

Corona children studies "Co-Ki": First results of a Germany-wide registry on mouth and nose covering (mask) in children

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EDITORIAL NOTE:

This study is based on a survey regarding the adverse effects of mask wearing in children. **Due to multiple limitations, this study cannot demonstrate a causal relationship between mask wearing and the reported adverse effects in children.** Most of the respondents were parents, and the survey was distributed preferentially in social media forums that, according to the authors, "criticize the

government's corona protection measures in principle". The limitations of the study include sampling bias, reporting bias, and confounding bias as well as lack of a control group. The use of masks, together with other precautionary measures, significantly reduces the spread of COVID-19 and is considered safe for children over the age of two years old.

Abstract

Background: Narratives about complaints in children and adolescents caused by wearing a mask are accumulating. There is, to date, no registry for side effects of masks.

Methods: At the University of Witten/Herdecke an online registry has been set up where parents, doctors, pedagogues and others can enter their observations. On 20.10.2020, 363 doctors were asked to make entries and to make parents and teachers aware of the registry.

Results: By 26.10.2020 the registry had been used by 20,353 people. In this publication we report the results from the parents, who entered data on a total of 25,930 children. The average wearing time of the mask was 270 minutes per day. Impairments caused by wearing the mask were reported by 68% of the parents. These included irritability (60%), headache (53%), difficulty concentrating (50%), less happiness (49%), reluctance to go to school/kindergarten (44%), malaise (42%) impaired learning (38%) and drowsiness or fatigue (37%).

Discussion: This world's first registry for recording the effects of wearing masks in children is dedicated to a new research question. The frequency of the registry's use and the spectrum of symptoms registried indicate the importance of the topic and call for representative surveys, randomized controlled trials with various masks and a renewed risk-benefit assessment for the vulnerable group of children: adults need to collectively reflect the circumstances under which they would be willing to take a residual risk upon themselves in favor of enabling children to have a higher quality of life without having to wear a mask.

Background And Questions

The question of a certificate of exemption from the obligation to wear a mouth and nose cover (hereinafter referred to as "mask") is a new phenomenon in pediatric practice. Parents, educators and doctors are increasingly reporting problems and health complaints in children in connection with wearing a mask. There are no manufacturer-independent studies on the use of masks for children and adolescents that are certified as medical products for occupational safety in professional applications. In addition, due to the unknown materials used, there are no findings on the potential protective effects or side effects of the often home-made "everyday masks" worn by the majority of children. In view of the ongoing measures to contain the COVID-19 pandemic, and in particular the varying obligations for children and adolescents to wear masks in school over a longer period of time, there is an urgent need for research.

Study Design And Research Methods

Based on the registry of adverse drug reactions at the Paul Ehrlich Institute (www.nebenwirkungen.pei.de), an online registry has been set up where parents, doctors, educators and others can enter their observations on the effects of wearing a mask on children and adolescents. On 20.10.2020, 363 doctors on the Co-Ki study distribution list were informed about the possibility of making entries there themselves and to communicate the registry to their patients and colleagues. The registry and the questionnaire can

be found online at www.co-ki-masken.de (Figure in Online Supplement S1) as part of the Co-Ki study complex (figure in Online Supplement S2). The data entered in the registry includes information regarding the role of the registrant, demographic data, previous illnesses, situation and duration of mask wearing, type of mask, existence of complaints from the child about an impairment via the mask, symptoms, behavioral problems, personal attitude to corona protection measures of the government and the possibility to leave name and e-mail address. A positive ethics vote from the University of Witten/Herdecke was obtained.

Results

By the evening of 26.10.2020, one week after the registry went online, 20,353 people had already taken part in the survey, with 48,657 entries. Of the survey participants, 17,854 (87.7%) were parents, 736 (3.6%) were teachers, 352 (1.7%) were doctors, and 1,411 (6.9%) were "others" (Figure S3 in the Online Supplement shows the analysis set of the entries of the first week). This article reports on the 17,854 entering parents with a total of 25,930 children and youth. The data of the entering doctors, teachers and other roles are published separately.

