wear high-quality surgical masks (filtering rate 98%) when leaving home for one month or a group that was not to wear masks during the same period. At the time of the study, masks were not mandatory in Denmark and wearing masks was uncommon.

The result was that no significant difference (p = 0.18) was observed in the infection rate between the mask group (infection rate: 1.8%) and the control group (infection rate: 2.1%). When only those individuals who actually wore the mask as prescribed were left in the mask group, the effect of mask wearing almost completely disappeared (infection rate mask group: 2.0% versus infection rate control group: 2.1%, p = 0.82). Thus, the first large randomized controlled trial of the effect of mask-wearing on SARS-CoV-2 infections confirms the lack of effect of mask-wearing observed in previous studies of other respiratory viruses. It should be noted that this study examined the effect of mask-wearing on self-protection. With regard to the protection of others - i.e. the extent to which masks prevent an infected person from infecting other people - there have been no randomized controlled trials to date.

At the end of November, an update of the aforementioned *Cochrane Review was* published [13], which includes the new studies added until then. 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."

Accordingly, there is still no evidence from randomized controlled trials that masks could prevent the spread of infection. With regard to the wearing of

cotton masks, in fact, the only randomized controlled trial [14] to date on the subject shows that wearing cotton masks not only fails to contain the risk of infection, but actually significantly increases it. The study tested the effect of mask-wearing on 1,607 hospital workers, one-third of whom wore cotton masks and one-third wore surgical masks, with the remaining third expected to behave as they usually do (in this condition, almost all individuals also wore either medical masks or cotton masks). The authors summarize the results in the abstract as follows:

> "The rates of all infection outcomes were highest in the cloth mask arm, with the rate of ILI [influenza-like illness] statistically significantly higher in the cloth mask arm (relative risk (RR) = 13.00, 95% CI 1.69 to 100.07) compared with the medical mask arm. Cloth masks also had significantly higher rates of ILI compared with the control arm."

The risk of infection was strongly increased as in the group with cotton masks. In the group with the medical mask, the risk of infection was reduced compared to the control condition. However, this should not be taken as an indication that medical masks may have actually had an effect. In the control group, subjects did not wear no masks, but wore 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.

Interestingly, there are two other studies by the same researchers with a very similar design, in which medical masks were compared with a real control condition without a mask. There was no difference in infection risk between the groups. The authors draw on these results to interpret the findings from the study on 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."

Thus, the authors conclude that the findings should probably be interpreted to mean that even medical masks do not reduce viral spread, but cotton masks additionally increase the risk of infection. Specifically, the main conclusion derived from the study reads in the abstract:

> "The results caution against the use of cloth masks."

Of particular interest with respect 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 modeling studies have quantified the contamination levels of masks. Self-contamination through repeated use and improper doffing is possible. For example, a contaminated cloth mask may transfer pathogen from the mask to the bare hands of the wearer. We also showed that filtration was extremely poor (almost 0%) for the cloth masks. Observations during SARS suggested double-masking and other practices increased the risk of infection because of moisture, liquid diffusion and 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, which can increase the risk of infection if handled incorrectly. Interestingly, the problems mentioned - long wearing time, higher moisture penetration, long-term use of the same mask without adequate cleaning and problematic handling - are exactly the problems that are typically observed when students wear masks in class.

The factor of correct handling of the masks when worn

It should be noted here that correct handling of masks is generally crucial for masks to be effective at all. The aforementioned WHO recommendation on the correct use of masks states this [7]:

> **WHO provides the following guidance on the correct use of masks:**
>
> - Perform hand hygiene before putting on the mask.
> - Inspect the mask for tears or holes, and do not use a damaged mask.
> - Place the mask carefully, ensuring it covers the mouth and nose, adjust to the nose bridge and tie it securely to minimize any gaps between the face and the mask. If using ear loops, ensure these do not cross over as this widens the gap between the face and the mask.
> - Avoid touching the mask while wearing it. If the mask is accidentally touched, perform hand hygiene.
> - Remove the mask using the appropriate technique. Do not touch the front of the mask, but rather untie it from behind.
> - Replace the mask as soon as it becomes damp with a new clean, dry mask.
> - Either discard the mask or place it in a clean plastic resealable bag where it is kept until it can be washed and cleaned. Do not store the mask around the arm or wrist or pull it down to rest around the chin or neck.
> - Perform hand hygiene immediately afterward discarding a mask.
> - Do not re-use single-use mask.

- Discard single-use masks after each use and properly dispose of them immediately upon removal.
- Do not remove the mask to speak.
- Do not share your mask with others.

As this list makes clear, the correct wearing of masks places high demands on the person wearing the mask. Considering the fact that students are required to wear masks in class for up to 10 hours a day (school bus, school grounds, morning and afternoon classes), it is hardly possible to implement correct handling in schools. In addition, for younger students, correct handling is cognitively demanding, which is not the case for younger children due to their development. For example, since the prefrontal cortex is not fully developed until around the beginning of adolescence [15], children's behavior is strongly controlled by automated behavioral tendencies, which can only be regulated by the child itself to a limited extent. Thus, requirements such as not touching the mask can hardly be implemented by children. Thus, there is a risk that the increased risk of infection due to incorrect handling outweighs the small to non-existent benefit according to randomized controlled trials.

From the perspective of evidence-based medicine, it is particularly critical to note that there are no randomized controlled studies on the effect of wearing masks in schools on the spread of the virus. In view of the situation described, it is questionable to what extent it can be justifiable at all to impose a comprehensive mask requirement without any really scientifically verifiable proof of a benefit. This is all the more the case since the prolonged wearing of masks can be associated with possible damage on a physical, psychological and social level - beyond a possibly even increased spread of the virus (see below).

The extent to which the risk of infection is reduced by means of mask-wearing in schools

It is important to note that the effect of a measure on the spread of viruses in the population does not depend solely on the effectiveness of a measure. The effect of a measure additionally depends on how many infections can be prevented at all in the setting in which the measure is used. If, for example, there are hardly any infections in a particular setting, even a highly effective measure can hardly influence the incidence of infection in the population because there are hardly any infections that can be prevented by the measure.

This point is particularly relevant if a measure is associated with potential side effects. 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 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 a single person, the use of the drug is to be classified as questionable.

With regard to the question of mask-wearing in schools, this point is particularly relevant because virtually all available data indicate that infections in schools are comparatively rare. This is the case simply because extensive meta-analyses indicate that children under 12 years of age in particular are less likely to become infected and less likely to pass on the virus than adults [16,17].

In addition, the very measure of keeping children with symptoms at home significantly reduces the number of infectious children in schools. As extensive meta-analyses show, on the one hand, asymptomatically infected individuals infect
- i.e., persons who have tested positive for SARS-CoV-2 but do not develop symptoms of the disease - hardly ever infect other persons. For example, a meta-analysis of studies of infection among persons living together in a household [17] found that the probability of contracting the disease from an asymptomatic person (secondary infection rate) was only 0.7 percent, with statistical analysis showing that the value was not significantly different from zero. A similar finding is found in another recently published large meta-analysis on contact tracing studies [18]. There, the estimated secondary infestation rate was 1.0% and was also not statistically significantly different from zero. Both meta-analyses show very clearly that asymptomatic infections play virtually no role. Thus, asymptomatically infected children do not pose a relevant risk of infection.

In the case of infected children with symptoms, it is the case that in approximately a maximum of two days before the onset of symptoms, infection can occur [19]. Thus, if children with symptoms stay at home, there is only a window of two days in which children developing symptoms can infect others, which significantly reduces the risk of infection.

In fact, numerous data confirm that there are hardly any infected children or infections at schools. The current figures from Austria are particularly interesting with regard to the wearing of masks, because no masks are worn at elementary school there, and at the same time, rapid tests are now carried out three times a week throughout the country. Thus, the number of infected pupils can be estimated relatively well. In the week of February 22-28 (most recent data set available), only 0.08 percent of rapid tests were positive at elementary schools [20]. Assuming that the number of false-positive and false-negative results is roughly balanced, the probability that a student would be infected within a week would be only 0.08 percent. The probability of an infected student infecting another person during close contacts without wearing a mask at school is also very small and, according to extensive contact tracing studies, is only in the order of 0.5 percent [21,22].

Based on these figures, an example calculation can be used to illustrate the extent of the risk reduction that can be achieved by wearing masks. The risk of an infection occurring in a class of 25 children over the course of a week is therefore 0.08 percent times 25 (probability of an infected child in a class) times 25 (number of contacts including teacher) times 0.5 percent (probability of infection per contact) = 0.25 percent.

This figure would correspond to the risk of infection that can potentially be reduced with measures in schools. The extent of the reduction depends on the effectiveness of a measure. If the non-significant effects from the randomized controlled trials are interpreted as zero effects, no risk reduction could be achieved with mask-wearing in schools.

If we assume the non-significant effect sizes in the current Cochrane Review mentioned above, according to which the probability of infection is reduced by a maximum of about 10 percent when medical masks are worn, the risk of infection at the level of a school class would be reduced from 0.25 percent to 0.225 percent, which would correspond to an absolute risk difference of 0.025 percent. Extrapolated to the *Number Needed to Treat, this means* that students in
4,000 elementary school classes wear a mask for one week to prevent a single infection. This is an extremely small effect size, and it would take just under 100,000 elementary school students to suffer the potential side effects of wearing a mask to prevent a single infection per week.

Assuming that masks would reduce the probability of infection in the order of 80 percent (result of the meta-analysis by Chu et al. mentioned in the S3 guideline 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 percent to 0.05 percent, which would correspond to an absolute risk difference of 0.2 percent. Extrapolated to the *Number Needed to Treat,* students in 500 primary school classes would still have to wear a mask for one week, and thus almost 12,500 primary school students would have to suffer the possible side effects to prevent a single infection per week.

To evaluate such a ratio, an example from the field of drug approval is helpful. Here, it would be difficult to imagine a positive evaluation of a drug if it had to treat 100,000 (reducing the probability of infection by 10 percent through masks) or 12,500 (reducing the probability of infection by 80 percent through masks) people and cause them to suffer from side effects in order to achieve a positive effect in a single person.

In summary, it can be concluded that the achievable extent of reduction of the risk of infection by mask-wearing at schools is very small, because infections occur very rarely at schools even without masks. It is intuitively plausible that an absolute risk reduction of 0.025 percent (reduction of the probability of infection by masks by 10 percent) and also an absolute risk reduction of 0.2 percent (reduction of the probability of infection by masks by 80 percent) cannot combat a pandemic in a relevant way. In addition, this small benefit is countered by numerous possible side effects on the physical, psychological and social well-being of children, from which numerous children would have to suffer in order to prevent a single infection (see below).

The currently observed increase in reported infections among children

Finally, the increase in the number of reported positive SARS-CoV-2 test results in children observed in the previous calendar weeks and the relevance of the new virus variant B.1.1.7 should be discussed. This increase is interpreted by the RKI and the media as a strong increase in the number of infections among children, which is somewhat related to the new virus variant B.1.1.7.
B.1.1.7 could have something to do with this. Both are used as arguments that more stringent measures are needed at schools.

However, the RKI overlooks a serious aspect here: In the previous calendar weeks, the number of Corona tests (PCR tests) performed in children approximately quadrupled (see the figures published by the RKI on the number of tests performed: [24]). However, an expansion of testing is automatically accompanied by an increased number of infections found, given an existing dark figure of persons infected but not yet detected, without the need for a change in the incidence of infection. The increase in the number of cases among children assumed by the RKI could therefore only be due to the fact that the number of tests among children has quadrupled, thus increasingly revealing the number of unreported cases.

Looking at the proportion of positive test results received, on the other hand, it is apparent that there has been no increase at all in the previous calendar weeks among 5-14 year-old children. Instead, the proportion of positive test results has been falling for several weeks. Contrary to the information provided by the RKI and disseminated in the media, there has been a decrease in the proportion of positive test results instead of an increase.

There is actually only one 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 driven by observing more and more people with corona-specific symptoms, who were then targeted with tests. However, this is most likely not the case with the current corona testing in children. This is indicated by the fact that more than 90 percent of the tests performed on children are negative. So the question of which children to test seems to be largely independent of whether or not children have corona-specific symptoms.

In fact, for weeks now, there has been very strong publicity for the widespread testing of children at schools and daycare centers regardless of symptoms. Due to the increasing mass testing regardless of symptoms, the number of unreported cases of infected but not yet detected persons is increasingly being uncovered, which causes the number of cases to rise due to testing. At the same time, the number of PCR tests independent of symptoms is also increasing in general. According to RKI calculations [25], in mass testing with rapid tests independent of symptoms, the probability of actually being infected when receiving a positive result is only two percent at an incidence of 50 (test specificity 80%, test sensitivity 98%). 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.

In addition, there is currently a sharp increase in respiratory diseases caused by rhinoviruses and the coronavirus hCoV in particular. According to the current

According to the influenza weekly report of the RKI [26], the number of rhinovirus-related and hCoV-related respiratory illnesses has more than tripled within the last four weeks according to the sentinel samples examined in the course of influenza surveillance. The graph published in the same weekly report on the age dependence of the virus spreads shows that the rhinovirus in particular is spreading mainly among children and adolescents in this context

Since, according to RKI guidelines [27], testing for SARS-CoV-2 is performed in the presence of acute respiratory symptoms of any severity, the current increase in rhinovirus- and hCoV-related respiratory illnesses is leading to an increasing number of individuals being tested for SARS- CoV-2, even though the majority of respiratory illnesses are due to another virus. In turn, because PCR test results can be positive weeks and sometimes even months after SARS-CoV-2 infection [19], this rhinovirus- and hCoV-related increase in the number of SARS-CoV-2 tests is leading to increasing detection of unreported cases of infections that are actually past but not yet detected.

Taken together, we can thus state from a diagnostic perspective: It is highly 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 tests is most likely due primarily to the advertised mass testing of children and the increasing number of rhinovirus- and hCoV-related respiratory illnesses among children. Both of these factors are increasingly leading to the discovery of unreported cases of children infected with SARS-CoV-2 but not yet detected, resulting in a test-count-related increase in the number of infections.

Interestingly, the results from the influenza surveillance sentinel samples, which are not distorted by the increase in the number of tests in the population, confirm that the new SARS-CoV-2 coronavirus is not currently spreading more than in previous weeks. As the virus detections to the sentinel samples show, the number of SARS-CoV-2 infections detected in the sentinel samples has been at a comparatively low level since the 4th calendar week, and a "third wave" is virtually not evident here.

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 risk of infection in children with the new mutations B.1.1.7. However, recent comprehensive studies have not been able to confirm this fear. This is the conclusion of a very comprehensive 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."

Comparable findings exist from a similarly large study from Portugal [29]. In summary, the German Society for Pediatric Infectiology and the German Society for Hospital Hygiene wrote in a recent statement [30]:"

> Initial media reports of an increased risk of infection or transmissibility for children compared with adults have not been confirmed."

Here it is important to point out a common statistical misintuition. Statements like "the new variant is 50 percent more contagious" intuitively sound like a lot. In reality, however, the resulting threat depends on how high the probability of infection is for the old virus variant: the percentage value does, after all, say by what percentage of the old probability of infection the new probability of infection is higher. If the old infection probability is small, however, the new infection probability is still small with a 50 percent increase.

