Unravelling the role of the mandatory use of face covering masks for the control of SARS-CoV-2 in schools: a quasi-experimental study nested in a population-based cohort in Catalonia (Spain)

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ABSTRACT

Objective To assess the effectiveness of mandatory use of face covering masks (FCMs) in schools during the first term of the 2021–2022 academic year.

Design A retrospective population-based study. **Setting** Schools in Catalonia (Spain).

Population 599 314 children aged 3–11 years attending preschool (3–5 years, without FCM mandate) and primary education (6–11 years, with FCM mandate). **Study period** From 13 September to 22 December 2021 (before Omicron variant).

Interventions A quasi-experimental comparison between children in the last grade of preschool (5 years old), as a control group, and children in year 1 of primary education (6 years old), as an interventional group.

Main outcome measures Incidence of SARS-CoV-2, secondary attack rates (SARs) and effective reproductive number (R*).

Results SARS-CoV-2 incidence was significantly lower in preschool than in primary education, and an increasing trend with age was observed. Six-year-old children showed higher incidence than 5 year olds (3.54% vs 3.1%; OR 1.15 (95% CI 1.08 to 1.22)) and slightly lower but not statistically significant SAR (4.36% vs 4.59%; incidence risk ratio 0.96 (95% CI 0.82 to 1.11)) and R* (0.9 vs 0.93; OR 0.96 (95% CI 0.87 to 1.09)). Results remained consistent using a regression discontinuity design and linear regression extrapolation approaches. Conclusions We found no significant differences in SARS-CoV-2 transmission due to FCM mandates in Catalonian schools. Instead, age was the most important factor in explaining the transmission risk for children attending school.

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BACKGROUND

Experimental studies have established the efficacy of masks showing 50%–90% reductions in emissions depending on the type of mask. ¹⁻⁶ Furthermore, some observational studies have shown that the use of masks can be effective in reducing the transmission of respiratory viruses in certain conditions or settings. ⁷⁻¹⁰

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Only laboratory or observational studies have been performed to explore the effect of face covering masks (FCMs) or its mandate in preventing COVID-19 transmission in schools.
- ⇒ To date, there have been no randomised controlled trials on the FCM mandate in schools.
- ⇒ There is a lack of scientific evidence supporting the decision to make FCM mandatory for children over 5 years of age.

WHAT THIS STUDY ADDS

- ⇒ We used a quasi-experimental design to study the effectiveness of the FCM mandate, comparing the outcome between children with FCM and children without.
- ⇒ The differences in secondary attack rate (SAR) or R* between children attending the last preschool year (P5) and children in the first year of primary education were not statistically significant.
- ⇒ Age dependency is key for understanding SARS-CoV-2 transmission with the Delta variant, reinforcing the same outcome that was observed with previous SARS-CoV-2 variants.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ FCM mandate for children attending school is based on insufficient scientific evidence.

The mandatory use of face covering masks (FCMs) was implemented in many countries, as one of the non-pharmaceutical interventions (NPIs) aimed at preventing the transmission of the SARS-CoV-2 during the COVID-19 pandemic. In addition, some countries extended FCM mandates to schools despite the European Centre for Disease Prevention and Control and WHO only recommended their use for children over 12, or in situations where community transmission is high. ¹¹ ¹²



Original research

COVID-19 is less severe in children probably due to several age-related factors in innate and adaptive immune response. Recent studies about the effectiveness of FCM mandates in educational settings show mixed results. Some of these studies have used an ecological design, and their findings may have been affected by various limitations and confounders.