Of the 17,854 entering parents, 6,877 (38.5%) stated that they had a university degree (bachelor, master, master's degree, diploma, state examination, doctorate), 671 (3.8%) had a master craftsman, 3,704 (20.7%) had completed an apprenticeship and 3,040 (17.0%) had a high school diploma (general qualification for university entrance) or subject-related higher education entrance qualification or technical college entrance qualification. 2,509 (14.1%) of the participants stated that their highest educational level was a secondary school leaving certificate (In Germany: *Mittlere Reife*, *Fachoberschulereife* or similar), 327 participants (1.8%) had a secondary modern school leaving certificate, and 31 participants (0.2%) stated that they had no school or training qualification. The remaining did not enter an education. The participation of contributors per state corresponds to the distribution of the population (Figure 1).

The demographic situation of the children and previous illnesses among the children from the parents' point of view are shown in Table 1: the genders are equally represented with a slight trend towards boys; and 55.6% of the children were between 7-12 years of age. In 79.4% of the children it was stated that they had no previous illnesses, 5.9% had asthma and 1.8% had another lung disease. Furthermore, there was the possibility of free text entries on other previous illnesses, which was used by 8.6%.

Table 1: *Demography and pre-existing conditions of children*

		Total age group	Age group 0-6 years	Age group 7-12 years	Age group 13-18 years	Test for difference
	Age group n (%)	25 926* (100%)	4 002 (15.4%)	14 407 (55.6%)	7 517 (29.0%)	
Gender	Male	12 589 (48.5%)	1 880 (47.0%)	7 027 (48.8%)	3 682 (49.0%)	p = 0.0002
	Female	12 248 (47.2%)	1 899 (47.5%)	6 790 (47.1%)	3 559 (47.3%)	
	Divers	62 (0.2%)	13 (0.3%)	32 (0.2%)	17 (0.2%)	
	Without specification	1 031* (4.0%)	210 (5.2%)	558 (3.9%)	259 (3.4%)	
Pre-existing conditions	No previous illnesses	20 586 (79.4%)	3 400 (85.0%)	11 606 (80.6%)	5 580 (74.2%)	p < 0.0001
	Asthma	1 541 (5.9%)	123 (3.1%)	801 (5.6%)	617 (8.2%)	
	Other lung diseases	458 (1.8%)	50 (1.2%)	251 (1.7%)	157 (2.1%)	
	Other previous illnesses (free text input)	2 232 (8.6%)	233 (5.8%)	1 178 (8.2%)	821 (10.9%)	
	Not specified	1 110 (4.3%)	196 (4.9%)	571 (4.0%)	343 (4.5%)	
* for four children the age specification is missing.						

Table 2 presents the situation of wearing masks with the children and whether any form of impairment from parents view was present. When asked about the situations in which the children wear a mask, 81.1% of the survey participants answered that the child wears the mask at school outside of class, i.e. during breaks and in the corridors, 48.6% also stated that the child also wears the mask in class at the seat during lessons. 68.5% of the children recorded wearing the mask in stores and 39% on the way to school 4.6% of the children never wear a mask. A mask exemption certificate had been granted to 6.7% of the registered children and youth. The average length of time the mask was worn varies greatly with age; it averaged 4.5 hours per day, and was much higher, especially among youth (13-18 years), averaging 6 hours (Table 2). In 16 913 children (65.2%) it was reported that fabric masks were worn, followed by surgical masks. FFP masks are hardly worn by children.

Regarding the question as to whether children themselves complain about impairments caused by wearing the mask, 67.7% of the respondents answered yes for their children; 26% answered no. The question as to whether the respondents themselves observed an impairment of the child by wearing the mask was answered yes in 66.1% (Table 2). The assessment of the health impairment is shown in Table 3. Four percent had no opinion when asked about their personal attitude to the government's corona protection measures, 11.7% of the participants thought that the measures should be more stringent,

11.0% considered the current measures appropriate and good and 41.7% were in favor of milder measures. A further 31.6% expressed a different opinion than the setting option specified in the selection option. In general, they described the policy measures as inappropriate, incomprehensible and undifferentiated.