An illustrative example of this, which is particularly relevant for the risk of infection emanating from children: according to the extensive contact tracing studies in schools mentioned above, the probability of an infected child infecting a contact at school (without masks at schools) is only about 0.5 percent. With a 50 percent increase, the probability of infection would still be only 0.75 percent. Extrapolated to 100 contacts, this would mean that despite a 50 percent increase in the probability of infection, less than a single additional person would still become infected. Even with a 50 percent increase in the probability of infection, the risk of infection at schools is therefore still very low, so that a tightening of the measures cannot be justified from a scientific perspective.

Summary evaluation

In summary, there is no high-quality scientific evidence to date that wearing face masks can significantly reduce the risk of infection. The recommendations of the RKI and the S3 guideline of the professional societies are based on observational studies, laboratory studies on the filter effect and modeling studies, which provide only low and very low evidence, because no really valid conclusions on the effect of masks in everyday life and at schools can be drawn from such studies due to the underlying methodology. In addition, the results of the individual studies are heterogeneous and more recent observational studies also provide contradictory findings.

The existing randomized controlled trials on the effect of mask wearing do not indicate any efficacy of masks, the observed effects are consistently small and meta-analytically not significant. On the contrary, the only comprehensive randomized controlled trial on the wearing of cotton masks to date indicates that cotton masks may even increase the risk of infection. A role is played here above all by the handling of the mask, which can have a negative effect on the risk of infection in the event of poor handling. This point is particularly interesting for schools, because handling problems in the school setting and especially with younger students are hardly avoidable.

In addition, the achievable extent of the reduction in the risk of infection through mask-wearing at schools is very low in itself, because infections very rarely occur at schools even without masks. Accordingly, the absolute risk reduction is so small that it cannot be used to combat a pandemic in any relevant way. In addition

This small benefit is countered by numerous potential side effects on the physical, psychological and social well-being of children (see below), from which many children would have to suffer to prevent a single infection.

The current alleged increase in the number of infections in children is very likely to be due to the fact that the number of tests carried out on children has risen sharply in the preceding weeks. Since the risk of infection at schools is very small in itself, even a possible increase in the infection rate with the new virus variant B.1.1.7 in the order of magnitude assumed in studies is not expected to significantly increase the spread of the virus at schools.

2. What physical, psychological, and educational harm can result from wearing masks, especially in children?

To answer this question, the above-mentioned list of the harms of mask-wearing from the official recommendation of the WHO and, as a supplement, the overviews from two specialist publications on the harms of mask-wearing are first presented for an overview. Subsequently, the results of an online registry on the physical and psychological side effects of mask-wearing in children are presented, which were recently published. After that, various physical and psychological harms will be discussed in more detail, especially with regard to the specifics in children. Finally, questionable plausibility arguments, which are often cited, will be discussed.

Overview studies on the harms of mask-wearing.

As already stated in the elaboration of question 1, the WHO recommendations on the wearing of masks [7], updated on December 1, 2020, mention numerous possible harms with reference to corresponding empirical evidence. These are presented again in the following list, the corresponding empirical evidence is linked in the bibliography at the end (see WHO recommendation, p. 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].

In January 2021, the peer-reviewed journal *Medical Hypothesis* published a comprehensive overview article on the state of the art regarding the physical and psychological harm of mask-wearing and the resulting health consequences [40]. As the following overview table from the article shows (see Table 1), there are additional indications of further - in particular 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 • Increaselactate concentration • Decline in pH levels • Acidosis • Toxicity • Inflammation • Self-contamination • Increase in stress hormoneslevel (adrenaline, noradrenaline and cortisol) • Increased muscle tension • Immunosuppression	• Activation of "fight or flight" stress response • Chronicstress 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 • Exacerbationofexisting 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, especially for children and schoolchildren, of prolonged mask-wearing [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 behavioral 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]."

The overview articles listed already show how numerous the possible harms of mask-wearing are. In particular, some other possible harms are still missing, such as the risk of discrimination against children who cannot wear masks for medical reasons, or developmental impairments. On the other hand, children are more susceptible to many of the listed side effects due to their developmental immaturity.

Results of a registry on side effects of mask-wearing in children.

Clear and impressive evidence of the range and numerical magnitude of the side effects of wearing masks in children is provided by the results of the world's first register, in which - comparable to the collection of side effects of medicines by the Paul Ehrlich Institute - parents, doctors, educators and others can enter their observations on the side effects of wearing a mask in children and adolescents. On the one hand, various possible symptoms are queried there by means of a checklist (see the following table from the article), and on the other hand, further symptoms can be specified in a free text field.

The first results were recently published in the journal *Monatsschrift Kinderheilkunde* [60]. Within one week after the start of the registry, 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 parent entries are reported. The reported average mask wearing time was 270 min per day. Overall, 68% of the entrants reported that children complained of impairment from mask wearing. For example, 13,811 of the children suffered from headaches, 12,824 from difficulty concentrating, 9,460 from drowsiness, 7,700 from shortness of breath, 6,848 from dizziness, 5,365 from fainting, and 4,292 from nausea. The following table from the article shows the frequency of claims 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 till 17** *n* **(%)**
Headache	13.811 (53,3)	960 (24,0)	7863 (54,6)	4988 (66,4)
Difficulty concentrating	12.824 (49,5)	961 (24,0)	7313 (50,8)	4550 (60,5)
Malaise	10.907 (42,1)	1040 (26,0)	6369 (44,2)	3498 (46,5)
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)

Tightness feeling under the mask	923 2 (35, 6)	968 (24, 2)	542 7 (37, 7)	283 7 (37, 7)
Feeling of shortness of breath	770 0 (29, 7)	677 (16, 9)	444 0 (30, 8)	258 3 (34, 4)
Dizziness	684 8 (26, 4)	427 (10, 7)	381 4 (26, 5)	260 7 (34, 7)
Dry throat	588 3 (22, 7)	516 (12, 9)	331 3 (23, 0)	205 4 (27, 3)
Powerlessness	536 5 (20, 7)	410 (10, 2)	288 1 (20, 0)	207 4 (27, 6)
Reluctance to move, reluctance to play	462 9 (17, 9)	456 (11, 4)	282 4 (19, 6)	134 9 (17, 9)
Itching in the nose	443 1 (17, 1)	513 (12, 8)	255 0 (17, 7)	136 8 (18, 2)
Nausea	429 2 (16, 6)	310 (7,7)	254 4 (17, 7)	143 8 (19, 1)
Feeling of weakness	382 0 (14, 7)	300 (7,5)	202 0 (14, 0)	150 0 (20, 0)
Abdominal pain	349 2 (13, 5)	397 (9,9)	229 2 (15, 9)	803 (10, 7)
Accelerated breathing	317 0 (12, 2)	417 (10, 4)	179 6 (12, 5)	957 (12, 7)
Feeling sick	250 3 (9,7)	205 (5,1)	132 8 (9,2)	970 (12, 9)
Tightness in the chest	207 4 (8,0)	161 (4,0)	112 2 (7,8)	791 (10, 5)

Eye flicker	202 7 (7,8)	149 (3,7)	104 7 (7,3)	831 (11, 1)
Loss of appetite	181 2 (7,0)	182 (4,5)	109 9 (7,6)	531 (7,1)
Tachycardia, heart palpitations Stitches	145 9 (5,6)	118 (2,9)	766 (5,3)	575 (7,6)
Noise in the ears	117 9 (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 damage was indicated:

- 269 Entries on worsened skin, especially increased pimples, rashes and allergic manifestations around the mouth area up to fungal diseases in and around the mouth
- 151 Nosebleed entries
- 122 entries for school dislike to school anxiety/school refusal
- 64 entries for increased sweating

- 52 entries for pressure sores and sores behind the ears
- 46 entries for sore or cracked and sometimes bloody lips
- 31 entries for increased frequency and severity of migraine attacks
- 23 entries for Impairment of vision
- 13 entries for aphthae

As the authors note, this means that more children and adolescents with mask-related physical symptoms were reported within a single week than the total number of children and adolescents with positive SARS-CoV-2 test results reported at that time.

Beyond the physical side effects, numerous psychological side effects were also registered, 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 till 17** *n* **(%)**
The child is irritable more often than usual	11.364 (60,4)	1041 (40,0)	6566 (62,1)	3757 (66,5)
The child is less cheerful	9286 (49,3)	959 (36,9)	5640 (53,3)	2687 (47,6)
The child no longer wants to go to school/kindergarten	8280 (44,0)	824 (31,7)	5168 (48,9)	2288 (40,5)
The child is more restless than usual	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	4762 (25,3)	713 (27,4)	2935 (27,8)	1114 (19,7)
The child sleeps more 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 further specified:

- In addition to a general fear of the future, fears of suffocating even with a mask and of death of loved ones from corona are the most common.
- In addition, there is the fear of stigmatization both by wearing and not wearing a mask in the social environment.
- Many parents also report nightmares and anxiety disorders, which refer to masked people whose facial expressions and identities are not recognizable to the children.

One limitation is that the entries could not be comprehensively 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 physicians. Registry entries are increasing daily in the multi-digit range, and additional validity checks are taking place to provide more robust data on the health situation of children in Germany with regard to wearing mouth-nose protection in the foreseeable future."

As an argument for the credibility of the data, the authors cite:

> "With few exceptions, the data sets in the free-text entries testify to a very differentiated approach and, on the whole, provide a balanced overall picture with a plausible spectrum of symptoms and a well comprehensible description of the impairments observed in children in connection with the mask. The response to hundreds of incoming e-mails by the study initiators with answers to questions about the existence of the registry, specification and supplementation of the entries made by participants, detailed case descriptions, and suggestions for further research, are a further indication of the high relevance of the topic and of the probity with which many participants devote themselves to the question."

Furthermore, the authors note that biased reporting cannot be ruled out with regard to preferential documentation of children who are particularly severely affected or who are fundamentally critical of protective measures.

Taken as a whole, this study on the world's first registry of possible side effects of mask-wearing in children shows very impressively that there is a very wide range of physical and psychological side effects. The authors' central conclusion is:

> "The frequency of use and the spectrum of symptoms indicate the importance of the issue and call for representative surveys, randomized controlled trials with different mask types, and risk-benefit consideration of mandatory masks in the vulnerable group of children."

The complaints described when children wear masks for long periods are also confirmed by further studies on other groups of people who also have to wear masks for long periods. There are now several studies on the complaints of people who work in the health sector and who also have to wear masks for long periods, although it should be noted here that, unlike in the school sector, other protective equipment has to be worn in addition to masks in some cases (e.g. protective goggles, protective suits). In a recently published meta-analysis of existing studies with a total of 11,746 participants on the physical side effects, the result was [61]:

> "The most frequent adverse events were headache (55.9%), dry skin (54.4%), dyspnea (53.4%), pressure injuries (40.4%), itching (39.8%), hyperhidrosis (38.5%), and dermatitis (31.0%)."

The studies described provide strong evidence that a wide range of side effects may be associated with mask wearing. In the following still

In the following, some side effects are discussed in more detail, 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 at the physiological level, especially during physical exertion. After just a few minutes, some studies find a slightly higher CO2 concentration in the blood, a faster heartbeat and faster breathing [62,63]. Wearing surgical masks for hours also shows a decrease in blood oxygen saturation [64]. On the one hand, it is important to note that there are also studies in which such effects are not observed [65]. On the other hand, it is important to note that the values when wearing masks in relation to the average values across the subjects studied are in an order of magnitude that does not reach clinical relevance according to current guidelines.

However, it should be noted that more extreme side effects such as panic, seizures, and impaired consciousness may still occur in the presence of unrecognized preexisting conditions [66]. In this regard, an important methodological issue should be noted when interpreting studies on possible side effects of masks: The mere observation that there is no statistically significant difference in average physiological values between the conditions with and without masks cannot be used to conclude the nonexistence of side effects.

The first problem is that in the case of small samples, existing mean differences only become statistically significant if the differences are very large. In medicine, however, even small effects can be quite relevant. The second problem is that even in the case of non-significant effects at the group level, extreme values can occur for individual persons, which are strongly detrimental to the persons concerned.

A negative example in this regard is a study by a group of researchers led by Michael Campos [67], which was widely disseminated in the media and allegedly showed that even people with lung disease would not show any physiological effects of wearing masks. However, on the one hand, the investigated sample is very small - in this study only 15 healthy or lung-sick people were tested - so that statistically only extremely large effects can be detected with this study. Second, despite the lack of a significant effect at the group level, extreme values occurred for individual subjects. Thus, the study states for the group of persons 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 CO_2 retention."

Thus, two of the patients with lung disease did show more fundamental side effects, only on the mean level there is no effect on average across all patients. If this were to be made the rule for drug approval, for example, rarer side effects would immediately no longer have to be taken into account - which is questionable.

In summary, a mini review of existing studies published in February 2021 [68] states:

> "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 possible physiological damage of mask-wearing in children, a fundamental problem is that there have been hardly any studies to date on the effects in children. This is particularly problematic because the effects described could be more pronounced in children because oxygen consumption is higher in children and the breathing reserve is lower, the percentage of the dead space volume of the mask in the total breathing 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 a single study that examined the physiological consequences of wearing N95 masks for five minutes in 7-14 year old children, once while reading and once during light physical activity [69]. It was found that CO2 (end-tidal carcon dioxide and fractional inspired carbon dioxide) concentrations increased by up to 34 percent (light physical activity) when the mask was worn in both cases, although the values still did not reach clinical relevance.

The problem, however, is that in the course of compulsory mask use in class, children do not just wear masks for five minutes, but for up to ten hours a day, five days a week. There are no studies on such long wearing times. This is particularly problematic because, from a medical ethics perspective, it is imperative that, when the state prescribes mandatory measures for millions of children, possible risks are examined and ruled out on the basis of evidence before the measure is prescribed, or that the risk is at least quantified.

Mouth diseases - the so-called "mask mouth

Wearing masks can be associated with a number of oral diseases, such as dental caries, bad breath, gingivitis, and inflammation of the oral region - this is where the technical term "mask mouth" was coined [70].

Deformation of the auricle

Children before puberty have undeveloped ear cartilage with less resistance to deformation. Prolonged pressure from the elastic loops of the mask may affect the correct growth and angulation of the outer ear and increase the angle of the outer auricle [71].

Accumulation of viruses and bacteria on the mask

Viruses, bacteria and fungi can accumulate on the masks, which are repeatedly inhaled and can cause illness, as shown, for example, by studies on the wearing of surgical masks [72]. While exhaled droplets and aerosols are normally released into the ambient air on exhalation and dry quickly, they remain in the mask when masks are worn, with the effect that bacteria and fungi can multiply in the constantly moist environment of the mask, be inhaled again and contaminate the body.

Possible toxins contained in masks

Problematic side effects can also occur if worn masks contain toxic substances. An article in the *Frankfurter Rundschau* reported the results of an investigation by the private Hamburg Environmental Institute (HUI) [73]. There, in some cases, considerable amounts of harmful substances were detected in the masks currently in use, including volatile organic hydrocarbons and formaldehyde. In addition, it was shown that microplastics are inhaled when worn for several hours and when used repeatedly - as is the case in schools. HUI Chairman, Professor Michael Braungart, is quoted as saying:

> "In trials, we have found up to 2000 fibers per day, some of which enter the lungs with the air we breathe."

