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# Epidemiological impact of revoking mask-wearing recommendation on COVID-19 transmission in Tokyo, Japan



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#### **ABSTRACT**

Despite the global implementation of COVID-19 mitigation measures, the disease continues to maintain transmission. Although mask wearing became one of the key measures for preventing the transmission of COVID-19 early in the pandemic period, many countries have relaxed the mandatory or recommended wearing of masks. The objective of the present study was to estimate the epidemiological impact of removing the mask-wearing recommendation in Japan. We developed a model to assess the consequences of declining mask-wearing coverage after the government revoked its recommendation in February 2023. The declining mask-wearing coverage was estimated using serial cross-sectional data, and a mathematical model was devised to determine the age-specific incidence of COVID-19 using the observed case count in Tokyo from week of October 3, 2022 to October 30, 2023. We explored model-based counterfactual scenarios to measure hypothetical situations in which the mask-wearing coverage decreases or increases relative to the observed coverage. The results show that mask-wearing coverage declined from 97% to 69% by the week of October 30, 2023, and that if the mask-wearing recommendation had continued, 427 lives could have been saved in Tokyo. If the mask-wearing coverage had declined to 25% of the observed level, the model suggests there might have been 1587 additional deaths. Thus, revoking the mask-wearing recommendation had a substantial epidemiological impact. In future pandemics, our proposed approach could provide a realtime quantification of the effects of relaxing countermeasures.

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### 1. Introduction

The COVID-19 disease, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), started spreading across the world in 2019, reaching 770 million confirmed cases and 7 million deaths as of March 4, 2024 ([Word Health Organization,](#page-11-0) [2024\)](#page-11-0). As the disease began to spread, various pharmaceutical and non-pharmaceutical countermeasures were implemented. In particular, mask wearing became a key individual measure for the prevention and control of COVID-19 because of the respiratory and aerosol-associated nature of infection. From the early phase of the pandemic, many countries adopted a mandatory mask-wearing policy ([Cheng et al., 2020\)](#page-9-0). A substantial fraction of secondary transmission can occur from pre-

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symptomatic ([Nishiura et al., 2020\)](#page-10-0) and asymptomatic individuals [\(Johansson et al., 2021](#page-10-1)), so the effectiveness of reactive countermeasures on symptom onset has not been sufficient to halt the transmission of the disease. Thus, recommending or mandating universal mask wearing regardless of symptoms has been considered useful. The population-based effect of mask wearing has been assessed in real time. For instance, in the United States, mandatory mask wearing in school settings was shown to reduce the risk of infection among children and staff [\(Cowger et al., 2022\)](#page-9-1), and mask wearing in households was demonstrated to prevent secondary transmission [\(Wang et al., 2020b](#page-10-2)). A systematic review indicated that imposing community-wide mask wearing is effective in reducing the incidence of infection, hospitalizations, and deaths associated with COVID-19 ([Ford et al., 2021\)](#page-9-2).

The Japanese government has never mandated mask wearing, and only recommended it throughout the course of the pandemic ([Ministry of Health, Labour and Welfare of Japan, 2023a\)](#page-10-3). Despite the voluntary nature of this recommendation, mask-wearing coverage remained high compared with other countries during the pre-vaccination period from 2020 to 2021 ([Nippon Research Center, 2021](#page-10-4)). From around early 2022, when vaccines and antiviral drugs became widespread and following the emergence of the Omicron variant (B.1.1.529), many countries started to downgrade the control policies associated with COVID-19, including the mask-wearing recommendation [\(European Union Aviation Safety Agency, 2022](#page-9-3)). Japan was no exception, and on February 8, 2023, the government announced that it was revoking the recommendation for mask wearing from March 13, 2023, emphasizing that mask wearing was a personal decision [\(Ministry of Health, Labour and](#page-10-5) [Welfare of Japan, 2023b](#page-10-5)). On May 5, 2023, the WHO stated that they no longer considered COVID-19 to be a public health emergency of international concern [\(World Health Organization, 2023\)](#page-11-1). Japan followed suit, legally downgrading COVID-19 from Class II to Class V (from universal reporting to sentinel surveillance) under the Infectious Diseases Control Law on May 8, 2023. At that time, the government canceled a variety of countermeasures that included movement restrictions, such as quarantine, case isolation, and the avoidance of indoor contact ([Ministry of Health, Labour and Welfare of Japan, 2023b](#page-10-5)).