Table 2: *Wearing situation of the mask and impairment*

	Wearing situation (Total Age group)		Wearing situation (Total Age group)	Wearing situation (Total Age group)	Wearing situation (Total Age group)	Wearing situation (Total Age group)	Wearing situation (Total Age group)
	Wearing time in minutes (IQR)**		270 (120;390)	90 (30;240)	240 (120;370)	360 (240; 450)	p < 0.0001
Type of Mask	Fabric mask		16 913 (65.2%)	2 501 (62,5%)	10 311 (71,6%)	4 101 (54,6%)	p < 0.0001
	Surgical Mask		5 542 (21.4%)	271 (6,8%)	2 619 (18,2%)	2 652 (35,3%)	
	FFP mask		536 (2.1%)	51 (1,3%)	273 (1,9%)	212 (2,8%)	
	Not specified		2 935 (11.3%)	1 179 (29.5%)	1 204 (8.4%)	552 (7.3%)	
Impairments	Impairment by mask according to child	Yes	17 550 (67.7%)	1 607 (40.2%)	10 244 (71.1%)	5 699 (75.8%)	p < 0.0001
		No	6 801 (26.2%)	1 431 (35.8%)	3 744 (26.0%)	1 626 (21.6%)	p < 0.0001
		Not specified	1.575 (6.1%)	964 (24.1%)	419 (2.9%)	192 (2.6%)	p < 0.0001
	Have you observed any adverse effects of a mask on your child?	Yes	17.125 (66.1%)	1.640 (41.0%)	9.980 (69.3%)	5.505 (73.2%)	p < 0.0001
		No	6.841 (26.4%)	1.367 (34,2%)	3.810 (26.4%)	1.664 (22.1%)	p < 0.0001
		Not specified	1.960 (7.6%)	995 (24.9%)	617 (4.3%)	348 (4.6%)	p < 0.0001
The child must wear a mask...	on the way to school		10.105 (39.0%)	668 (16.7%)	5.704 (39.6%)	3.733 (49.7%)	p < 0.0001
	in school outside the classroom (corridor, playground)		20.124 (81.1%)	1.834 (45.8%)	12.682 (88.0%)	5.608 (86.6%)	p < 0.0001
	at school in class		12 593 (48.6%)	713 (17.8%)	6 880 (47.8%)	5 000 (66.5%)	p < 0.0001
	in kindergarten		361 (1.4%)	295 (7.4%)	53 (0.4%)	13 (0.2%)	p < 0.0001
	in stores		17 763 (68.5%)	2 060 (51.5%)	10 237 (71.1%)	5 466 (72.7%)	p < 0.0001
	never		1.198 (4.6%)	933 (24.8%)	155 (1.1%)	50 (0.7%)	p < 0.0001
	has a certificate of mask release		1.732 (6.7%)	144 (3.6%)	1.045 (7.3%)	543 (7.2%)	p < 0.0001
		** IQR (interquartile range) n = 4427 (17.1%) missing.					

The frequency distribution of the above-mentioned side effects associated with masks is similar in the different age groups, with headaches, concentration difficulties, discomfort, learning difficulties and drowsiness / tiredness being the most common (Table 3). Other complaints were described in the free text. First of all: 269 entries on worsened skin, especially increased pimples, rashes and allergic phenomena around the mouth area up to fungal diseases in and around the mouth. There were 151 entries on nosebleeds, 122 entries on school displeasure up to school anxiety / refusal to attend school, 64 entries on increased sweating, 52 entries on pressure points and wounds behind the ears, 46 entries on sore or cracked and partly bloody lips, 31 entries on increased migraine attacks in frequency and severity, 23 entries on impaired vision, 13 entries on aphthae. Table 3 shows the classification of a possible health impairment of the children, as assessed by the parents. Table 4 shows further behavioral problems in the children, above all with 60.4% an increased irritability, 49.3% less happy children, 44% children who do not want to go to school anymore, in each case children in the age category 7-12 years are affected most. In 25.3% of the children it was stated that they have developed new anxieties (Table 4). In addition, 2,672 entries in this question alone mention explicit specifications of anxiety or the reappearance of several anxieties in free text entries. In addition to a general fear of the future, the fear of suffocation even with a mask, as well as the fear of death of relatives through corona, is most frequently represented. 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 that relate to masked people whose facial expressions and identity are not recognizable to the children. A detailed evaluation and publication of the free text entries is planned.