A recent article by the German Allergy and Asthma Association (DAAB) states [74]:

> "The DAAB received several inquiries about odors on protective masks during the Corona pandemic. Especially at the beginning of the pandemic, there were certainly more products on the market that contained harmful substances. But even now, this can still be the case in isolated cases, as the magazine WISO has now currently verified. Harmful substances in masks can enter the lungs directly through breathing".

Since the certification of medical masks only requires testing of filter performance and germ load, but not necessarily the presence of toxic ingredients (see DIN EN 14683, 5.2.7 Summary of performance requirements), this could indeed be a problem for some medical masks. If it is true that medical masks may contain problematic ingredients, children would be exposed to a health risk when wearing medical masks. Because the masks are mandatory to wear in class, on school grounds, and on the school bus, a period of wear is reached when such risks would be particularly high.

Psychological side effects

As already described on the basis of the entries in the above-described register on the side effects of mask-wearing in children, far-reaching negative effects on the development and maturation of children are to be expected at the psychological level if masks are compulsory in schools for a longer period of time. In a recent review of the side effects of mask-wearing on emotional experience and social communication, neuroscientist Manfred Spitzer points to the following three problems [75]:

Restriction of nonverbal communication

Wearing masks extremely limits nonverbal communication, which is one of the most important channels for the development of a sustainable social relationship, especially for younger children. Furthermore, facial expression is one of the central signals through which we communicate our own emotional state and infer the emotional state of the other person, which is one of the fundamental building blocks of the development of high emotional and social competence. Children in particular have yet to learn how to reliably interpret these signals in the faces of others.

Negative distortion of emotional experience

In addition, there is another negative effect: According to studies, fear and sadness are more likely to be read from the eyes and joy from the mouth region. Furthermore, without the signal from the mouth region, emotional facial expressions are misinterpreted. A happy facial expression is often misinterpreted as a skeptical facial expression, a surprised facial expression is often misinterpreted as anger or sadness. The wearing of masks could therefore lead to the fact that one perceives less positive and more negative emotions in the faces of others.

Impairment of empathy

Furthermore, empathy - feeling the emotional state of the other person - is impaired by wearing masks. As studies show, when communicating with each other, people unconsciously take on the facial expression of the other person and thus feel the inner state of the other person, which is prevented by wearing a mask.

In summary, Manfred Spitzer writes in one of his overview papers:

> "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 aforementioned psychological side effects of wearing masks are also addressed in the Bavarian Act on the Education, Upbringing and Care of Children in Kindergartens, Other Daycare Facilities and in Daycare (BayKiBiG). Although this law deals with kindergarten children, the corresponding content can also be transferred to elementary school age. The following article [76] can be found there in Part 3 on safeguarding the best interests of the child:

Article 9a: Prohibition of face covering

Employees in daycare facilities may not cover their faces during visiting hours, unless there are care-related reasons for not doing so. Sentence 1 applies accordingly to daycare staff.

On the official page of the Bavarian State Ministry for Family, Labor and Social Affairs there is a more detailed interpretation. There, the various pedagogical justifications for the ban on face covering are given [77]:

Excerpt from the explanatory memorandum to Art. 9a BayKiBiG:

One of the goals of daycare centers and childcare is to teach children cooperation and communication skills and to enable them to integrate. Particularly in the area of very young children, it is essential for the development of a child that good pedagogical work is done. This would be severely jeopardized if the child were to find itself face to face with a caregiver or another person working in the daycare center 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. Furthermore, a veiled

face in particular communication and interaction between children and educators and thus impairs the development of attachment and relationships, which are essential for the education and upbringing of children. After all, it is precisely the personal and familiar contact between child and staff that is enormously important for early childhood education.

It is therefore necessary that employees in daycare facilities do not cover their face (between chin and forehead) during visiting hours and at events of the facility. (...) The prohibition does not apply if there are care-related reasons for not doing so. Care-related reasons would be, for example, a disguise in a role play or at a carnival party.

In view of the fact that the aforementioned negative effects of mask-wearing on children's development are perceived as so important in the BayKiBiG that a ban on mask-wearing is prescribed by law there, it is all the more surprising that none of the aforementioned side effects is given any attention in the context of the current regulation of a mask requirement in elementary schools - nor among educators in Kinderarten.

In addition, there are a number of other possible psychological side effects:

Restriction of speech transmission

Wearing masks is further associated with negative effects on 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, which impairs verbal communication and is associated with the risk of misunderstandings. This has a particularly detrimental effect on the learning of a new language, so that foreign language acquisition and especially children with a migration background are affected by this.

Danger of discrimination

Finally, there are negative side effects at the psychological level for children who are not allowed to wear a mask for medical reasons. Here, there is a risk that such children - justified by hygiene-related arguments - will be discriminated against and excluded from the social class group, with negative consequences for their psychological and social well-being. I know of cases where children who cannot wear a mask for medical reasons have to wear yellow armbands for the entire school day. In another case, a corner is taped off in the classroom and in the playground where children who cannot wear masks for medical reasons have to stay. The risk of discrimination is also evidenced by the fact that in the register described above on the side effects of mask-wearing among children, one of the fears mentioned is the fear of being stigmatized both by wearing and by not wearing a mask in the social environment.

The danger of such discrimination is reinforced by questionable statements by experts in the media. For example, the youth psychiatrist Dr. Biskup-Meyer said in an interview with the SZ newspaper about compulsory masks in elementary school [79]:

> "When teachers wear a mask and students are made to believe that this is just necessary, elementary school children are certainly the ones who are most willing to comply. Part of that is that there is a unity in the class because everyone is wearing a mask."

If a need to wear a mask is strongly communicated to children by teachers, and if a corresponding peer pressure arises due to social dynamics, the risk that some children will be discriminated against is all the greater.

In addition, children who are not allowed to wear a mask for medical reasons find themselves 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 wear a mask, he or she 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.

The triggering and maintenance of developmentally inappropriate fears

With regard to Corona measures at elementary schools, there is also the problem that measures such as wearing masks or keeping a distance permanently convey to the children that they are a great danger to themselves and to others. This can be accompanied by fears and feelings of guilt, which a child is unable to deal with due to its developmental immaturity. If this is the case, anxiety disorders develop, which impair the child's development.

Prolonged anxiety has a problematic effect on various levels of the psyche. For example, thoughts begin to revolve around the fearful event, so that the child can no longer concentrate on other things. At the level of motivation, the avoidance-related behavioral system is chronically activated, which leads to the child no longer striving for things he or she wants to achieve, but increasingly viewing the world through the lens of possible threatening events that he or she wants to avoid. The consequence is that the child increasingly stops in its development and increasingly withdraws. In extreme cases, this can go so far that a depression develops. On the level of brain development, this can lead to
"biological scars" may occur, resulting in a lifelong increased vulnerability to physical and psychosocial stressful 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 that has little relevance for us humans. In the case of a fear of snakes, for example, this does not necessarily have to be severely debilitating because snakes are not a relevant part of our human lives. The fears that can be triggered by Corona measures in schools, on the other hand, concern one of the most central aspects of human life: contact with other people. Humans are genuinely social beings, the need for closeness and good social relationships is a basic human need, just like eating, drinking or sleeping [81].

The measures taken in schools, such as wearing masks and keeping a distance, therefore violate children's basic social needs. If this is compounded by the fact that children develop a fear of the other person, there is a risk that psychological disorders in the social sphere will be acquired and that children's social health - and thus their psychological development as a whole - will be permanently impaired.

Indeed, there is now ample empirical evidence that mental health problems in children are on the rise, although it is important to note at the outset that these are not

can be causally attributed to mask-wearing, but are a product of the problematic overall situation.

For example, the so-called COPSY study of the University Medical Center Hamburg-Eppendorf [82] showed that at the time of the school closures in spring 2020, 71 percent of the children and adolescents felt burdened by the contact restrictions. For 39 percent of the children and adolescents, the relationship with friends deteriorated due to the restricted personal contacts, which burdened almost all respondents. The proportion of children and adolescents with reduced health-related quality of life increased from 15 to 40 percent, and the risk for mental health problems increased from about 18 to 30 percent.

Current studies also point to the dramatic situation. For example, the child and youth psychologist Prof. Dr. Julian Schmitz from the Institute of Psychology at the University of Leipzig summarized his current findings in a recent interview as follows [83]:

> "We are not currently seeing an increase in just one group of disorders, but a sharp increase in mental distress across the spectrum, such as depression, anxiety, obsessive-compulsive disorder, and behavioral disorders. In this, on the one hand, children and adolescents who already went into the pandemic with a mental health disorder are suffering, and their situation has often worsened greatly. On the other hand, we also see that many children who were mentally healthy before the crisis have now become mentally ill during this time - especially the lockdowns. (...) Our research data show very clearly that the majority of mental disorders do not go away on their own, but rather these disorders often take a chronic course and other disorders are added over time. So we cannot assume that after the end of the pandemic, the situation of children, adolescents and adults with mental illnesses will simply completely ease again on its own."

Austrian psychology professor Manuel Schabus summarized the results of his recent surveys in an interview thus [84]:

> "FOCUS Online: Mr. Schabus, how do you assess the effects of the month-long lockdown, especially on children and young people?
>
> They will suffer greatly from this lost year - maybe it will even be a lost year and a half or two years. We see this in our survey data. The main fear of 6- to 18-year-olds is that their lives will never be the same as they were before the pandemic and the lockdowns. They assume that their future will be negatively impacted in a lasting way. For example, three-quarters of the children and youth surveyed do not expect Corona to be "over" until 2022 or 2023. We have to assume that youth will have a major problem with fear in their psychological development.
>
> Psychotherapists tell me that the children have very diffuse fears, not only because of Corona. Fears come from all corners, which they respond to because they are downright conditioned to be afraid and to live under this pressure. We have to assume that this will then also lead to more psychosomatic excesses and physical illnesses. If one is permanently exposed to increased stress, the immune system naturally suffers and every infection and disease has an easier time. It is not

rule out that even cancer cases will accumulate in the coming years because of this, since this connection is scientifically well known."

Questionable plausibility arguments

As an argument for the alleged harmlessness of wearing masks, 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 room physicians, who also wear masks for hours during operations without any alleged adverse effects. On the one hand, physiological side effects such as a drop in oxygen saturation in the blood have also been proven there [63]. For another, wearing masks in the classroom is not comparable to wearing masks in operating rooms. Operating rooms are equipped with high-power ventilation systems that maintain positive pressure and increase the oxygen content of the room air [85]. In addition, masks there are changed immediately if they become soaked, which is not possible in the classroom because of the limited number of masks per child. Furthermore, OR physicians are highly trained in the hygienic and sensible use of the mask, so that infections due to the accumulation of germs on the mask via the hands are minimized, which is impossible with elementary school children due to their developmental psychological maturity level.

Another questionable argument comes from the spokesman of the Professional Association of Pediatricians and Adolescents (BVKJ), Dr. Jakob Maske. He expressed himself to the German Press Agency as follows (quoted from Welt [86]):

> "Even small children could wear a mouthguard. 'It's not a problem at all,' the expert explains. Suppose a child actually didn't breathe in enough oxygen or too much CO2, he or she would get tired and feel sluggish, the medical expert said. In that case, the child would take off the mask on its own."

In view of the fact that there are no empirical studies on this, this statement is a mere hypothesis. However, from a psychological perspective, if strict rules are imposed by social authorities and there is social pressure in the classroom, it is not to be expected that smaller children in particular will remove their masks of their own accord in such a case.

A third questionable argument is that children themselves would not make a disaster out of wearing masks and would quickly get used to it. To conclude from the observation that children would not make a disaster out of wearing masks that it would not bother children is highly negligent. Even if a child is abused, it does not necessarily make a catastrophe out of it, because a child still lacks the rational evaluation standards. To conclude from this that it would then be okay would be absurd. This is exactly 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 may not be noticeable for a long time, because children simply become quieter and thus less noticeable. What is needed here is a very good eye on the part of teachers and parents.

Summary evaluation

In summary, there is ample evidence of the range of potential harms at the physical, psychological, and social levels that may be associated with prolonged mask wearing in children in particular. This is evidenced firstly by several studies on the various side effects, particularly in relation to adults, and secondly by the existing registry on the side effects of mask wearing by children. In addition, from a psychological perspective, there are concerns that prolonged mask wearing in schools may be associated with very lasting psychological impairments in children's development, which, although currently not clearly demonstrated, are highly likely to occur according to various psychological theories.

It is particularly problematic that, despite the numerous side effects to be feared, there is not a single randomized controlled study in which the side effects of prolonged mask-wearing in children have been investigated. Before mandatory measures for millions of children are prescribed at all, it would be absolutely necessary from a medical ethics perspective to examine possible 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 particularly problematic that, in view of the existing evidence for numerous possible side effects, these are neither mentioned nor taken into account in the recommendations of the RKI, nor in the S3 guideline, nor in the corresponding government statements.

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

This question has already been answered in the course of answering question 1 (see section "The extent of reduction of the risk of infection by means of wearing masks at schools" on p. 10 ff).

4. Can compliance with spacing requirements reduce the risk of infection, especially in children?

In relation to this question, a recently published study is relevant [87]. There, a very large sample (537,336 students* and 99,390 school staff) and a large time period (September 24 to January 27) were used to examine the extent to which it made a difference whether schools required a three-foot or six-foot distance. The results show that the size of the distance did not make a difference in either student infections or teacher infections. Accordingly, there is no effect of further increasing the distance, at least above a distance of 90 cm. It should be noted that from secondary school onward, universal mask wearing was mandatory at the schools studied; at primary school, mask wearing was mandatory in 70 percent of the cases. The results of this comprehensive study also reconfirm that infections are far more common among school staff than among students, providing further compelling evidence that students pose a lower risk of infection.

5. Might children even provide "protection" from spread with SARS-CoV-2 coronavirus in the sense that they are more likely to slow the spread of the virus and more likely to protect against severe covid-19 illness?

To answer this question, extensive studies are first presented showing that the risk of severe COVID-19 is lower when adults have much contact with children. Then, current findings are discussed that show that children have a lower viral load - contrary to initial assumptions - which may reduce the risk of infection and the resulting disease severity according to current findings. Finally, the findings from sick leaves are critically examined, namely that occupational groups involved in the education and care of children would most frequently have been taken off sick due to COVID-19, which is often used as an argument that children pose a particular risk.

The lower risk of becoming severely ill with COVID-19 when in close contact with children.

In one of the most comprehensive studies to date on the factors influencing the risk of developing severe COVID-19 disease, all of the corona cases that occurred in Scotland were analyzed [88]. This showed that teachers (no mask-wearing of pupils up to the age of about 15 years) have a 64% reduced risk of developing severe COVID-19 compared to other occupations (rate ratio of 0.36, 95% CI 0.19 to 0.69). Furthermore, the risk of severe COVID-19 disease in adults was found to be reduced by 28 percent when children lived in the same household (rate ratio of 0.72, 95% CI 0.63 to 0.82). This effect of children was seen even when adults were in a high-risk group (e.g., cancer, severe asthma and other severe chronic respiratory diseases, hypertension, immunosuppression, etc.). Comparable findings are also available from Sweden, where the risk of severe disease was reduced by 57% for teachers compared to other occupational groups (relative risk of 0.43, 95% CI, 0.28 to 0.68) [89].