Even with these changes, the mask-wearing rate in Japan remained relatively high [\(Li et al., 2023\)](#page-10-6), but gradually decreased. The time-varying mask-wearing rate provided us with a precious opportunity to retrospectively evaluate the policy of revoking the mask-wearing recommendation as part of the country's exit strategy. While numerous published studies have discussed the positive epidemiological impact of mask-wearing recommendations and universal mask-wearing mandates ([Abaluck et al., 2022;](#page-9-4) [Barros et al., 2022](#page-9-5); [Boulos et al., 2023](#page-9-6); [Britton, 2021;](#page-9-7) [Bundgaard et al., 2021](#page-9-8); [Chu et al., 2020](#page-9-9); [Cowger](#page-9-1) [et al., 2022](#page-9-1); [Donovan et al., 2022;](#page-9-10) [Ford et al., 2021;](#page-9-2) [Hansen](#page-10-7) & [Mano, 2023](#page-10-7); [Howard et al., 2021](#page-10-8); [Islam et al., 2022](#page-10-9); [Leech et al.,](#page-10-10) [2022a](#page-10-10); [Li et al., 2022;](#page-10-11) [Lu et al., 2021;](#page-10-12) [MacIntyre](#page-10-13) & [Chughtai, 2020;](#page-10-13) [Mitze et al., 2020](#page-10-14); [Rader et al., 2021](#page-10-15); [Sugimura et al., 2021](#page-10-16); [Talic et al., 2021;](#page-10-17) [Wang et al., 2020a;](#page-10-18) [Wang, Tian, et al., 2020](#page-10-2); [Wong](#page-11-2) & [Balzer, 2022\)](#page-11-2), it would be interesting to explicitly assess the population impact of removing the mask-wearing recommendation on the epidemiological dynamics, potentially offering critically important evidence for public health policy.

In the present study, we explored the epidemiological impact of removing the mask-wearing recommendation on subsequent epidemics. Our study objective was to quantitatively assess the extent to which the removal of the mask-wearing recommendation promoted the transmission of COVID-19 in Japan, providing insights into evidence-based public health policy. Model-based counterfactual scenarios were also explored, measuring hypothetical situations in which the maskwearing rate decreased and increased more radically.

# 2. Method

#### 2.1. Data source

We examined the incidence of COVID-19 as extracted and estimated from sentinel surveillance in Tokyo ([Okada et al.,](#page-10-19) [2024\)](#page-10-19). To estimate the mask-wearing coverage, the percentage of people that self-reported as likely to/always wear a mask in public was retrieved from an open data source at various points in time [\(Loyalty Marketing Inc., 2023, October 14](#page-10-20); [Nippon Research Center, 2023](#page-10-21)). The study period lasted from the week of October 3, 2022 to October 30, 2023. During this period, the eighth and ninth waves of the pandemic occurred, respectively dominated by the BA.5 and XBB1.16/EG.5 variants ([Bureau of Public Health: Tokyo Metropolitan Government, 2023a;2023b](#page-9-11)). These waves were selected for analysis because the universal case count was estimated during these waves ([Okada et al., 2024\)](#page-10-19) and the weekly incidence estimate was consistently accessible to the authors. Data from the eighth wave were used to calibrate the baseline model. Data from the ninth wave, which extended over the legal downgrading of COVID-19, lasted from April 14 to October 30, 2023, were used for counterfactual analysis. The population structure as of January 1, 2023 ([Bureau of General Affairs: Tokyo Metropolitan](#page-9-12) [Government, 2023](#page-9-12)) and cumulative cases by age groups during the eighth and ninth waves in Tokyo are summarized in Supplementary Table S1. Additionally, weekly reported case numbers and estimated case counts, both from a published study ([Okada et al., 2024\)](#page-10-19), are available as supplementary data.

Other than the incidence, we extracted the age-specific estimate of the case fatality risk (CFR) during the corresponding waves. These data were used to compute the mortality for the counterfactual scenarios. We specifically used the agedependent estimate provided by Yamanashi prefecture (Supplementary Table S2), and computed the CFR of COVID-19 cases, regardless of the reported cause of death ([Yamanashi Center for Infectious Disease Control and Prevention, 2024](#page-11-3)).