In Catalonia (Spain), schools include children between 3 and 12 years old. Despite education not being mandatory until 6, almost all children between 3 and 5 years old go to school and share the same building or educational space with older children. After school closures in March 2020, schools reopened in September 2020 for face-to-face classes with some NPI including FCM (mandatory for 6 years and older) and bubble groups with a fixed and stable number of students and teachers. The whole bubble group was quarantined and tested whenever a positive case was detected. 22 A study performed during the first term of the 2020-2021 academic year showed an age dependency on SARS-CoV-2 transmission in schools.²³ At the beginning of the first school term of 2021-2022, before the Omicron wave, Delta was the most prevalent variant, vaccination coverage was 92% for teachers, and children under 12 were not yet eligible for vaccination.²⁴ This situation allowed us to perform a quasiexperimental study for analysing the effectiveness of the FCM mandate in schools.

We analysed routinely collected health data to compare the incidence of SARS-CoV-2, secondary attack rates (SARs) and the effective reproductive number (R*) among school children, comparing those without mandatory FCM (3–5 year olds) and those with FCM (6–11 year olds) during the first term of the school year 2021–2022, to assess the effect of FCM mandates on SARS-CoV-2 transmission within schools.

METHODS

Study design and data sources

A retrospective population-based cohort study was designed using data from the official census of school age children in Catalonia linked to the regional central database of reverse transcriptase PCR (RT-PCR) and lateral flow tests (LFTs) for SARS-CoV-2. During the whole study period, each time a positive case was detected by the health system, the whole bubble group was immediately quarantined for a 10-day period, and all children were tested with an RT-PCR 4–6 days after their last contact with the initial case, with a recommendation of a second test if symptoms appeared despite a negative test result.

Participants, cohorts and follow-up

The study population was a cohort of children aged between 3 and 11 years assigned to a stable bubble group according to the 2021–2022 academic census from the Catalan Department of Education. We excluded those with either more than 30 or less than five members, to ensure better intra-group stability. We also excluded schools that did not have bubble groups for all nine academic years, to ensure similar in-school protocols for both cohorts.

We used data from the first term of the 2021–2022 academic year (13 September to 22 December 2021) for the purposes of recruiting, and allowed for 10 more days (until 1 January 2022) for the occurrence of possible secondary cases for SAR and R* calculations.

We defined an index case as the first case in a bubble group in a 10-day window, and secondary cases were defined, according to Catalan SARS-CoV-2 guidelines, as any case testing positive within the 10 days following an index case in their bubble group.

A student testing positive after this 10-day period was considered as a new index case.

Analyses were performed at bubble group and academic year levels. Groups were analysed by school year, three in the preschool stage (P3, P4 and P5 according to the age of the students in each group) and six in the primary education stage (years 1–6, ages 6–11 years). In Catalonia, preschool and primary education children share the same school buildings, while kindergarten is only for younger children (under 3 years).

Our main analysis was the comparison of the epidemiological variables between children at P5 year and children at year 1 of primary education. The only difference between them, regarding NPI, was the FCM mandate: children at P5 without the mandatory use of FCM and children at year 1 of primary education with mandatory use of FCM. To contextualise, we have also compared the results of the other school years.

Study outcomes and epidemiological measures

The primary outcome was SARS-CoV-2 infection, defined by the date of the first positive RT-PCR or LFT, regardless of the presence of any symptom or clinical diagnosis.

For each school year, we calculated three epidemiological variables:

- ► Incidence of SARS-CoV-2 infection: as the number of children with a positive test divided by the population.
- ► SAR: the number of new cases in a bubble group divided by the total number of at-risk group members after subtracting the index case. SAR was calculated for each bubble group, and then summarised for each year as the mean and the median
- ▶ R*: the average number of secondary cases for each index case as described elsewhere. ²³ The average R* was calculated for all bubble groups within each school year.

Statistical analysis

For descriptive analysis, we expressed continuous variables as mean (SD) or median (IQR) and summarised categorical variables as number (percentage). We calculated a 95% CI for SARS-CoV-2 incidence and SAR. We used a logistic regression model to estimate the OR and 95% CI of SARS-CoV-2 incidences and a negative binomial model to estimate the incidence risk ratio (IRR) and 95% CI of SAR between the P5 school year, and the first year of primary education. From the distribution of cases, we fitted a negative binomial distribution to obtain the mean (R*) and the 95% CI from the SD.