The study authors suggest that this may be because contact with children increases pre-existing immune protection due to cross-reactions with other 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 proven that the viral load in children is lower than in adults. Initially, it was assumed, based in particular on a study by a research team led by Christian Drosten, that children had the same viral load as adults and that children therefore posed a similar danger. However, this study contained a very classical and fundamental methodological error.

error, as pointed out, for example, by the renowned statistician David Spiegelhalter of the University of Cambridge [90].

Due to the small sample size in childhood and the division into numerous age groups in adulthood and the subsequent correction for multiple testing, the power of the study - i.e., the probability of detecting an existing difference between the child and adult groups in a statistically significant manner - is so low that the study could not have detected any differences statistically in principle. To conclude a null hypothesis in the case of a non-significant effect is methodologically absolutely inadmissible in the case of a low power. This is actually basic statistical knowledge (the so-called "error of the 2nd kind", see e.g. [91]).

Interestingly, as David Spiegelhalter demonstrates, the study by the research team led by Christian Drosten actually shows - if it had been evaluated correctly - that the viral load in children is lower. Descriptively, in the study, the viral load in 0-10 year old children is only 27 percent of the viral load in adults over 20 years of age (this is the actual comparison group; the artificial division in adulthood in the article into 10-year increments is difficult to understand given the actual research question - viral load in children versus adults - because such a division only substantially reduces power). Indeed, this is supported by a study recently published as a preprint with much larger samples (2654 children and adolescents) than in the study by Christian Drosten's research team (117 children and adolescents) [92].

As recent studies have shown [93], the risk of developing a severe COVID-19 disease decreases with the viral load of the person from whom the infection originates. Thus, the lower viral load in children when infected could be protective against the development of more severe COVID-19 disease. However, it should be noted that direct scientific evidence that lower viral load mediates the beneficial effect of frequent contact with children on lower disease severity has not yet been established.

Common COVID-19 diagnoses among child care-related occupations

Finally, a reference to a misleading representation in the media is important. At the end of 2020, the Scientific Institute of the AOK published the results of an analysis [94] of which occupational groups were most frequently taken off sick with the diagnosis "COVID-19" from March to October. Surprisingly, occupational groups involved in the education and care of children were in first place. In the media, it was concluded that educators were supposedly the most likely to fall ill with COVID-19.

A closer look at the study, however, reveals that this is a misleading presentation. With regard to the diagnosis "COVID-19", there are two different diagnosis codes [95]: one is a diagnosis with confirmation by a positive PCR test (diagnosis code U07.1!) and the other is a mere suspected diagnosis without confirmation by a positive PCR test (diagnosis code U07.2!). Since individuals with a mere suspected diagnosis do not have a

positive SARS-CoV-2 test result, it is very likely that such cases are really just a harmless cold.

It is a common practice in daycare centers that daycare workers always have themselves tested immediately in case of mild cold symptoms and then have to take sick leave until the test result is received. The suspected diagnosis U07.2! is then noted on the sick note. If the test result shows that there is actually no SARS-CoV-2 infection, the initial suspected diagnosis U07.1! is actually a false COVID-19 diagnosis.

The problem with the AOK's analysis is that it does not distinguish whether a "COVID-19 diagnosis" on a sick note is only a suspected diagnosis. Thus, it could be that people working with children simply get tested especially often on a suspicion (diagnosis U07.2!), but in reality do not get sick more often with COVID-19 (U07.1!).

This is indeed confirmed by a more detailed analysis of the AOK data, which was recently published [96]. According to this, occupations in child rearing and child care are indeed in first place in terms of the total number of "COVID-19" diagnoses received. However, 48.0 percent of the cases are merely suspected diagnoses. Occupations in geriatric care or health care and nursing are only in second and third place in terms of the total number of "COVID-19" diagnoses received. However, only 31.8 and 28.9 percent, respectively, are mere suspected diagnoses there. In terms of actually confirmed COVID-19 illnesses, on the other hand, the occupational groups in geriatric care (22.9 percent more cases) or health care and nursing (25.7 percent more cases) are clearly ahead of the occupational groups in child education and child care. In reality, therefore, educators are significantly less likely to contract COVID-19 than workers in elder care, health care, and nursing.

Summary evaluation

In summary, there is indeed robust evidence from very extensive scientific studies that frequent contact with children may indeed be protective against the development of severe COVID-19 disease. In particular, a large study now shows that children indeed have a 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 deficiencies of existing studies on the incidence of infections in schools and on the effectiveness 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 for ranking the quality of evidence from studies" on p. 1 ff).

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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, in particular the main areas of human biology, immunology and cell biology.

The expert provided her expert molecular biology opinion, which is inserted here in its entirety, as follows:

Regarding the evidentiary question, "What is the power of the RT-qPCR assay and currently used rapid tests to detect SARS-CoV-2 coronavirus infection?"

1. nucleic acid detection by RT-qPCR assay

Reverse transcriptase-quantitative polymerase chain reaction (**RT-qPCR**) assays are unsuitable as a diagnostic tool for active infection with SARS-CoV-2 at the outset for numerous reasons.

1. Explanation of terms/basics

In a **polymerase chain reaction** (**PCR),** a defined short piece of deoxyribonucleic acid (DNA) (usually 100-1000 bases) is amplified using the enzyme polymerase. 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 primer sequence) that specifically match the regions on the DNA that flank the section to be amplified. To ensure PCR specificity, these primers must explicitly match only this flanking region and no other region of a DNA. With the help of large gene databases and corresponding software programs(e. g. primer blast https://www.ncbi.nlm.nih.gov/tools/primer-blast/), these primers can be designed highly specifically in the PCR design. Specialized companies then synthesize the molecular chains from the primer sequences submitted and deliver them to the PCR laboratory or the manufacturer of PCR kits. Here, these primers must then be tested with valid positive and negative controls under a wide variety of experimental conditions and optimized in use. This ensures that only the DNA to be searched for is detected and amplified with the primer pair used, and that no other similar DNA segments are detected.
Once the primers have been found and are specific, the DNA to be amplified can be mixed with the primer pair, various auxiliary chemicals and the polymerase enzyme in a reaction batch and the chain reaction started.

PCR procedure: This runs in cyclic repetitions of the following individual steps:
1. The mixture is boiled at over 90°C (denatured). This separates the DNA strands, which are usually present as a double strand, into single strands to enable the subsequent attachment of the primers.
2. During subsequent cooling to the so-called "**annealing temperature**", the primers can attach to their matching regions on the separated DNA strands. The binding of the primers, the annealing, only occurs in a narrowly limited temperature range, the so-called melting temperature. This depends mainly on the base composition of the primers and therefore their sequence will ideally always be chosen so that both primers have the same melting temperature of about 60°C. The annealed primers form the DNA strands. The attached primers form the starting point for the polymerase.
3. Starting from the primers, this polymerase completes the single-stranded DNA present due to heating back to a matching double strand (**elongation**) usually at approx. 72°C.

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 always works in one direction only. At the end of this step, two identical double-stranded DNA molecules have been created from the original double-stranded DNA, which are separated again by boiling, then amplified into 4 identical DNA molecules with the aid of the primer addition and the polymerase, and so on. Each PCR cycle consisting of boiling, annealing and elongation results in a doubling of the DNA section sought, so that the amplification takes place in the logarithm of 2 and thus an extremely high number of copies of the original starting material is available very quickly.
Thus, after 10 PCR cycles, ^{210} = 1,024 DNA copies are already obtained from one DNA strand, with 20 cycles already over 1 million (1,048,576) and at 30 cycles over 1 billion (1,073,741,824) copies.

In the **quantitative PCR** (**qPCR**) technique, which is currently used worldwide mainly for the detection of genomic RNA from SARS-CoV-2, a third short piece of DNA, similar to the two primers, is used which can bind appropriately in the middle of the DNA section being searched for, the "**probe".** Unlike the two primers, this probe is still connected to two molecules, a fluorescent dye at one end and another molecule (quencher), which can prevent the emission of fluorescence as long as both are simultaneously (i.e. in close proximity to each other) on the sample. During the elongation step, the polymerase now degrades this probe. This separates the quencher and the fluorescence molecule can now emit its color signal. This color signal is detected and measured in the device performing the PCR (thermocycler). Thus, with each PCR cycle, more and more fluorescence signals are released according to the increasing number of copies, the probe "glows" more and more. And the curve of color signal intensity increases with each cycle. At a certain value, the curve then exceeds the background noise (threshold) and is considered positive. The number of cycles at which this threshold is exceeded is referred to as the **CT value** (CT stands for "cycle threshold").
The faster the fluorescence increases (lower CT), the more initial copies of the sought DNA were present in the PCR assay. Since neither the primers nor the enzyme polymerase always work 100% specifically, a fraction of non-specific DNA is also copied in each PCR run. And the more cycles the PCR runs through, the greater the risk that even these few non-specific reactions will then exceed the threshold value. Therefore, from a CT value of 40, a false positive signal due to non-specific starting materials must be assumed with the greatest probability. A reliable PCR should therefore require no more than 30-35 cycles to generate a clear "positive" signal; in the case of active infections with sought-after viruses, a sufficient number of cycles of 25-30 can be assumed (see also point 3.2.).

The **reverse transcriptase reaction** (**RT**) is required if the starting nucleic acid to be amplified is not present as DNA but as ribonucleic acid (RNA), as is the case with SARS-CoV-2 as an RNA virus. Since only DNA can be amplified in PCR, RNA must first 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, which then serves as the starting material for the PCR.

In order to evaluate the reliability of a result obtained by RT-qPCR or even PCR, the sensitivity and specificity of the test system used are assessed using defined samples of diluted correct target genes (e.g. RNA of the sought virus) and very similar but not sought target genes (e.g. closely related viruses).
Sensitivity indicates how sensitively the test can detect even the smallest amounts of the target gene, while **specificity** describes how reliably the test can rule out the possibility that other, closely related genes may also lead to a positive result (**false**

positive). The higher the specificity, the more certain it is that false positive results will not be obtained by the PCR system itself.

However, this does not exclude false positive events, which can be caused by **laboratory contamination** with target genes, contamination **of test chemicals** and **contamination directly during sample collection.** These contamination-related false positive results can be excluded by rigorous quality assurance and standard operating procedures (SOPs), the use of specially trained personnel and permanent external control in the form of interlaboratory comparisons.

2. Basic information on the diagnostic significance

The inventor of the PCR test, Nobel Prize winner Kary Mullis, who died in August 2019, repeatedly pointed out that his test is solely suitable for making a molecule (deoxyribonucleic acid, DNA) or fragment of DNA, which is otherwise invisible to the human eye, visible by amplification. But not to allow a statement on whether what has been made visible is dangerous or causes illness.

In particular, a PCR test - even if performed correctly - cannot provide any information on whether a person is infected with an active pathogen or not. This is because the test cannot distinguish between "dead" matter*, such as a completely harmless genome fragment as a remnant of the body's own immune system's fight against a cold or flu (such genome fragments can still be found many months after the immune system has "dealt with" the problem), and
"living" matter, i.e. a "fresh" virus capable of reproduction.

For example, PCR is also used in forensics to amplify residual DNA from hair residues or other trace materials by means of PCR in such a way that the genetic origin of the perpetrator(s) can be identified ("genetic fingerprint").

Thus, even if the PCR, including all preparatory steps (PCR design and establishment, sample collection, preparation and PCR performance), is carried out with
is done "correctly" and the test is positive, i.e.: detects a genome sequence which may also exist in one or even the specific "Corona" virus (SARS-CoV-2), this does not mean under any circumstances that the person who tested positive could be infected with a replicating SARS-CoV-2 and consequently infectious = dangerous for other persons.

Rather, additional, and specifically diagnostic, methods such as isolation of replicable virus must be used to detect active infection with SARS-CoV-2 (gold standard).

3. Factors influencing the reliability of the PCR test

In fact, however, the results of a PCR test depend on a number of parameters which, on the one hand, give rise to considerable uncertainties and, on the other hand, can be **deliberately** manipulated in such a way that many or few (apparently) positive results are obtained.

3.1. Number of independent target genes ("**targets**")

The protocol " ***Diagnostic detectionofWuhancoronavirus2019byreal-timePCR*** " (https://www.who.int/docs/default-source/coronaviruse/wuhan-virus-assay-v1991527e5122341d99287a1b17c111902.pdf), originally published by WHO on Jan. 13, 2020, describes the sequence of PCR detections of 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 followed by the WHO with the protocol " ***Diagnostic detection of2019-nCoVbyrealtimePCR***" (https://www.who.int/docs/default- source/coronaviruse/protocol-v2-1.pdf?sfvrsn=a9ef618c_2) in which the N-gene was removed as detection and thus instead of the original 3 targets only 2 targets were recommended. On 02.03.2020, in a again updated test protocol of the WHO. "***Laboratory testing for coronaviurs disease 2019 (COVID-19) in suspected human cases***" (https://apps.who.int/iris/bitstream/handle/10665/331329/WHO-COVID-19-laboratory-2020.4-eng.pdf?sequence=1&isAllowed=y) pointed out that *".... In areas where COVID-19 virus is widely spread a simpler algorithm might be adopted in which for example screening by RT-PCR of a single discriminatory target is considered sufficient....."* (page 3 below) whereupon the laboratories widely switched to analyzing only 1 target, whereupon many laboratories specialized only in the E-gene introduced as the first target as a valid PCR, as e .g. explicitly described by the Augsburg laboratory on 03.04. (only available in the internet cache: https://www.oder-spree-piraten.de/wp- content/uploads/2020/05/Ge%C3%A4ndertes-Befundlayout-der-SARS-CoV2-PCR- Ergebnisse-_-Labor-Augsburg-MVZ-GmbH.pdf

The outstanding importance of the number of independent target genes analyzed by PCR results from the following calculation:

The three targets E, RdRp and N gene originally specified in the WHO protocol for the detection of SARS-CoV-2 were rapidly used in many laboratory and commercial test systems. An interlaboratory test from the Instand e.V. Institute (https://corona- ausschuss.de/wp-content/uploads/2020/07/Instand-Ring-Test-Virus-Genome-Detection- SARS-CoV-2.pdf) showed a mean specificity for these genes of:

Target gene of SARS-CoV-2 Genomes	Number of tests checked	Specificity cell culture only (without viral RNA)	Specificity with related coronaviruses (HCoV 229E)	%	Mean specificity absolute	Mean error rate (1-abs. Spec.)
E-Gen	24	99,46%	95,17%	97,31	0,9731	0,0269
RdRp gene	13	97,80%	90,66 %	94,23	0,9423	0,0577
N gene	21	98,20%	87,95 %	93,08	0,9308	0,0692

In a mixed population of 100,000 tests, even if no person were genuinely infected, this would result from the mean error rate:

For an E-only genetic test: 100,000 x 0.0269 =2690false positives.
For E and RdRp test in sequence: 100,000 x (0.0269 x 0.0577) =155false positives.
For all three genes (E, RdRp, N): 100,000 x (0.0269 x 0.0577 x 0.0692) =10 false positives.