Table 3: Symptoms in children in parental report

	Total age group	Age group 0-6 years	Age group 7-12 years	Age group 13-18 years	Test for difference
Headaches	13.811 (53.3%)	960 (24.0%)	7.863 (54.6%)	4.988 (66.4%)	p < 0.0001
Concentration difficulties	12.824 (49.5%)	961 (24.0%)	7.313 (50.8%)	4.550 (60.5%)	p < 0.0001
Discomfort	10.907 (42.1%)	1.040 (26.0%)	6.369 (44.2%)	3.498 (46.5%)	p < 0.0001
Impairment in learning	9.845 (38.0%)	621 (15.5%)	5.604 (38.9%)	3.620 (48.2%)	p < 0.0001
drowsiness / tiredness	9.460 (36.5%)	729 (18.2%)	5.163 (35.8%)	3.568 (47.5%)	p < 0.0001
Tightness under the mask	9.232 (35.6%)	968 (24.2%)	5.427 (37.7%)	2.837 (37.7%)	p < 0.0001
Feeling of shortness of breath	7.700 (29.7%)	677 (16.9%)	4.440 (30.8%)	2.583 (34.4%)	p < 0.0001
Dizziness	6.848 (26.4%)	427 (10.7%)	3.814 (26.5%)	2.607 (34.7%)	p < 0.0001
Dry neck	5.883 (22.7%)	516 (12.9%)	3.313 (23.0%)	2.054 (27.3%)	p < 0.0001
Syncope	5.365 (20.7%)	410 (10.2%)	2.881 (20.0%)	2.074 (27.6%)	p < 0.0001
Unwillingness to move, unwillingness to play	4.629 (17.9%)	456 (11.4%)	2.824 (19.6%)	1.349 (17.9%)	p < 0.0001
Itching in the nose	4.431 (17.1%)	513 (12.8%)	2.550 (17.7%)	1.368 (18.2%)	p < 0.0001
Nausea	4.292 (16.6%)	310 (7.7%)	2.544 (17.7%)	1.438 (19.1%)	p < 0.0001
Feeling of weakness	3.820 (14.7%)	300 (7.5%)	2.020 (14.0%)	1.500 (20.0%)	p < 0.0001
Abdominal pain	3.492 (13.5%)	397 (9.9%)	2.292 (15.9%)	803 (10.7%)	p < 0.0001
Accelerated respiration	3.170 (12.2%)	417 (10.4%)	1.796 (12.5%)	957 (12.7%)	p < 0.0001
Disease feeling	2.503 (9.7%)	205 (5.1%)	1.328 (9.2%)	970 (12.9%)	p < 0.0001
Tightness in the chest	2.074 (8.0%)	161 (4.0%)	1.122 (7.8%)	791 (10.5%)	p < 0.0001
Flickering eyes	2.027 (7.8%)	149 (3.7%)	1.047 (7.3%)	831 (11.1%)	p < 0.0001
Loss of appetite	1.812 (%)	182 (4.5%)	1.099 (7.6%)	531 (7.1%)	p < 0.0001
tachycardia, stumbling heart stings	1.459 (5.6%)	118 (2.9%)	766 (5.3%)	575 (7.6%)	p < 0.0001
Noise in the ears	1.179	107	632	440	p < 0.0001

	(4.5%)	(2.7%)	(4.4%)	(5.9%)	
Short-term impairment of consciousness / fainting spells	565 (2.2%)	39 (1.0%)	274 (1.9%)	252 (3.4%)	p < 0.0001
Vomiting	480 (1.9%)	40 (1.0%)	296 (2.1%)	144 (1.9%)	p < 0.0001

Table 4: Further behavior of the children, changed by wearing the mask, from parents' point of view