In addition, we performed a regression discontinuity design (RDD) analysis for incidence considering age instead of grade, as a part of a post hoc analysis. Finally, we ran a simulation analysis assuming that the age trend observed in previous studies²³ is a parameter that should be maintained in our data across the different grades (see online supplemental material for further details of both analyses).

We used R V.4.0.0 and MATLAB V.2021b for the analyses.

RESULTS

A total of 1907 schools, 28575 bubble groups and 599314 (94.7%) pupils were included in the analysis after the exclusions (figure 1).

The number of SARS-CoV-2 infections during the study period was 24762 (4.13%). Table 1 summarises the number of students, bubble groups and SARS-CoV-2 infections for each school year.

Figure 2 shows the 7-day moving average of SARS-CoV-2 infections by school year. We observed that all school years

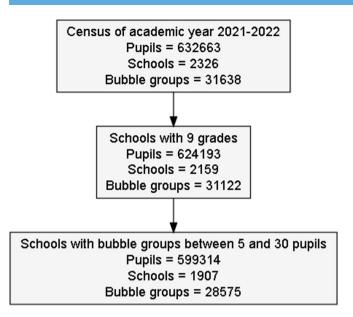


Figure 1 Population flow chart.

follow a similar pattern, and preschool years were consistently less infected than older children. Incidence was lower in preschool stage than in primary education, ranging between 1.74% in P3 and 5.91% in year 6 of primary education (table 2).

We analysed 13 404 outbreaks during the study period. On average, 57% had no secondary cases, but there were more outbreaks without secondary cases in preschool (70%) than in primary education (53%) (table 1). Median SAR was 0 in all years except for year 6 of primary education (table 2). Figure 3 shows the mean SAR by school year. While lower values were observed in preschool (2.34%, 2.77% and 4.59% in P3, P4 and P5, respectively), the highest value was in year 6 of primary education, with a mean SAR of 7.17%. The same pattern was observed for R*, highlighting the low values in preschool P3 and P4 and the R*>1 for years 3, 4, 5 and 6 of primary education (figure 3).

Our main analysis shows that SARS-CoV-2 incidence and the percentage of positive tests were significantly higher for year 1 of primary education than in P5: incidence was 3.54% vs 3.1%, with an OR of 1.15 (95% CI 1.08 to 1.22); and test positivity was 7.98% (95% CI 7.69% to 8.27%) and 6.82% (95% CI 6.55% to 7.10%), respectively. Conversely, SAR and R* were similar for both years. Median SAR was 0, and mean SAR was slightly

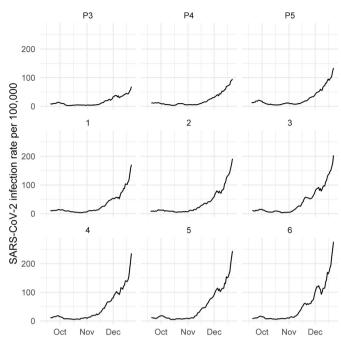


Figure 2 The 7-day moving average of daily SARS-CoV-2 infection rates per 100 000 population by school year (P3–P5 for preschool, and years 1–6 for primary education).

lower—but not statistically significant—in year 1 of primary education than in P5, 4.36% vs 4.59%, respectively (IRR 0.96 (95% CI 0.82 to 1.11)). Furthermore, R* was not significantly lower for year 1 of primary education either: 0.90 vs 0.93 (OR 0.96 (95% CI 0.87 to 1.09)) (see table 2 and figure 3). Additionally, the RDD analysis found a non-statistically significant absolute difference of -0.0089% (p value 0.930); and the simulation analysis extrapolating the regression from primary education rendered expected values for incidence, SAR and R* in P5 not significantly different from the observed (online supplemental material).