This means that the WHO's requirement to successively reduce the number of target genes of SARS-CoV-2 to be tested from 3 to 1 resulted in an increase in false positives.

tested persons in the above calculation example from 10 with 3 genes to almost 3000 with only the E gene per 100,000 tests performed. If the 100,000 tests carried out were representative of 100,000 citizens of a city/county within 7 days, this question alone of the target genes used would result in a difference of 10 compared to 155 compared to 2690 with regard to the "/-daily incidence" and, depending on this, the severity of the restrictions on the freedom of the citizens taken.

Evaluation: The calculation example also shows how the daily case numbers can be manipulated by "playing by the rules" regarding the targets to be detected for the laboratories. In view of 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 specification of the WHO (and also of the RKI) for the reduction of target genes was clearly suitable for artificially inflating the "pandemic" by a factor of 300 through incorrect test specifications.
This is an evidence-free approach that, on the one hand, imposes enormous personal restrictions of quarantine/isolation that those falsely "tested positive" must endure, and on the other hand, willingly accepts the enormous societal and economic restrictions and damages via the "7-day incidence number."
If the correct target number of three or even better (as e.g. in Thailand) up to 6 genes had been consistently used for PCR analysis, the rate of positive tests and thus the "7-day incidence" would have been reduced almost completely to zero.

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 CT value represent a decisive adjusting screw. The **smaller the CT value of a sample in a qPCR, the higher the initial amount of DNA in the sample**. Under standardized conditions, this correlates with (in the case of viruses) the initial amount of viruses, the so-called viral **load,** which should ideally be expressed as "number of viral copies" per ml of sample. This viral load also correlates in the case of SARS-CoV-2 with the cultivability of infectious viruses in cell culture as published with the participation of C. Drosten already in March 2020. (Figure 1e in Wölfel et al., https://doi.org/10.1038/s41586-020-2196-x) Here, a minimum amount of ^{106} RNA copies/ml was required to appropriately grow viruses from the sample, whereas RT-qPCR from the original protocol (Corman V et al., 10.2807/1560- 7917.ES.2020.25.3.2000045) can already deliver a positive result at approx. 4 copies per sample preparation (5µl corresponding to approx. ^{103} copies/ml), i.e. already by a factor of 1000 earlier than in a sample with an actual infectious virus load.
Also **commercial PCR test systems**, so-called kits, sometimes show 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-R-gene_V200204_09155376001%20%282%29.pdf).

In technical terms, a distinction must be made here between a "colonization" of the pharynx with a few individual viruses, which do not cause an infection, and a genuine "infection".
"infection." The latter is accompanied by viruses capable of replication, which then leads to a) symptomatic disease and b) infectivity, i.e. the ability to infect others.

This aspect was already mentioned by Christian Drosten in 2014 in an interview in the Wirtschaftswoche (https://www.wiwo.de/technologie/forschung/virologe-drosten-im-gespraech-2014-die-who- can-only-recommendations-express/9903228-2.html)inconnectionwithMERS

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, for example, flits across the nasal mucosa of a nurse for just one day* (note: this would be the above-mentioned "colonization") without her *falling ill or noticing anything else about it, then she is suddenly a Mers case. Where previously deathly ill people were reported, now suddenly mild cases and people who are actually perfectly healthy are 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 is, I think, questionable. Even more questionable is whether they can pass the virus on to others."*** The latter is a crucial statement also with respect to the SARS-CoV-2 viruses, which are very closely related to MERS. But it is precisely this point about virus transmission (and thus driving the pandemic) that is the rationale for the intervening measures such as quarantine/isolation orders, the "lockdowns," and the so-called AHA rules.

Further evidence for the relevance of the CT value

A Canadian study by Jared Bullard/Guillaume Poliquin in Clinical Infectious Deseases 2020, which can be read at the link (https://doi.org/10.1093/cid/ciaa638), came to the conclusion as early as May 2020 that above a CT value of 24, no more reproducible virus was found - this means that the attempt to subsequently cultivate reproducible viruses from smear samples that only led to a positive test at a higher CT value failed. According to this study, above a CT value of 24, the amount of detectable viral genetic material is so low that the positive test could no longer be interpreted in terms 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 sample material at a CT value of 30 .
In his NDR podcast of Feb. 16, 2021, C. Drosten explicitly named that an increase in CT from 25-27 across the border of 28 means that individuals from whom these smears were obtained with the higher CT are no longer infectious. "*And again, you see a Ct shift from 25 to 27 approximately, 27, 28. And that's a range where, in our estimation, that's really where infectivity ends. If you see such a patient sample and you would ask, is the patient still infectious, I would say: No, this is now slowly no longer an infectious area. You can correlate t h a t* "Page4(rightcolumnabovein: https://www.ndr.de/nachrichten/info/coronaskript270.pdf)

Unanimous scientific opinion (including from Dr. Fauci of the US CDC, but also from 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, which are only detected from a cycle of 35, have no scientific (i.e.: no evidence-based) basis. The RT-qPCR test for the detection of SARS-CoV-2, on the other hand, which was propagated worldwide with the help of the WHO, was (and following it all other tests based on it as a blueprint) set to 45 cycles without defining a CT value for "positive".

Also as early as May 2020, the National Centre for Infectious Disease in Singapore issued a position paper (https://www.ncid.sg/Documents/Period%20of%20Infectivity%20Position%20Statementv2.pdf) that indicates that

1. It is important to note that viral RNA detection by PCR does not equate to infectiousness, nor viable 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 the viral RNA content, already detects viral RNA from a CT of 30, 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 multicenter 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 states on its homepage as of Aug. 11, 2020 (https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Vorl_Testung_nCoV.html#d oc13490982bodyText4) "*First results from diagnostics at the RKI show that the loss of cultivability in cell culture was accompanied by an RNA amount of <250 copies/5 µL RNA determined by real-time PCR (note: is RT- qPCR). 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) places the cutoff 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) it was shown that of 64 RT-qPCR positive patient samples (one gene tested) only 33 (=52%) could be cultured. These infectious samples were already positive up to a mean CT value of 26 (Supplementary Figure 1), whereas virus cultivation was no longer possible from the samples with a higher CT.

In the Instand e.V. ring trial (http://www.finddx.org/covid-19/pipeline/?section=molecular-assays#diag_tab.) see also next point, the enormous range of CT values even for highly standardized samples between the different laboratories and also with regard to the different target genes becomes apparent. Here, for example, the CT 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 shows an extreme lack of test standardization within the participating (and certified) laboratories.

Against this background, it is disconcerting when RT-qPCR is still considered by the RKI as a "gold standard" is considered without defining the exact validations and external certification conditions (and without these apparently being fully monitored by the authorities).

Rating:
In general, RT-qPCR cannot detect intact, interrogatable (infectious) viruses, not even the complete intact viral genome, but only nucleic acid of the sought section. In general, it is possible to define a threshold value (CT) for well adjusted and correctly performed PCR tests **by validation with a parallel virus cultivation in cell culture,** above which a positive PCR signal no longer correlates with interrogable viruses. This has been a well-practiced routine in the monitoring of blood products for years.
This stringent validation then allows - as long as the test system is NOT changed - as a surrogate marker an estimation of the viral load and thus the possible infectivity of the tested sample, but never the definitive detection. As soon as a component on the PCR test system (be it chemicals, plastic goods, enzymes, protocol sequences or

machines) is changed in one of the applied steps, it is mandatory to recalibrate the system again.

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 irrespective of the test system used. The CT range 25-35 may still be validly assessed as "positive in the sense of infectivity" in a test-dependent manner if, as described, it has been compared with a virus cultivation by adequate validation in the performing laboratory.

CT≤ 25: positive
CT 26-35: positive only if matched with virus culture

CT > 35: negative

The strict evaluation of the CT value plays a role mainly when the target number is one, but generally applies to each individual target.

However, the CT value is worthless as an evaluation criterion of a positive PCR detection without information about the comparison with a certain number of viral genomes (viral load) and the correlation with a cultivability of corresponding virus quantities.

3.3. Adequate **controls**

In order to correctly assess the **sensitivity** and **specificity of** RT-qPCR, adequate samples must be included in each reaction run. This starts at the test site with "blank swabs" to reliably exclude contamination at the sample collection site, continues with extraction controls to ensure the correct isolation of reproducible RNA with all subsequent processing steps, i.e. an artificially produced defined RNA, which is carried and processed in all work steps of sample preparation up to PCR and for which PCR is then also carried out with the aid of suitable primers. This excludes the possibility of inhibitory substances or errors preventing the amplification of RNA during sample processing.
Furthermore, each correct test series must include a series of external negative controls (i.e., carried in parallel as patient samples) and a positive control, ideally consisting of an inactivated defined SARS-CoV-2 virus strain. This would be an original task of the RKI (with the assistance of other suitable public institutions such as the Bernhard Nocht Institute or the Friedrich-Löffler Institute) to isolate a sufficient number of SARS-CoV-2 viruses from patient samples in the laboratory facilities available there (safety level 4), to cultivate defined strains from these as controls, to inactivate these and to deliver them in defined virus numbers as controls to the testing laboratories via the local supervisory authorities. However, since this important service is still not offered even after more than a year of the "pandemic", the positive control usually consists of a synthetic RNA that 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. This is specified by some commercial kits as 20 or fewer viral genomes per sample and thus (see point 1.3.2.) already detects a virus quantity in the smear that is below the infectious dose by a factor of ^{105,} i.e. has no diagnostic/prognostic value whatsoever. An overview of the currently used commercial kits with their line data can be found at http://www.finddx.org/covid-19/pipeline/?section=molecular-assays#diag_tab.

Round robin tests:

Correctly performed controls also include the participation of the laboratories performing the tests in so-called "**ring tests**" (see also 1.3.1.). In these, an anonymized panel of test samples is made available 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 samples with different dilutions of the virus sought (inactivated) to determine the sensitivity (from which number of viruses does the PCR become positive, with which CT value).

In the case of SARS-CoV-2, the first EQA scheme "Virus Genome Detection - SARS- CoV-2 (340)" by the association "INSTAND e.V." was ready in April 2020. 488 laboratories participated in this EQA scheme according to the report, of which 463 reported results. The results can be read in the published commentary (Zeichhardt M: *Kommentar zum Extra RingversuchGruppe340Virusgenom-NachweisSARS-CoV-2* ",verfügbarunter: https://corona-ausschuss.de/wp-content/uploads/2020/07/Instand-Ringversuch-Virusgenom- Nachweis-SARS-CoV-2.pdf) and show two deviations from the usual EQA scheme procedure, which already here pointed to laboratory problems with RT-qPCR for the detection of SARS-CoV-2: Page 4 of the publication states: "*Important evaluation notice: only 4 of the 7 samples tested in this Extra EQA will be* considered for *obtaining a certificate of successful participation*." The footnote on page 10 of the commentary states, "*In the April 17, 2020 interim evaluation, all participants in the Extra INSTAND EQA trial (340) Virus Genome Detection of SARS-CoV-2 April 2020 were prematurely notified of the sample characteristics of samples 340059, 340060 and 340064. The results of these 3 samples will not be considered for granting a certificate* [ ]"
The reason for this exclusion of certain samples is explained on page 4 of the commentary: "*While the extra ring test was still running, INSTAND e.V. received urgent requests from Germany and abroad to reveal the properties of the samples to be tested before the end of the extended submission period, i.e. before April 28, 2020, so that laboratories can improve their test method at short notice in the event of any incorrect measurements.*" (page 4 above in INSTAND e.V. report))

This procedure is very unusual for a true interlaboratory comparison and thus no longer represents an independent external verification procedure of the participating laboratories.
Despite the samples already detected and the reduced testing scope, sample mix-ups occurred at a large number of laboratories - as stated on page 18 of the commentary, "*For sample 340064 (SARS-CoV-2 positive diluted 1 : 100 000), the reduced success rate of only 93.2% is largely due to incorrect result assignments (mix-ups) for sample 340064 and sample 340065 (negative for SARS-CoV-2 and positive for HCoV 229E). The mix-ups for samples 340064 and 340065 involved 24 laboratories with a total of 59 results per sample. See also section 2.4.2.1* [...]." Thus, a large number of laboratories mistakenly confused sample 340064 (slightly diluted SARS- CoV-2) with sample 340065 (negative for SARS-coV-2 and positive for the closely related virus HCoV 229E).
Apart from the startling fact that a considerable number of samples were obviously interchanged even under highly standardized procedures in an interlaboratory comparison (which raises the question of the corresponding rate of sample interchanges and thus wrongly assigned swab samples under mass testing conditions), it is striking that all reported interchanges concerned only these two samples, but not the samples with the final number 61 (very highly diluted SARS-CoV-2) and 62 (negative), which were also evaluated. The detailed results of a second interlaboratory comparison from June/July 2020 (https://www.instand-ev.de/System/rv-files/summary%20of%20sample%20properties%20and%20setpoints%20virology

%20340%20June%20July%2020200911a.pdf) are still not available for public review.

3.4. Exclusionofcontaminantsfromreagentsand "**problemsintheprocess**".

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 PCR is an extremely sensitive method (exponential reaction course) that can detect few molecules of a DNA, laboratory contamination by PCR end products is a major problem in clinical diagnostics (described e.g. already in 2004 in Aslanuadeh J et al., http://www.annclinlabsci.org/content/34/4/389.full.pdf+html: "*A typical PCR generates as many as ^{109} copies of target sequence and if aerosolized, even the smallest aerosol will contain as many as ^{106} amplification products [6]. If uncontrolled, within a relatively short time the buildup of aerosolized amplification products will contaminate laboratory reagents, equipment, and ventilation systems [6]*). This extreme risk of contamination requires that diagnostic laboratories working with PCR take the utmost care in testing - highly skilled personnel, contamination-proof environment, permanent independent control.

Already in the above-mentioned round robin 340 in April a problem with false positive results appeared, which was commented as follows (page 20 below): "*In addition, in some cases the tests with the SARS-CoV-2 negative control samples 340060, 340062 and 340065 indicate specificity problems, which are independent of mix-ups of the samples 340064 and 340065. Clarification is needed as to whether these* ***false positives are due*** *to a* ***specificity problem with the tests used or to carryover of SARS-CoV-2 during test performance or to mix-ups with other samples*** *in this EQA at the laboratories in question.*" (Bottom of page 21 in https://www.instand-ev.de/System/rv-files/340%20DE%20SARS-CoV-2%20Genome%20April%2020%20200502j.pdf). For confounding in this EQA scheme, see details item 3.3. end of paragraph.

If, against this background, one further sees how, for example, according to a BBC report, work is carried out openly and extremely contamination-prone with untrained personnel in large test laboratories in England (https://www.youtube.com/watch?v=Uk1VK1reNtE), it is not surprising if even in Germany (where such reports have not yet been filmed) occasional reports of "false positive cases" due to laboratory contamination are 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 safely excluded in such a highly sensitive method. Thus, the problem of false positive PCR results in SARS-CoV-2 diagnostics due to laboratory procedures and already pointed out 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 problably to handling issues* "

Even if the course of action in the laboratory functions optimally and is extremely monitored in order to greatly minimize laboratory-related **contamination**, an unexpected source of false positive results can **arise** here in the **contamination of the materials/chemicals used ex-manufacturer.** For example, the swab materials used to take samples may already be contaminated ex works - as in the case of the "Phantom of Heilbronn", in which the cotton swabs used to take DNA traces at the crime scenes were contaminated with the DNA of a packaging employee of the manufacturing plant, thus hindering forensics with false traces for years.