	Total age group	Age group 0-6 years	Age group 7-12 years	Age group 13-18 years	Test for difference
The child is more often irritated than usual	11 364 (60.4%)	1 041 (40.0%)	6 566 (62.1%)	3 757 (66.5%)	p < 0.0001
The child is less cheerful	9 286 (49.3%)	959 (36.9%)	5 640 (53.3%)	2 687 (47.6%)	p < 0.0001
The child no longer wants to go to school/kindergarten	8 280 (44.0%)	824 (31.7%)	5 168 (48.9%)	2 288 (40.5%)	p < 0.0001
The child is more restless than usual	5 494 (29.2%)	773 (29.7%)	3 515 (33.2%)	1 206 (21.4%)	p < 0.0001
The child sleeps worse than usual	5 849 (31.1%)	633 (24.3%)	3 507 (33.2%)	1 709 (30.3%)	p < 0.0001
No other abnormalities	7 103 (27.4%)	1 400 (35.0%)	3 834 (26.6%)	1 869 (24.9%)	p < 0.0001
The child has developed new fears	4 762 (25.3%)	713 (27.4%)	2 935 (27.8%)	1 114 (19.7%)	p < 0.0001
The child sleeps more than usual	4 710 (25.0%)	319 (12.3%)	2 183 (20.6%)	2 208 (39.1%)	p < 0.0001
The child plays less	2 912 (15.5%)	400 (15.4%)	1,998 (18.9%)	514 (9.1%)	p < 0.0001
The child has a greater urge to move than usual	1 615 (8.6%)	253 (9.7%)	1,124 (10.6%)	238 (4.2%)	p < 0.0001

The optional possibility to leave name and e-mail address for possible questions was used by 27.1% (5 513) of the participants. A validation performed with the software *Bouncer* proved 4 710 (85.4%) of the mail addresses to be reachable.

Discussion

The explosiveness of the topic and the need for communication of the interviewees are made clear by the "viral" use of the registry within a few days after publication, leading within one week to 25 930 parental

entries for affected children in Germany (approx. 0.2% of the population). The fact that 23.1% of the participating parents used the optional possibility of leaving their name and valid e-mail address for possible questions shows the seriousness of the entries. According to the status report of the Robert Koch Institute (RKI) of October 25, 2020, there were a total of 429 181 reported infections in Germany, with an increasing trend, of which 8 764 (3.6% of the reported) were under 10 years of age and 16 548 (6.7% of the reported) were between 10 and 19 years of age [1]. This is less than the number of children reported in this registry within one week. It is still unclear whether children are less likely than adults to be infected with SARS-CoV-2 and transmit the infection to adults in such a way that the latter become seriously ill [2-5]. However, it has been shown that the majority of infected children, especially up to the age of 10, develop no or only mild symptoms [6-9]. In rare cases, children up to the age of 10 years develop severe courses of the disease. The one child and two adolescents who have died of COVID-19 (as of 25.10.2020, not yet described in detail by the RKI) had chronic pre-existing conditions [10, 11]. In Europe, children under 10 years of age rarely seem to be spreaders in this infection process, although data from India, a country with a different hygiene background, do ascribe a certain transmission role to children (although without differentiation between 5-year-olds and 17-year-olds) [12]. A Scottish study of 300 000 households found that the more children in the household, the less likely adults are to be hospitalized with COVID-19 [13]. A recent study suggests that children emit less aerosol when singing and talking than adults [14].

Based on our data, it can be said that the effects of compulsory masks on the quality of life and presumably also on the health of individual children should not be ignored by politics and society. While many children tolerate the mask relatively easily, there are clearly children who cannot be expected to wear a mask in good conscience, especially when the effectiveness of the mouth and nose protection in smaller children is questionable. Parents, teachers and doctors report stigmatization, exclusion and aggressive behavior towards children who do not wear a mask for psychological or medical reasons. Inappropriate use of masks, which tends to be the case in children, may increase the risk of pathogen spread and transmission through the increased tendency to put their fingers in their face, and may thus be worse than not wearing a mask at all in some cases [15]. Looking at the symptom spectrum of the complaints, 66.1% of the interviewees show a clear and broadly diversified burden of complaints, both in the physical (rashes, headaches, etc.), as well as in the mental (fears, irritability, etc.) and intellectual (concentration disorders) areas in the children of the interviewees. In addition to acute health impairments with, in individual cases, significantly experienced health impairments, the long-term effects on the various developmental areas that go beyond well-being, such as language, play, learning, communication, sensomotoric development and empathy of children are difficult to assess. The often mentioned headaches and concentration difficulties should be seriously explored in their importance for cognitive development. It is noticeable that the distribution of complaints fits well with the age of the children (Tables 3 and 4), which supports the plausibility of parental input.