DISCUSSION

The main findings of the study show no significant differences for children in the last grade of preschool (P5) and the first year of primary education in COVID-19 transmission indicators during the study period, despite their difference in FCM mandate and the strong age dependency of transmission of

School year	Mean age (SD)	Students (n)	Bubble groups	Cases from 13 September to 22 December 2021	Index cases (outbreaks)	Secondary cases	% of outbreaks without secondary cases
P3	3.1 (0.3)	54210	2932	942	724	307	75.3
P4	4.0 (0.2)	60 094	2994	1388	976	526	72.7
P5	5.0 (0.3)	63 344	3040	1966	1133	1052	64.2
1	6.0 (0.2)	66 204	3148	2346	1405	1269	61.3
2	7.0 (0.2)	67 455	3186	2781	1569	1566	56.3
3	8.1 (0.3)	66614	3131	3074	1638	1877	53.1
4	9.0 (0.3)	71 590	3292	3703	1879	2436	52.6
5	10.1 (0.3)	73 702	3349	4062	2029	2611	51.0
6	11.0 (0.3)	76 101	3503	4500	2051	3092	48.8
Preschool education (P3–P5)		177 648	8966	4296	2833	1885	70.0
Primary education (years 1–6)		421 666	19609	20 466	10571	12851	53.3
Total		599314	28575	24762	13 404	14736	56.8

Table 2 SARS-CoV-2 incidence, secondary attack rate (SAR), effective reproductive number (R*) and percentage of positive tests by school year

		SAR	SAR		
Year (age in years)	SARS-CoV-2 incidence (95% CI)	Mean (SD)	Median (IQR)	R* (95% CI)	% of positive tests (95% CI)
P3 (3)	1.74% (1.63 to 1.85)	2.34% (5.53)	0.00 (0.00-0.00)	0.42 (0.35 to 0.49)	3.26 (3.06 to 3.45)
P4 (4)	2.31% (2.19 to 2.43)	2.77% (6.55)	0.00 (0.00-4.17)	0.54 (0.46 to 0.61)	4.89 (4.65 to 5.12)
P5 (5)	3.10% (2.97 to 3.23)	4.59% (9.30)	0.00 (0.00-5.00)	0.93 (0.82 to 1.04)	6.82 (6.55 to 7.10)
1 (6)	3.54% (3.40 to 3.68)	4.36% (8.38)	0.00 (0.00-5.00)	0.90 (0.81 to 0.99)	7.98 (7.69 to 8.27)
2 (7)	4.12% (3.97 to 4.27)	4.92% (8.95)	0.00 (0.00-5.88)	1.00 (0.91 to 1.08)	8.67 (8.38 to 8.96)
3 (8)	4.61% (4.45 to 4.77)	5.57% (9.52)	0.00 (0.00-7.62)	1.15 (1.05 to 1.24)	9.09 (8.80 to 9.37)
4 (9)	5.17% (5.01 to 5.33)	6.10% (9.76)	0.00 (0.00-8.33)	1.30 (1.20 to 1.39)	10.02 (9.74 to 10.31)
5 (10)	5.51% (5.35 to 5.67)	6.06% (9.86)	0.00 (0.00-8.33)	1.29 (1.20 to 1.38)	9.55 (9.29 to 9.81)
6 (11)	5.91% (5.74 to 6.08)	7.17% (11.8)	3.85 (0.00-9.09)	1.51 (1.40 to 1.61)	10.36 (10.09 to 10.63)

SARS-CoV-2 in schools. This reinforces the results published for the year 2020–2021, but with a more transmissible SARS-CoV-2 Delta variant.²³

The age trend observed for P5 and older children follows a different pattern when P3 and P4 are included in the analysis. With no mandatory use of FCM, the youngest children have significantly lower transmission indicators when compared with any other group. These findings may be related to the age decrease trend of the innate or adaptive immunological response, and a shift towards an adult-like immunological response pattern as the child enters primary school as had already been described. If Finally, as primary infection with several human coronaviruses typically occurs early in childhood, higher production of cross-reactive T cells in younger children is to be expected. This might explain the low intraclass transmission of the SARS-CoV-2 found here and in some studies.