(https://www.faz.net/aktuell/gesellschaft/kriminalitaet/dna-ermittlungspanne-das-phantom-von-heilbronn-is-refuted-1925411.html).
In the case of SARS-CoV-2 diagnostics, a contamination problem due to PCR primers containing positive controls ex works was also published in June 2020 (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 SARS- CoV-2 detection in RT-qPCR: "*However, there were also primers/sample sets that displayed very low-level contaminations, which were detected only during thorough internal validation.*"
Also, some false-positive results ofSARS-CoV-2RT qPCR testing 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-falsche- test results,SEh5Qq4).

Rating:
Even with ideal RT-qPCR design and good laboratory practice with adequate validation, problems in daily handling procedures as well as from outside via already factory contaminated samples can significantly influence the result quality of RT-qPCR and lead to false positive results.

3.5. Commercial PCR Test Kits: Approval for Diagnostics?

Very early on, commercial PCR test systems, the "PCR kits" were used in routine laboratories for diagnostics, although a large proportion of them were declared for "RUO" ("research use only").
The first and therefore most prominent test manufacturer, the Berlin-based company TIB Molbiol, whose owner (Olfert Landt) was already listed on the WHO protocol recommendations as an author alongside Christian Drosten, deserves special mention. The kits, which are based on the WHO recommendations, are used by Roche on their large-scale automated testing machine "Cobas" and therefore probably make up the majority of kits used for routine diagnostics in Germany.
Exact numbers cannot be determined, however, TIB Molbiol has already delivered more than 60 million tests of these worldwide in 2020 according to its own information (https://www.tib-molbiol.de/en/covid-19), although these are still declared as "***Not tested for use in diagnostic procedures***" (e.g. header in https://www.roche-as.es/lm_pdf/MDx_53-0777_96_Wuhan-R- gene_V200204_09155376001%20%282%29.pdf). The corresponding package inserts with the protocol information and kit descriptions of the company TIB Molbiol were astonishingly according to metadata of the originally available PDFs (can be provided electronically) already on **15.01.2020** (!!!) completely with ROCHE SAP number are still available unchanged (albeit with metadata analysis 06.02.2020) parallel to other test kits, which now have approval for in vitro diagnostics.

4. Relationship of positive nucleic acid detection in RT-qPCR and infectivity.

Only those who are actually infected can pass on the virus and carry the risk of contracting the disease and are thus to be used to determine the course of an infection rate and wave of disease

"*PCR detection is the standard test for diagnosing viral infections such as SARS-CoV-2.* ***The test detects individual pathogen genes but not intact pathogens.***" And, *"There is a possibility that the test can detect beyond the duration of infection*

positive because "viral debris" is still present in the nose or throat. ***Reliable proof of infectivity is only possible with elaborate tests, in which it is examined in the laboratory whether the material from the swabs can kill living cells."***

This was written in the GermanMedical Journal onFebruary1, 2021. (https://www.aerzteblatt.de/nachrichten/120745).

"*The PCR assay detects gene segments of SARS-CoV-2; it does not tell us whether they are infectious viruses or viral remnants after passed through infection. This would require pathogen culturing*." Was in an August 2020 publication by the head of Frankfurt's public health department (https://www.laekh.de/fileadmin/user_upload/Heftarchiv/Einzelartikel/2020/10_2020/Die_Covi d-19-Pandemie_in_Frankfurt_am_Main.pdf).

In a CDC publication dated 7/13/20 titled *"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), on p. 38 under the heading "Limitations" (still 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 an infectious virus or that 2019-nCoV is the causative agent for clinical symptoms."*

The fact that a pure mRNA detection of SARS-CoV-2 does not necessarily correlate with a disease and must not be used as the sole criterion for the assessment of the disease, but only as an aid to confirm a clinical diagnosis, is also clearly described 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 are* ***not*** *consistent* ***with the clinical picture****, a new sample should be taken and retested with 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 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 all contacts, and epidemiologic 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), the authors refer to the RT-qPCR test as follows: "*In our view, current PCR testing is therefore not the appropriate gold standard for evaluating 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, PCR still comes up positive even after those tested are no longer positive, since the RNA can continue to persist in the body for weeks and months even after the immune system has successfully fought it off, without the person still being infectious. "*Once the replication of SARS-CoV-2 is stopped by the*

immune system has been brought under control, RNA levels detectable by PCR in respiratory secretions drop to very low levels at which individuals are much less likely to infect others. The remaining RNA copies can take weeks, occasionally months, to disappear, 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."*

5. Conclusion: informative value of RT-qPCR tests for the detectability of SARS-CoV-2 coronavirus infection.

1. In light of the problems outlined in section 1.3, RT-qPCR is not a suitable reliable (and approved) diagnostic tool for the detection of infectious (replication-capable) SARS-CoV-2 viruses.
2. Furthermore, the pure RT-qPCR test result is only a laboratory value which, in view of the aspect outlined under point 1.4, does not allow any statement to be made about the presence of infectious viruses and may only be used at all in conjunction with a clinical symptom diagnosis (ascertained by healthcare providers, in Germany medical doctors).

Summary: RT-qPCR is not suitable for the detection of SARS-CoV-2 infection in asymptomatic individuals by means of a nasopharyngeal swab, as is done uncritically in large numbers and predominantly by non-medical personnel WITHOUT (crucially here: contrary to the WHO requirement!) taking anamnesis and symptoms from the persons tested.

2. The 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. This detects a protein component (protein) of the virus.

An **antigen** is a three-dimensional structure of proteins and other organic materials that can be recognized and bound by antibodies (immunoglobulins).
In the case of **viral antigens,** these are usually individual protein components (proteins) from the virus structure. These can be either complete structural proteins such as the "spike" protein located on the surface (S protein, these are the "stalked buttons" in the virus drawings) or the envelope protein ("envelope" - E protein) or that protein from which the nuclear envelope is built (nucleocapsid = N protein). Fragments of these complete structural proteins are also often sufficient to be bound by antibodies. These are the so-called **epitopes, which** also represent the actual antibody binding site on the intact structural protein. Each structural protein usually has a large number of epitopes, so that different antibodies can bind simultaneously to different epitopes of the same protein.

In SARS-CoV-2, the major antigens (the above-mentioned, S, E, and N proteins) are those that trigger an immune response in the body when infected with the virus. As a result, the body forms antibodies that specifically recognize these antigens, then bind to them (**antigen-antibody reaction**) to neutralize the viruses and render them destructible to immune cells.

This antigen-antibody reaction can be used in the laboratory to search for the antigens in any sample using synthetically produced antibodies.
The basic principle of the so-called **antigen tests in the** laboratory (these aim at the detection of antigens by antibodies, unlike RTPCR, which detects nucleic acids) is to prepare two matching antibodies in vitro, which recognize two different epitopes of the antigen sought, a so-called
"**Antibody pair**". Both antibodies must be selected in such a way that they can only recognize and bind to the desired epitope on the antigen sought, but not to other structures on similar antigens. They must therefore be highly specific in order to be used in diagnostics. This **high specificity of diagnostic** antibodies is ensured in test development by matching them with many very similar epitopes. In this process, all antibodies that bind undesired epitopes are discarded until only one ideal antibody pair remains in each case that meets the requirements: very high specificity, high binding property (sensitivity) and no mutual interference.

The antigen test is then built on this pair of antibodies, in which the antigen sought is bound by both antibodies simultaneously and is sandwiched between them like the fry inside the sandwich bun (hence "**sandwich test**").
For the lateral flow **rapid antigen tests** currently used in broad-spectrum population testing for the detection of SARS-CoV-2 antigens, this sandwich test system is now being used.

The first of the two specific antibodies is bound to a carrier material in such a way that its antigen binding site points freely upwards. This is the later region in the rapid test at which a color change results in the "positive" signal. The second antibody is coupled with a detection system, which is later responsible for the color reaction, and is located as a depot directly next to the site in the rapid test at which the sample is dripped on.

Test procedure: If the antigen, in this case the protein of SARS-CoV-2, is present in the swab sample, it binds with the first specific antibody from the depot after dropping into the test field of the detection cassette. Capillary forces cause the mixture of antigen with bound first antibody and excess unbound antibody to migrate from the depot towards the test field. Here, the second specific antibody fixed there then binds the antigen with the first antibody already bound to it. The solution migrates beyond the test field over another field where the excess antibodies are captured (control field). The detection system of the test begins to show a **chemical color reaction wherever** the first antibodies are bound. In the control field, this was caused by the excess first antibodies that are now bound here and have "brought along" the detection system, thus indicating that the test has in principle functioned without interference.
In the test field, there is only a color change if an antigen was actually 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, the chemical color reaction also begins here, which leads to the color change (usually violet stripe) at the test region.
Whenever, therefore, the antigen sought was present in the smear sample, this can bind the first antibody and transport it together with the detection system to the fixed second antibody, which then intercepts this antigen-antibody-detection system complex and thus causes the positive signal at this point.
The color change at the test field ("positive" signal), which causes the visible stripes in the rapid test, is a **chemical reaction** and therefore depends on the reaction conditions such as

pH or chemicals that come with the sample can be influenced and a clear weakness in the reliability of the test.
This explains the many videos circulating on the Internet that detect SARS-CoV-2 using the rapid antigen tests in apple juice, red wine, beer, and so on.

2.2. Basic information on the diagnostic significance of the rapid antigen test

Like RT-PCR, rapid antigen tests cannot in principle detect whether the viral antigen found belongs to an intact, infectious virus or is a remnant (fragment) of viruses that have been killed by the immune system.
Irrespective of this general limitation of the significance with regard to infectivity, rapid tests only have an indicative character, not a reliable diagnostic significance.

The most well-known rapid test before Corona times was the rapid pregnancy test, which works according to the same principle of the antibody-antigen test. However, here the pregnancy hormone (HCG) acts as an antigen. If this is present in sufficient quantity in the tested urine, the test indicates "positive" - in this case presumably pregnant. However, the rapid test alone will never be sufficient as a well-founded proof of pregnancy; in this case, the doctor will use HCG detection in the blood as well as an ultrasound to make the diagnosis.
Similarly, rapid antigen tests for the detection of SARS-CoV-2 components can only provide an indication of possible colonization or infectivity and are subject to similar limitations as RT-qPCR.

2.3. Factors influencing the reliability of rapid antigen tests

2.3.1. Pretest probability

In an infographic entitled "Understanding Corona rapid test results" (https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Infografik_Antigentest_PDF. pdf?blob=publicationFile), the RKI clearly explains how the probability that a test result is correct depends on the so-called **pre-test probability, i.e.,** on the true number of genuinely infected individuals in the tested population. This aspect of pre-test probability applies to both the rapid antigen tests and equally to the RT-qPCR tests.

The calculation example presented by the RKI for the interpretation of the antigen rapid tests assumes a realistic scenario based on a sensitivity of the antigen tests of 80% and a specificity (reliability) of 98%, whereby it is also explicitly mentioned here (https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Vorl_Testung_nCoV.html): "The *considerable differences in performance of the various commercially available tests must be taken into account here (* reference to: https://www.medrxiv.org/content/10.1101/2020.10.01.20203836v1)."

Assuming 5 persons out of 10,000 tested are truly infected with SARS-CoV-2, **200 false positive tests** and 4 true positive tests will still show up. This means that 1 truly infected person per 10,000 would be missed, but 200 would get a false positive result and therefore have to be quarantined/isolated until testing with RT-qPCR then gives the "all clear". This would mean in the case of a school test with e.g. 1000 students that 20 would get a false "You are Corona positive" and the school would first be closed as an "outbreak site" until then the retesting by RT-qPCR gives the all-clear. Such cases have already been reported in the press.

- In Altdorf near Nuremberg, for example, 29 of 180 high school students tested positive in a rapid antigen test, and28 of them turned out to be negative when tested (Merkur: https://www.merkur.de/bayern/nuernberg/nuernberg-corona-bayern-test-fiasko-schnelltests-fehlerhaft-positiv-schule-altdorf-gymnasium-zr-90253265.html).
- In Potsdam, 12 of 36 teachers tested positive with a rapid antigen test and were sent into quarantine. After review, all test results proved to be false positive (https://www.news4teachers.de/2021/03/sorgen-schnelltests-fuer-chaos-an-schulen- false-alarm-puts-primary-school-lame/).

- Medscape even headlines, "200 false positives, 8 detected, 2 missed - why pediatric and adolescent physicians are skeptical of mass rapid testing (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 calculation example from the RKI (with 1000 out of 10,000 tested persons), the hit rate of the rapid tests would be poor and 180 persons would receive a false positive result and 200 a false negative test. In this case, the poor sensitivity of the test would have a particularly significant effect.

In the "***Hinweisen zur Bewertung der Ergebnisse aus AG-Testen***" (Note: Antigen-Schnelltests) on the page of the RKI, the **problem of false positive antigen tests is** addressed: "*A **positive test result** by means of AG test triggers the suspicion of a transmission-relevant infection with the SARS-CoV-2 and requires a follow-up test by means of PCR to avoid false positive results. In view of the potentially significant consequences of incorrect results, there are high requirements not only for the sensitivity of antigen tests, but also for their specificity. Thus, with low prevalence/pretest probability and low test specificity, **a high number of false-positive results and a corresponding additional burden on the ÖGD through the imposition and, if necessary, withdrawal of measures** would have **to be expected.***"
" https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Vorl_Testung_nCoV.html

2.3.2. Sensitivity (**Sensitivity**)

Since the antigen test does not provide such a strong (exponential) amplification of the output signal as RT-qPCR, but only a limited signal amplification due to the chemical color reaction, **this type of** test **is significantly less sensitive than the RNA detection by RT-qPCR used for comparison.**

This "underperformance" of rapid antigen tests is the subject of a Lancet article (https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00425-6/fulltext#%20), but here the negative test result in the rapid antigen test (here called LTF, lateral flow test) is put into perspective to: "*[...] in all six observed cases, **viral loads were very low** (Ct ≥29, reflecting about <1000 RNA copies per mL in the laboratory used) - **when the LFT should be negative.***" In the original: "*[.....] in all six observed cases, viral loads were very low (Ct ≥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 this finding that in asymptomatic individuals, the rapid tests have an unsatisfactorily high inaccuracy and that only in symptomatic individuals are the actual infected individuals detected reasonably accurately. The authors conclude, "*Our results show that the test correctly identifies most infectious individuals. Nevertheless, the sensitivity is considerably lower than PCR",* in the original: "*Our results indicate that the test correctly identifies most infectious individuals. Nevertheless, the sensitivity is considerably lower than for PCR*".

This **supposed lack of sensitivity** is the most common criticism when the unreliability of rapid antigen tests is reported. For example, Pharmazeutische Zeitung (https://www.pharmazeutische-zeitung.de/in-der-praxis-deutlich-unzuverlaessiger- as-on-paper-123017/) writes: "*Rapid antigen tests could detect mostly "highly infectious people with high viral loads," Keppler explains. "However, it is not the case that an infection could be reliably ruled out by the negative result of a rapid test.*" Here, however, the basis is comparing the rapid antigen test with RT-qPCR and criticizing the fact that only some of the RT-qPCR positive swab samples also become positive in the rapid antigen test.