Direct effects of indoor CO₂ concentration on cognitive functions have been demonstrated [16]. This is not directly transferable to the air breathed under the masks, but increased CO₂ concentrations could occur under some mask types. This may be particularly true in small children with large fabric masks,

which sometimes have a thicker material and which were used particularly frequently by the children in the registry (65.2%). Families are currently free to choose their children's mask type according to the thickness of the material and thus there is still a margin between breathable and multi-layer, rather airtight models, yet the problem remains that parents, regardless of whether or not they themselves approve of the corona protection measures, can overburden their children through ignorance or fear of infection by using masks that are inappropriate for their child. A benefit-risk analysis is therefore called for. However, this is complicated by the fact that the study situation is extremely weak both in terms of benefits and risks. Both the calculations of a benefit from masks and almost all studies of the risks of masks are based on adults. It must also be assumed that the SARS-CoV-2 protection standards for schools, such as those of the German statutory accident insurance, are not known everywhere [17]. In particular, they contain recommendations on recovery times when wearing masks for schoolchildren with short breaks and, at the latest after three hours of wearing, a subsequent recovery time of 15-30 minutes [17].

Limitation of the results: Even though the rapid development of the registry and the high number of participants within a few days is impressive, this first evaluation of the Co-Ki mask registry has limitations. The fact that 38.5% of the participants indicated a university degree could be an indication that the registry was not equally accessible to all groups of people as an online version and due to its complexity. All online registries have this problem. A reporting bias (also with regard to the preferential documentation of particularly severely affected children) cannot be ruled out. In addition, the link to the registry was also found in social media forums, among other places, which criticize the government's corona protection measures in principle, which is partly reflected in the results of the query on attitudes to the government's corona protection measures. At the same time, other participants reported that their children had no complaints.

Both the gender distribution and the distribution of participants according to federal states, as well as the distribution of symptoms according to age, speak in favor of the data being representative for the German population of children. With a few exceptions, the data sets in the free text entries reflect differentiated, sincere parents and, taken as a whole, provide a balanced overall picture with a plausible spectrum of symptoms and a comprehensive description of the impairments observed in children in connection with the mask. The hundreds of incoming e-mails to the study initiators, including questions about the existence of the registry, specification and completion 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 the honesty with which many participants address the question. Naturally, an openly accessible registry can never provide a medical counter-validation of all submissions. The number of entries in the registry is continuing to increase daily. The registry questionnaire will be expanded and validated on the basis of the new symptoms entered by parents in the free text information.

Conclusion

Many children are subject to great challenges and families try to master these as best they can. While the proportion of people tested positive for SARS-CoV-2 and also the number of intensive care patients in

Germany is high in many places, we report here on a relatively small, unrepresentative problem: several thousand children who seem to suffer from wearing the mask or who may experience health problems from the mask. Our study provides the basis for a representative survey on which a precise benefit-risk analysis of mask wearing in children can be built.

" Conclusion For The Practice"

- A certain percentage of children and adolescents have non-negligible complaints when wearing the mask. These children should not be stigmatized.
- This worldwide first registry on side effects of the mask reflects the spectrum of symptoms in children and adolescents.
- A precise benefit-risk analysis is urgently required. The occurrence of reported side effects in children due to wearing the masks must be taken seriously and requires a precise clarification of the accompanying health circumstances, the situation of wearing the mask (duration, breaks and mask type) and the school situation.
- Furthermore, all parents, doctors, pedagogues and others are invited to participate in www.co-ki-masken.de to document their observations on effects that occur when wearing the mask. The registry will also be available in English from 15.12.2020.

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Supplemental Information

Supplemental Information is not available with this version.

Figures



Figure 1

Distribution of participants by federal state. First row: Name of the federal state, second line: Parents in the registry, as absolute and relative frequency (as of 26.10.2020). Third line: Population in Germany in

comparison, as absolute and relative frequency. The distribution of contributors corresponds approximately to the respective share of the population.