Despite no significant differences between P5 and year 1 of primary education being found in transmission indicators, the extrapolation analysis of SAR and R* from primary education suggests transmission was slightly higher than expected in P5, although non-statistically significant. This could be explained

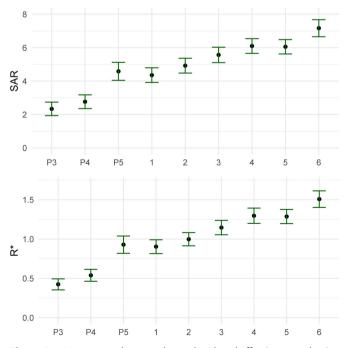


Figure 3 Mean secondary attack rate (SAR) and effective reproductive number (R*) with 95% CI by school year (P3–P5 for preschool and years 1–6 for primary education).

by different classroom dynamics that may involve closer contact between the younger children, and by the lower test positivity in P5 compared with primary education suggesting a greater diagnostic effort.

Other studies that found some effects of FCM have certain limitations due to their ecological design, with no distinction between children and adolescents in their analyses, or to not taking differences in staff vaccination status or testing rate into account.²⁰ ²⁷ It should be noted that substantial reductions in transmission have only consistently been detected in laboratory settings and in tightly controlled environments.^{4 9 10} However, our results are similar to other studies analysing the impact of mask-wearing policies for students in educational settings.^{28 29}

Our study has certain limitations. We performed an intentionto-treat analysis. This means that there may have been children in P5 who did use FCM, and also children in year 1 of primary education who used them incorrectly. However, the aim of our study was not to measure the individual effectiveness of FCM, but to evaluate the effectiveness of mask mandates in the realworld context of schools. Although both cohorts were balanced at territorial and socioeconomic levels given the study design, there may be other variables that were not considered (ie, classroom dynamics or the density of students in the classroom). Besides, we are probably over-reporting the study outcomes because we do not distinguish possible concomitant cases in a 10-day window. In addition, a higher percentage of asymptomatic infections in younger children might produce reduced detection of single individual asymptomatic cases, but huge diagnostic efforts to detect secondary infections have been in place since the previous academic year.³⁰ Finally, although quasi-experimental designs lack the randomised controlled trial (RCT) ability to equally distribute confounding between groups, they are a better approach than other designs commonly used in this field.

During the study period, Delta was the most prevalent SARS-CoV-2 variant. However, at the beginning of January 2022, Omicron became the dominant variant (>95% on 5 January 2022 according to Catalan authorities). At the beginning of the second term (10 January 2022), 7-day cumulative COVID-19 per 100 000 inhabitants was 2391.6 (see official Catalan website about COVID-19: https://dadescovid.cat/?lang=eng). That could affect the odds to find a secondary case that in fact is a concomitant case. In addition, school guidelines were the same during the analysed term but changed for the second term of the academic year 2021–2022. Finally, the vaccination campaign for children between 5 and 11 years was launched at the end of December 2021. Data from the second term are thus not comparable to the data analysed in our article. Nevertheless, it is

unlikely that the effectiveness of the mask mandate measure will increase with a more transmissible variant.

This study also has strengths. We analysed two homogeneous cohorts (P5 and year 1 of primary education), the latter with mandatory use of FCM, acting as an interventional group, and the former without, as a control group. We do not expect to find great differences in the host response due to the age or in the behaviour between both grades that could influence the results obtained, although it should be considered that classroom dynamics may be different. Given the difficulty of conducting RCT in educational settings, this quasi-experimental analysis is the best possible approach to the aim of the study. In addition, the analysis of the rest of the years of primary education shows an age-dependency increase trend for all the epidemiological measures, suggesting that age is an important component. This is consistent with the findings of a study performed with data from the first term of the previous academic year and different SARS-CoV-2 variant.²³ Finally, our results are consistent using different statistical approaches.