For example, in Epidemiological Bulletin 3/2021, the RKI reports on a study with rapid tests in a Stuttgart clinic(from page 11 in: https://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2021/Ausgaben/03_21.pdf;jsessionid=1 5E8B09E615AECED77C34439BB8052AF.internet051?blob=publicationFile). Here, Table1showsthatof18RT-qPCRpositiveforSARS-CoV-2RNAtested asymptomatic individuals, only 7 also had a positive signal in the rapid antigen test, and of symptomatic individuals, 36 of 42. Accordingly, the discussion states, "*Because of the very limited sensitivity of the antigen test in asymptomatic individuals, single testing in this population cannot adequately exclude infection with SARS-CoV-2. Highly contagious individuals with low Ct levels (i.e., high viral load) are detected with adequate confidence.*" Here, the data show, "*From a Ct value of 22 or less, the detection rate of the antigen test was 100%. *“

This example shows very clearly that a reliable antigen test, when performed correctly, correlates very well with rapid response in RT-qPCR (low CT value) for symptomatic individuals, but not for asymptomatic, and RT-qPCR positive only with high CT value. **This speaks to the real-world significance of rapid antigen testing in terms of detecting a high viral load in symptomatic individuals**. However, according to these data, the test is unsuitable for testing asymptomatic persons, both to reliably identify possibly infected persons and to reliably identify healthy persons as negative.

Such a finding was also obtained in the current Frankfurt study (https://www.mdpi.com/2077-0383/10/2/328), where three rapid antigen tests (there AG-RDT, antigen rapid diagnostic test) were compared with a virus culture from the same samples in cell culture and correlated to RT-qPCR. Regarding this, the authors write in the abstract: "*In contrast, three Ag-RDTs demonstrated a more significant correlation with cell culture infectivity (61.8-82.4%).*" This means that from those samples which were positive in the antigen test, a positive result was also seen in the virus culture with a significantly higher hit rate than with the clearly more sensitive RT-qPCR "postives".

A recently published study by the CDC also points to the high concordance of the antigen test with actual replicable virus in a sample from symptomatic patients (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7821766/). Here, a commercial rapid antigen test was matched with a virus cultured in cell culture and RT-qPCR. It showed a high hit rate (positive result) of the antigen test only if the samples also contained **replicable virus.** Here, viruses could be grown from 85 of the total 147 samples (=58%), which were positive in the rapid antigen test and RT-PCR (here with a CT of approx. 22), but only from 11 of the 124 samples (= 9%), which 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 grown in cell culture, i.e. which have a high (infectious) viral load, are tested with good accuracy by the

Rapid antigen tests and identified by low CT (below 25) RT-PCR, but are in large majority from symptomatic individuals.

- Samples from which no viruses can be grown in cell culture are mostly negative in evaluated and correctly applied rapid antigen tests (apart from the false positives - see 2.3.3) and show high CT values (mostly above 33) in RT-qPCR. These samples are predominantly from asymptomatic tested individuals and prove that these random "positives" without clinical symptoms do not have an infectious viral load.

2.3.3. Reliability (**specificity**) - exclusion of false positive results

Many of the rapid antigen tests used have not yet undergone a regular conformity assessment procedure for CE marking and have so far only been granted **special approval** by the BfArM **in accordance with Section 11 of the Medical Devices Act** (https:// www.bfarm.de/DE/Medizinprodukte/Antigentests/_node.html). Furthermore, these tests are widely used by untrained, non-medical personnel or even as a "Self-tests" conducted.

Regarding this problem of performing rapid antigen tests, Professor Oliver Keppler, M.D., head of virology at the Max Pettenkofer Institute at Munich's Ludwig- Maximilians University, urges in an article in the Jan. 13, 2021, issue of Pharmazeutische Zeitung (DOI: 10.1007/ s00430-020-00698-8), "*[....] these tests would also absolutely have to be performed correctly. "This should be in the hands of trained professionals," he says. "Now there is the idea of recruiting large numbers of job seekers to perform such tests in nursing homes.* ***If untrained personnel are used, I'm concerned that the reliability of the test results will suffer even further***"
A recent Cochran review article (https://www.cochrane.de/de/news/aktualisierter- cochrane-review-evaluated-to-reliability-of-rapid-tests-for-detection-of-covid)also concludedthat rapid antigen tests are significantly more reliable in symptomatic individuals than in asymptomatic tested individuals. However, even in symptomatic individuals, the reliability of the best of the rapid tests evaluated in this study is significantly limited, leading the authors to describe the following scenarios:

1. "In a population of **1000 people with symptoms, 50 of whom actually** have **COVID-19**, these rapid tests can be expected to **correctly identify** about **40 people as COVID-19 infected** and miss between 6 and 12 cases of COVID-19. **Between 5 and 9 of the positive test results would turn out to be false positives upon review."**
2. "In a group of **10,000 people without symptoms,** in which **50 people** are truly infected with SARS-CoV-2, between **24 and 35 people would be correctly** identified **as virus carriers**, and between 15 and 26 cases would be missed. One would have to expect that testing would result in between 125 and 213 would yield positive results and **that between 90 and 189 of these positive results would actually be false positives.**

For the consequences of false positive results due to lack of test specificity, see under 2.3.1 "Pre-test probability".

2.5.Conclusion

The rapid antigen tests used for mass testing cannot **provide any information about infectivity**, as they can only detect protein components without any connection to an intact, replicable virus.

1. To allow an estimation of the infectivity of the tested individuals, the respective positive test performed (similar to RT-qPCR) would have to be individually matched with a cultivability of viruses from the test sample, which is impossible under the extremely variable and unverifiable test conditions.

2. The low specificity of the tests causes a **high rate of false positives**, which result in unnecessary personnel (quarantine) and societal (e.g. schools closed, "outbreak notifications") consequences until they turn out to be false alarms.

For further details, please refer to the written submissions of the parties.

B: Reasons for decision

I. Admissibility of the suggestion to the family court

The suggestion to the family court to examine a risk to the welfare of a child is admissible. In particular, legal recourse to the ordinary courts is open and the family courts have subject-matter jurisdiction.
According to § 13 GVG, family cases belong to the ordinary courts.
The subject-matter jurisdiction results exclusively from section 23a (1) no. 1 GVG. According to this, the local courts are responsible for 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 cases also include matters of parent and child. Pursuant to section 151 no. 1 of the Family Proceedings Act, parental custody is one of the child-related matters. Parental custody also includes the provision in section 1666 of the Civil Code, according to which the family court must take the necessary measures if the physical, mental or psychological welfare of the child or his or her property is at risk and the parents are unwilling or unable to avert the risk. In this context, the family court may also take measures with effect against a third party in matters of personal care in accordance with section 1666 (4) of the Civil Code.
Nor does Section 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 available for proceedings endangering the welfare of children. This is because proceedings for endangerment of the welfare of children are assigned by federal law to another court,

namely the family court, expressly assigned, Section 40 (1) sentence 1 VwGO in conjunction with Section 1666 BGB.

This is also based on constitutional necessities.
Child protection in German law is structured on several tracks. For proceedings before the general civil courts or the administrative courts, genuine applications in the legal sense are necessary. Only if such an application has been filed can the above-mentioned courts take action.
Proceedings under section 1666 of the Civil Code, on the other hand, do not belong to the application proceedings within the meaning of section 23 of the Family Proceedings Act, but to those under section 24 of the Family Proceedings Act, which can be initiated ex officio; 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, section 1697a of the Civil Code.

Endangerment of the child is to be affirmed in the case of a present danger to the mental, physical or psychological well-being of the child to such an extent that, in the case of further development without intervention, considerable damage can be foreseen with a high degree of certainty (Palandt-Götz, § 1666 Rn. 8).

According to the current state of science, such a hazard is at least likely to be caused by the wearing of a mouth-nose covering, so that the court had to initiate proceedings in order to examine this question.

In accordance with the principle of equal treatment under Article 3 of the Basic Law and the state community's duty to guard the family, which is enshrined in Article 6 of the Basic Law, it would be unacceptable under constitutional law if some children could hope that an application would be made on their behalf to a court that appeared to be suitable, while others could not. Even children whose parents would in principle be willing and able to file applications that seem appropriate in the circumstances may fall behind if their parents fail to do so or at least delay doing so out of fear of disadvantages for their children. Section 1666 of the German Civil Code applies to all children. In the proceedings themselves, the principle of official investigation applies, § 26 FamFG.

According to the prevailing view, the parents are therefore not forced to first take recourse to general civil law (Palandt-Götz, § 1666 marginal no. 41). They are also not compelled to first take administrative legal action against the order on which the order is based and, if necessary, to seek a judicial review. This follows, moreover, from the fact that the administrative proceedings involve a different

legal protection goal than is pursued by the order sought here against the child's school principal and teachers.

Finally, the admissibility requirements for the issuance of a temporary injunction pursuant to Sections 49 et seq. of the German Judicature Act (FamFG) are also met.
In particular, a temporary injunction is admissible because it is asserted here that this is justified under the provisions governing the legal relationship (§ 1666 BGB) and that there is an urgent need for immediate action in view of the school lessons taking place with the obligation to wear a face mask.

II. Merits of the request to the family court

1. General

The suggestion to the family court to make a provision apparent from the operative part in order to avoid a risk to the welfare of the child is justified under section 1666 of the Civil Code.
Endangerment of the child is to be affirmed in the case of a present danger to the mental, physical or psychological well-being of the child to such an extent that, in the case of further development without intervention, considerable damage can be foreseen with a high degree of certainty (Palandt-Götz, § 1666 Rn. 8).
Such a danger is present here. This is because the children are not only endangered in their mental, physical and psychological well-being by the obligation to wear face masks during school hours and to keep their distance from each other and from other persons, but they are also already being harmed. At the same time, this violates numerous rights of the children and their parents under the law, the constitution and international conventions. This applies in particular to the right to free development of the personality and to physical integrity from Article 2 of the Basic Law and to the right from Article 6 of the Basic Law to upbringing and care by the parents (also with regard to measures for preventive health care and the costs to be borne by children).
"objects"). However, this also applies to other rights of the children, such as those cited by the children's mother in A IV.
The children are physically, psychologically and pedagogically harmed and their rights are violated without any benefit for the children themselves or third parties.
The school administrators, teachers and others cannot rely on the provisions of state law, as detailed in A II. This is because these regulations are unconstitutional and therefore null and void.

The obligation in Article 100 (1) of the Basic Law to submit a possibly unconstitutional law to the Federal Constitutional Court or a Land constitutional court applies expressly only to formal laws of the Federation and the Länder, but not to substantive laws such as statutory instruments or the general decree at issue. According to the established case law of the Federal Constitutional Court (fundamentally BVerfGE 1, 184 ((195 et seq.)), each court must decide for itself whether they are compatible with the constitution, as also already AG Weimar, judgment of January 11, 2021 - 6 OWi - 523 Js 202518/20 -, juris.
How the family court may respond to threats to the welfare of children that invoke formal federal or state laws to justify, beyond referral to the federal or a state constitutional court, is not relevant to the decision here and therefore requires no further elaboration.

The provisions of state law, as detailed in A II. (this also applies to content identical or similar to them that update them), are unconstitutional because they violate the principle of proportionality rooted in the rule of law, Articles 20, 28 of the Basic Law.
According to this principle, which is also referred to as the prohibition of excessiveness, the measures intended to achieve a legitimate purpose must be suitable, necessary and proportionate in the narrower sense - in other words, when the advantages and disadvantages they achieve are weighed up.
The measures that are not evidence-based, contrary to Section 1 (2) IfSG, are already unsuitable to achieve the fundamentally legitimate purpose pursued with them, to avoid overloading the health care system or to reduce the incidence of infection with the SARS-CoV- 2 virus. In any case, however, they are disproportionate in the narrower sense, because the considerable disadvantages/collateral damage caused by them are not offset by any recognizable benefit for the children themselves or third parties.

The inappropriateness and disproportionality of the prescribed measures is substantiated below. Nevertheless, it must be pointed out that it is not the parties involved who would have to justify the unconstitutionality of the encroachments on their rights, but conversely the Free State of Thuringia, which encroaches on the rights of the parties involved with its state law provisions, would have to prove with the requisite scientific evidence that the measures it prescribes are suitable for achieving the intended purposes and that they are proportionate, if necessary. This has not yet been done to any degree.

2. Failure to wear masks and to observe distance rules for the children themselves and third parties

The expert Prof. Dr. med. Ines Kappstein evaluated the entire international scientific data on masks in her complete expert opinion, see A VIII.

To the conviction of the court, it summarizes that an effectiveness of masks for healthy persons in public is not supported by scientific evidence. Likewise, 'third-party protection' and 'unnoticed transmission', which the RKI used to justify its 'reassessment', are not supported by scientific facts. Plausibility, mathematical estimates and subjective assessments in opinion pieces cannot replace population-based clinical-epidemiological investigations. Experimental studies on the filtering performance of masks and mathematical estimates are not suitable to prove effectiveness in real life. While international health authorities advocate the wearing of masks in public spaces, they also say that there is no evidence for this from scientific studies. On the contrary, all currently available scientific results suggest that masks have no effect on the incidence of infection. Throughout, all publications cited as evidence for the effectiveness of masks in public spaces do not support this conclusion. 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 estimation or modeling study based on theoretical assumptions without real contact tracing with authors from the field of macroeconomics without epidemiological knowledge - fails to take into account, as explained in detail by the expert, the decisive epidemiological circumstance that the infection levels already declined significantly before the introduction of the mask obligation in Jena on April 6, 2020 (about three weeks later in the whole of Germany) and that there was already no longer any relevant infection occurrence in Jena at the end of March 2020.

Any mask, as the reviewer goes on to say, must be worn properly to be effective in principle. Masks can become a contamination risk if they are touched. However, on the one hand, they are not worn properly by the general public and, on the other hand, they are very often touched with the hands. This can also be observed with politicians who are seen on television. The population was not taught to use masks properly, it was not explained how to wash hands on the way or how to perform effective hand disinfection. Furthermore, it was not explained why hand hygiene is important and that one must be careful to

not to touch the eyes, nose and mouth with their hands. The population was virtually left alone with the masks.
The risk of infection is not only not reduced by wearing the masks, but is even increased by the incorrect handling of the mask. In her expert opinion, the expert explains this in detail, as well as the fact that and for what reasons it is "unrealistic" to achieve the appropriate handling of masks by the population.
The transmission of SARS-CoV-2 through 'aerosols', i.e. through the air, is medically implausible and scientifically unproven. It represents a hypothesis, which is mainly based on aerosol physicists, who, according to the expert, are understandably not able to judge medical correlations from their field of expertise. The 'aerosol' theory is extremely harmful to human coexistence and leads to the fact that people can no longer feel safe in any indoor space, and some even fear infection by 'aerosols' outside buildings. Together with the 'unnoticed' transmission, the 'aerosol' theory leads to seeing a risk of infection in every fellow human being.
The changed statements of the policy on masks, first fabric masks in 2020, then since the beginning of 2021 either OP masks or FFP2 masks, lack any clear line. Even though OP masks and FFP masks are both medical masks, they have different functions and are therefore not interchangeable. Either the politicians who made these decisions themselves did not understand what which type of mask is suitable for in principle, or they are not interested in this, but only in the symbolic value of the mask. From the expert's point of view, the policy-makers' mask decisions are not comprehensible and, to put it mildly, can be described as implausible.

The reviewer further points out that there is no scientific research on spacing outside of medical patient care.
In summary, in their opinion, to the conviction of the court, only the following rules can be established in this regard:

1. Keeping a distance of about 1.5 m (1 - 2 m) during vis-à-vis contacts when one of the two persons has symptoms of a cold can be described as a sensible measure. However, it is not proven in a scientific sense, but there is only evidence or can be called plausible that it is an effective measure to protect against pathogen contact by droplets of respiratory secretion when the person in contact has signs of a cold. An all-around distance, on the other hand, is not useful for protecting oneself when the contact person has a cold.

2. Keeping 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. However, this greatly impairs people's ability to live together and, in particular, carefree contact among children, without any discernible benefit in terms of protection against infection.
3. However, close contacts, i.e. under 1.5 m (1-2 m), among pupils or between teachers and pupils or among colleagues at work, etc., do not pose a risk even if one of the two contacts has signs of a cold, because the duration of such contacts at school or even among adults somewhere in public is far too short for droplet transmission to occur. This is also shown by studies from households where, despite living in close quarters with numerous skin and mucous membrane contacts, few members of the household become ill when one has a respiratory infection.

The reviewer convincingly highlights the problem of mathematical modeling. Mathematical modeling (also called mathematical estimation) is well known from weather forecasting and climate research, but has also been used for many years to predict the course of epidemics and the impact of various preventive measures. They are used especially when there is little meaningful data from direct studies. A very large proportion of all studies on SARS-CoV-2 (e.g., effectiveness of masks) are mathematical modeling exercises that have very limited power because their results do not reflect 'real' life but are based on assumptions. The results depend on these 'set screws' and therefore reflect a simplified picture of reality. Such studies can therefore only ever provide 'if-then' results. On one side of the spectrum, there are purely theoretical modeling studies and, on the other, those that work with as much clinical epidemiologic data as is available. In each case, however, as the reviewer points out in detail, the result has very limited validity, and the quality of the scientific evidence is moderate at best. However, the results of such studies in the context of SARS-CoV-2 are often vastly overestimated in their relevance to reality and, if positive, are taken as evidence of the effectiveness of interventions. This could be observed repeatedly in the course of the pandemic, and, as the reviewer explicitly points out, even among scientifically active physicians and among bioscientists.

The expert also points to this problem when asking what transmission rates can be expected from symptomatic, presymptomatic and asymptomatic people. Pre-symptomatic transmissions are possible according to her explanations, but not inevitable. In any case, according to her, they are significantly lower when real contact scenarios are evaluated than when mathematical modeling is used.

From a systematic review with meta-analysis on Corona transmission in households published in December 2020, it contrasts a higher but still not excessive transmission rate in symptomatic index cases of 18% with an extremely low transmission in asymptomatic cases of only 0.7%. The possibility that asymptomatic persons, formerly referred to as healthy persons, transmit the virus is therefore meaningless.

In conclusion, the expert states in response to evidentiary questions 1, 3, and 4:

There is no evidence that face masks of various types can reduce the risk of infection by SARS-CoV-2 at all, or even appreciably. This statement applies to people of all ages, including children and adolescents, as well as asymptomatic, presymptomatic, and symptomatic individuals.

On the contrary, the even more frequent hand-face contact when wearing masks increases the risk of coming into contact with the pathogen oneself or bringing fellow humans into contact with it.

For the normal population, there is no risk of infection in either the public or private sector that could be reduced by wearing face masks (or other measures).

There is no evidence that compliance with distance regulations can reduce the risk of infection. This applies to people of all ages, including children and adolescents.

These results are confirmed by the extensive findings of the expert Prof. Dr. Kuhbandner. According to these findings, there is also no high-quality scientific evidence to date that the risk of infection can be significantly reduced by wearing face masks. According to the expert's findings, the recommendations of the RKI and the S3 guidelines of the professional societies are based on observational studies, laboratory studies on the filter effect, and modeling studies, which provide only low and very low levels of evidence, because no evidence can be derived from such studies due to the

underlying methodology, no really valid conclusions can be drawn about the effect of masks in everyday life and at schools. Moreover, the results of the individual studies are heterogeneous and more recent observational studies also provide contradictory findings.
With regard to the randomized controlled studies on the effect of wearing masks that have been conducted to date, the expert points out that they do not indicate any effectiveness of masks. On the contrary, the only comprehensive randomized controlled study to date on the wearing of cotton masks indicates that cotton masks can even increase the risk of infection. A role is played here above all by the handling of the mask, which can have a negative effect on the risk of infection if it is poorly handled. However, handling problems are unavoidable for schoolchildren, especially younger ones. The expert Prof. Dr. med. Kappstein had already pointed out that the handling problem leads to the fact that the wearing of masks not only does not help from the point of view of infection prevention, but even harms.
In addition, the achievable extent of the reduction in the risk of infection through mask-wearing at schools is very low in itself, because infections very rarely occur at schools even without masks. Accordingly, the absolute risk reduction is so small that it cannot be used to combat a pandemic in any relevant way.

According to the expert, the current alleged increase in the number of infections in children is very likely to be due to the fact that the number of tests carried out on children has risen sharply in recent weeks. Since the risk of infection at schools is very small in itself, even a possible increase in the infection rate with the new virus variant B.1.1.7 in the order of magnitude assumed in studies is not expected to lead to a significant increase in the spread of the virus at schools.

This small benefit is countered by numerous potential side effects on children's physical, psychological, and social well-being, from which numerous children would have to suffer to prevent a single infection.

The expert presents these in detail, among other things, on the basis of the side effect register published in the scientific journal Monatsschrift Kinderheilkunde.

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

In her expert opinion, Prof. Dr. med. Kappstein already points out that the PCR test used can only detect genetic material, but not whether the RNA originates from viruses that are capable of infection and thus capable of replication.

Also the expert Prof. Dr. rer. biol. hum. Kämmerer confirms in her expert opinion on molecular biology that a PCR test - even if performed correctly - cannot provide any information on whether a person is infected with an active pathogen or not.
This is because the test cannot distinguish between "dead" matter*, e.g. a completely harmless genome fragment as a remnant of the body's own immune system's fight against a cold or flu (such genome fragments can still be found many months after the immune system has "dealt with" the problem) and
"living" matter, i.e. a "fresh" virus capable of reproduction.
For example, PCR is also used in forensics to amplify residual DNA from hair residues or other trace materials by means of PCR in such a way that the genetic origin of the perpetrator(s) can be identified ("genetic fingerprint").

Thus, even if the PCR, including all preparatory steps (PCR design and establishment, sample collection, preparation and PCR performance), is carried out with
is done "correctly", and the test is positive, i.e.: detects a genome sequence which may also exist in one or even the specific "Corona" virus (SARS-CoV-2), this does not mean under any circumstances that the person who tested positive is infected with a replicating SARS-CoV-2 and consequently infectious = dangerous for other persons.
Rather, additional, and specifically diagnostic, methods such as isolation of replicable virus must be used to detect active infection with SARS-CoV-2.

Independently of the impossibility in principle to detect an infection with the virus SARS-CoV-2 with the PCR test, the results of a PCR test depend, moreover, according to the explanations of the expert Prof. Dr. Kämmerer, on a number 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.
Of these sources of error, two prominent ones are to be singled out.

One of these is the number of target genes to be tested. This was successively reduced from the original three to one in accordance with WHO specifications.
The expert calculates that the use of only one target gene to be tested in a mixed population of 100,000 tests with not a single person actually infected would result in 2,690 false positives based on a mean error rate determined in an Instand interlaboratory test. Using 3 target genes would result in only 10 false positives.
If the 100,000 tests performed were representative of 100,000 citizens of a city/county within 7 days, this reduction in the target genes used alone would result in a difference of 10 false positives versus 2690 false positives in terms of "daily incidence" and, depending on this, the severity of the restrictions on citizens' freedom taken.
If the correct "target number" of three or even better (as e.g. in Thailand) up to 6 genes had been consistently used for PCR analysis, the rate of positive tests and thus the "7-day incidence" would have been reduced almost completely to zero.

On the other hand, the sources of error include the so-called ct value, i.e. the number of amplification
/doubling steps up to which the test is still considered "positive".
The expert points out that, according to unanimous scientific opinion, all the
"positive" results, which are only detected from a cycle of 35, have no scientific (i.e.: no evidence-based) basis. In the range of ct value 26-35, the test can only be considered positive if matched with virus cultivation. In contrast, the RT-qPCR test for the detection of SARS-CoV-2, which was propagated worldwide with the help of the WHO, was (and following it all other tests based on it as a blueprint) set to 45 cycles without defining a ct value for "positive".

In the 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 legal notice of the court). According to this, as far as the test result does not correspond to the clinical findings of an examined person, a new sample must be taken and a further examination must be carried out as well as 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-users-2020-05
This requirement is as little observed in Thuringia and nationwide as multiple counts are excluded in the case of multiple testing of the same person (No. 13 of the court's legal guidance).

According to the expert report, 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.
To allow an estimation of the infectivity of the tested individuals, the respective positive test performed (similar to RT-qPCR) would have to be individually matched with a cultivability of viruses from the test sample, which 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 positives, which have unnecessary personnel (quarantine) and social (e.g., schools closed, "outbreak reports") consequences 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 individuals.

It remains to be stated that the PCR test used, as well as the antigen rapid tests, as proven by the expert opinion, are in principle not suitable for the detection of an infection with the virus SARS-CoV-2. In addition, the described and other sources of error listed in the expert opinion with serious effects, so that an adequate determination of the infection with SARS-CoV-2 in Thuringia (and nationwide) is not rudimentarily available.

In any case, the term "incidence" is misused by the state legislature. For
"Incidence" actually means the occurrence of new cases in a (repeatedly tested and, if necessary, medically examined) defined group of persons in a defined 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 passed off as "incidence" is merely simple reporting data.

In any case, according to a metastudy by medical scientist and statistician John Ioannidis,one of theworld's most citedscientists, published in a WHO bulletin in October 2020, the infection fatality rate is 0.23%, no higher than in 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

4. Violation of the Right to Informational Self-Determination through Rapid Testing in Schools

The right to informational self-determination as part of the general right to privacy in Article 2 (1) of the German Basic Law is the right of individuals to determine for themselves in principle the disclosure and use of their personal data. This personal data also includes a test result. Furthermore, such a result is a personal health "data" in the sense of the Basic Data Protection Regulation (GDPR), which is basically nobody's business.
This encroachment on fundamental rights is also unconstitutional. This is because, given the concrete procedures of the testing process in schools, it seems unavoidable that numerous other people (classmates, teachers, other parents) would become aware of a "positive" test result, for example.
This applies mutatis mutandis when similar test barriers are erected for access to shopping or cultural events.

In addition, any mandatory testing of schoolchildren under state law is already not covered by the Infection Protection Act - irrespective of the fact that the latter itself is subject to considerable constitutional concerns.
According to § 28 IfSG, the competent authorities may take the necessary protective measures in the manner specified therein if "sick persons, suspected sick persons, suspected infected persons or excretors" are identified. According to § 29 IfSG, these persons can be subjected to observation and must then also tolerate the necessary examinations.
In its decision of March 2, 2021, Case No. 20 NE 21.353, the Bavarian Administrative Court rejected the idea of considering employees in nursing homes to be ill, suspected of being ill or excretors from the outset. This is likely to apply to students as well. However, classification as suspected of being infected is also out of the question.
According to the case law of the Federal Administrative Court, anyone who has had contact with an infected person with a sufficient degree of probability is considered to be suspected of being infected within the meaning of Section 2 No. 7 IfSG; a mere remote probability is not sufficient. It is necessary that the assumption that the person concerned has ingested pathogens is more probable than the opposite. The decisive factor for a suspicion of infection is exclusively the probability of a past infection process, cf. judgment of 22.03.2012 - 3 C 16/11 - juris marginal no. 31 et seq.

The BayVGH, loc. cit., has rejected this for employees in nursing professions. Nothing else applies to students.

5. The right of children to education and schooling

School children are not only subject to compulsory education under state law, but also have a legal right to education and schooling.
This also arises from Articles 28 and 29 of the UN Convention on the Rights of the Child, which is applicable law in Germany.
According to this, all signatory states must not only make attendance at elementary school compulsory and free of charge for all, but must also promote the development of various forms of secondary education and vocational training, make them available and accessible (!) to all children and take appropriate measures such as introducing free education and providing financial support in cases of need. The educational goals of Article 29 of the UN Convention on the Rights of the Child must 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 harms the children physically, psychologically, pedagogically, and in their psychosocial development, without more than a marginal benefit at best for the children themselves or third parties.
Schools do not play a significant role in "pandemic" events.

The PCR tests and rapid tests used are in principle and already in the approach not suitable for detecting an "infection" with the virus SARS-CoV-2.
According to the expert reports, this is already clear from the Robert Koch Institute's own calculations. According to RKI calculations, as expert Prof. Dr. Kuhbandner explains, the probability of actually being infected when receiving a positive result in mass testing with rapid tests, regardless of symptoms, is only two percent at an incidence of 50 (test specificity 80%, test sensitivity 98%). 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.

A (regular) compulsion to mass test asymptomatic children, i.e. 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, regular compulsory testing puts children under psychological pressure, because their ability to attend school is constantly put to the test.

Based on surveys in Austria, where no masks are worn in elementary schools, but rapid tests are carried out three times a week throughout the country, the expert Prof. Dr. Kuhbandner states:

100,000 elementary school students would have to put up with all the side effects of wearing masks for a week to prevent just one infection per week.

To call this result merely disproportionate would be a wholly inadequate description. Rather, it shows that the state legislature regulating this area has become distanced from the facts to an extent that seems historic.

By ordering such measures, the best interests of the children, as presented, are jeopardized, § 1666 BGB. The teachers are therefore not allowed to order them. They cannot invoke the relevant state-law ordinances and the general decree cited in this connection, as these already violate the principle of proportionality due to their unsuitability to achieve the intended goals, but in any case due to their disproportionality, and are therefore unconstitutional and void.

In addition, children have a legal right to accessible schooling.

Based on the current state of the investigation, it seems very likely that this result will be confirmed in the main proceedings. Further statements are reserved for a decision there.

When issuing a temporary injunction, the consequences must be weighed up against the disadvantages that arise if the family court does not initially make the arrangement sought by the parents of the children in the temporary injunction proceedings, but then does make it later in the main proceedings, and the effects that arise if the family court already makes the arrangement sought by the parents of the children in the temporary injunction proceedings, but does not confirm it later in the main proceedings.

The disadvantages for the children if the intended settlement is delayed by the family court outweigh the disadvantages considerably.

In any case, the parents are not in a position to avert the danger, § 1666 BGB. In view of the imminent end of the Easter vacations, there is also an urgent need to take immediate action.

After all this, the decision apparent 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 decision for them.

The decision on costs is based on § 81 FamFG.