In conclusion, FCM mandates in schools showed no significant differences in terms of transmission. Conversely, we found that age is a key component explaining transmission in children. Considering the non-effectiveness of FCM mandates found in our quasi-experimental approach, and the negative impact on children's health of some measures implemented to mitigate transmission, such as school closures, ^{31 32} policymakers should ensure that all measures within schools are evaluated (including school closures, home schooling, bubble groups, ventilation, test and trace, etc), and that the risks and benefits of such interventions are balanced.

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Supplementary material of:

Unravelling the role of mandatory use of masks for SARS-CoV-2 control in schools: A quasi-experimental study nested in a population-based cohort in Catalonia (Spain)

Appendix 1: Details of the regression discontinuity design (RDD)

Methods

In order to maintain the assumptions required for a RDD analysis and to increase the number of observations, we use age in months at the end of the study period instead of grade. This limit our analysis only for incidence since it is not possible to calculate SAR or R* by age in months. These two main transmission indicators are aggregate measures as they are calculated at the bubble group level. The cutoff of the RDD analysis was set at 72 months of age, coinciding with the limit between P5 (without FCM mandate) and year 1 of primary education (with mandatory use of FCM). In addition, to focus on two more comparable ages, the same analysis was performed only for children aged between 60 and 83 months.

Results

Figure S1 shows the result of the RDD analysis for SARS-CoV-2 incidence. We found a non-statistically significant absolute difference of -0.0089% (p-value: 0.930).

The same analysis was performed with the two nearest ages around the cutoff (5 and 6 years) and we also found a non-statistically significant difference of -0.0634% (p-value: 0.728) (**Figure S2**).

Figure S1. RDD analysis for SARS-CoV-2 incidence using age in months. Observed incidences by months of age are split at the cutoff at 72 months (discontinued black line). The shadow areas indicate the 95% CI of the corresponding regression lines (green: 36 to 71 months, blue: 72 to 143 months)

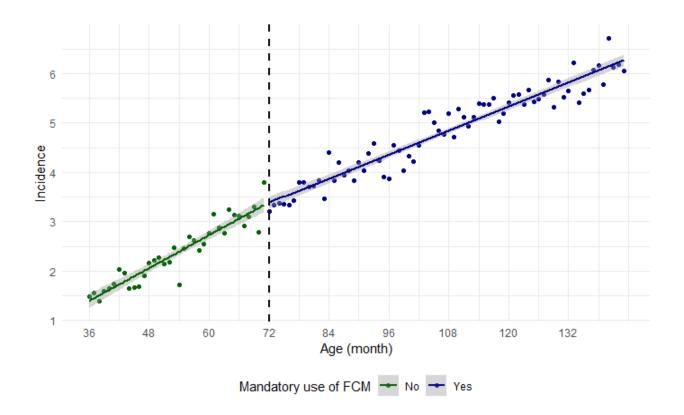
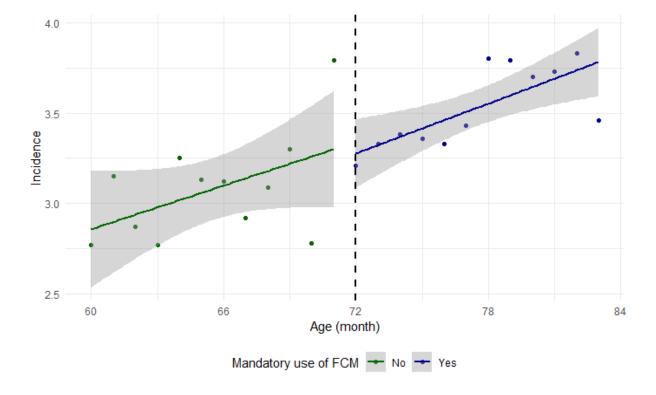


Figure S2. RDD analysis for SARS-CoV-2 incidence using age in months for children aged between 60 and 83 months (5 and 6 years old). Observed incidences by months of age are split at the cutoff at 72 months (discontinued black line). The shadow areas indicate the 95% CI of the corresponding regression lines (green: 60 to 71 months, blue: 72 to 83 months).



Appendix 2: Details of the regression model (simulation)

<u>Methods</u>

We performed a simulation analysis assuming that the age trend observed in previous studies is a parameter that should be maintained in our data across the different grades. First, we fitted a linear regression model to data of primary education (6 to 11 years of age) for incidence, SAR and R*. Then, we extrapolated the model to preschool groups and assessed which the expected values would be if the primary trend was followed. The fittings were performed using the function *fitlm* of Matlab 2021b. The 95% CI were assessed using the function *predict*. This function was also used to extrapolate the model to preschool grades.

Results

The linear regression model to data from primary education grades provides an R² of 0.99 (incidence-age), 0.95 (SAR-age) and 0.96 (R*-age). After extrapolating a backward regression to P5, we observe that both SAR and R* are, non-significantly, 18% higher than those expected from the regression model, while the incidence remains 2% below the expected value. The difference between the number of expected and observed secondary cases for P5 was 162 (95% CI: -28–352) in a population of 63,344 students (0·3%) during the whole study period. On the other hand, P3 and P4 show mean SAR values that are 19% (P3) and 18% (P4) lower than those expected from the regression model. The observed R* values would be 24% (P3) and 20% (P4) lower than those expected, and the incidences would be 21% (P3) and 14% (P4) below the expected values (**Figures S3, S4** and **S5**).

Figure S3. Linear regression model of incidence with age. The regression model is fitted to data of primary grades (6 to 11 years old). The shadow indicates the 95% CI of the fitting. Observed values are split between those that were used in the regression model (black points, primary education grades) and those that were not (blue points, preschool grades).

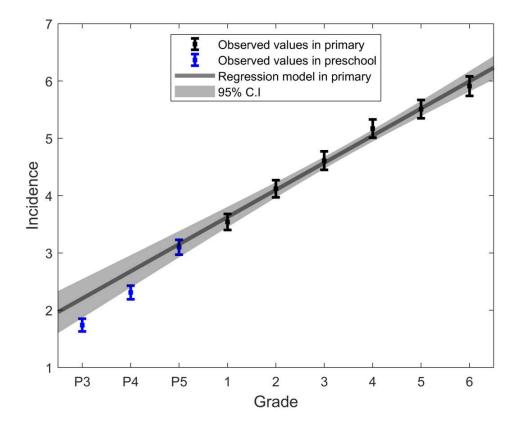


Figure S4 Linear regression model of secondary attack rate (SAR) with age. The regression model is fitted to data of primary education grades (6 to 11 years old). The shadow indicates the 95% CI of the fitting. Observed values are split between those that were used in the regression model (black points, primary education grades) and those that were not (blue points, preschool grades).

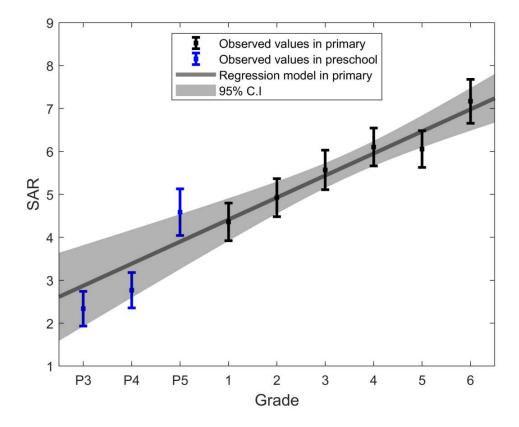


Figure S5 Linear regression model of effective reproduction number (R*) with age. The regression model is fitted to data of primary education grades (6 to 11 years old). The shadow indicates the 95% CI of the fitting. Observed values are split between those that were used in the regression model (black points, primary education grades) and those that were not (blue points, preschool grades).