#### 2.2. Model

# 2.2.1. Mask-wearing coverage

<span id="page-2-2"></span>We assumed that the mask-wearing coverage in week  $k$ ,  $w_k$ , remained stable before the mask-wearing recommendation was revoked on February 8, 2023. The equilibrium level is denoted by a constant  $\delta$ , i.e.,

$$
w_k = \delta. \tag{1}
$$

From the date on which the cancellation of this recommendation was announced, we employed an exponential function to describe the decreasing mask-wearing coverage. Let d be the number of days elapsed from February 8, 2023. We have

$$
w_{t(d)} = \delta \exp(-\varepsilon d), \tag{2}
$$

where t(d) denotes the calendar week by which d days had elapsed since February 8, 2023. We estimated the parameters  $\delta$ and  $\varepsilon$  using a nonlinear regression model (i.e., a Gaussian-distributed regression method).

#### 2.2.2. Estimating infection cases by age groups

We computed the effective reproduction number using a method proposed elsewhere, with suitable modifications to incorporate heterogeneity among age groups [\(Nishiura et al., 2010](#page-10-22)). The serial interval of the Omicron variant has been shown to be highly variable in published studies ([Madewell et al., 2023;](#page-10-23) [Park et al., 2023](#page-10-24); [Xu et al., 2023](#page-11-4)). Assuming that the mean generation time is the same as the serial interval, we hereafter set the generation time to be 3.5 days, which is the midpoint of the serial interval range from 2.1 to 4.8 days for the Omicron variants in a meta-analysis [\(Madewell et al., 2023\)](#page-10-23). Thus, it was assumed that each week contains exactly two generations of COVID-19 cases during the eighth and ninth waves of COVID-19 caused by SARS-CoV-2 Omicron variants.

As a preparation for describing the model used in the present study, we first introduce a multi-type renewal equation model that describes transmission between heterogeneous groups ([Green et al., 2022\)](#page-10-25). Here, a constant generation time distribution  $g(t)$  across all age groups is assumed. Let  $I_a(t)$  be the newly infected cases in age group a at time t. By covoluting,  $g(\tau)$  with  $I_a(t-\tau)$  ([Fraser, 2007\)](#page-10-26), the time-dependent distribution of primary cases  $J_a(t)$  can be expressed as follows:

$$
J_a\left(t\right) = \int_0^\infty I_a(t-\tau)g(\tau)\,d\tau\tag{3}
$$

<span id="page-2-0"></span>Then, the distribution of secondary cases,  $I_a(t)$  for each age group a can be expressed as a linear combination of  $J_a(t)$ :

$$
\begin{pmatrix} I_1(t) \\ \vdots \\ I_n(t) \end{pmatrix} = \begin{pmatrix} r_{11} & \cdots & r_{1n} \\ \vdots & \ddots & \vdots \\ r_{n1} & \cdots & r_{nn} \end{pmatrix} \begin{pmatrix} J_1(t) \\ \vdots \\ J_n(t) \end{pmatrix} . \tag{4}
$$

Here,  $r_{ii}$  represents the average number of secondary infection cases in group *i* resulting from cases in group *j*, and this  $n \times n$  matrix in Eq. [\(4\)](#page-2-0) constitutes the next generation matrix. To handle the weekly number of cases, we assumed that the weekly cases can be discretized into two generations and this structure remained unchanged during the study period in the present study.

Based on these premises, let  $\mu_k$  be a vector representing the expected number of cases in week k, including four different age groups;  $\mu_{ka}$  represents the expected number of cases of age group a in week k, which has the same meaning as  $I_a(k)$ . Age groups 1–4 represent people aged from 0 to 19, 20–39, 40–59, and  $\geq$  60 years, respectively. From these,  $\mu_k$  is expressed as

$$
\mu_{\mathbf{k}} = \begin{pmatrix} \mu_{k,1} \\ \mu_{k,2} \\ \mu_{k,3} \\ \mu_{k,4} \end{pmatrix} = \mu_{\mathbf{k}}^{\{1\}} + \mu_{\mathbf{k}}^{\{2\}},
$$
\n(5)

<span id="page-2-1"></span>where  $\mu_k\{1\}$  is a vector indicating the expected number of cases in the first generation of week k. Under the assumption that the next generation matrix,  $K_{\bm k}$ , remains unchanged within week k,  $\mu_{\bm k}{}^{\{2\}}$  is described as

$$
\mu_{\mathbf{k}}^{\{2\}} = \mathbf{K}_{\mathbf{k}} \mu_{\mathbf{k}}^{\{1\}}.
$$

Eq. [\(6\)](#page-2-1) is the same concept as Eq. [\(4\)](#page-2-0). Moving on to the next week, the weekly effective reproduction number is  $R_{k+1}$ . Then,  $\mu_{k+1}$ <sup>{1}</sup> is computed as

$$
\mu_{k+1}^{\{1\}} = K_{k+1} \mu_k^{\{2\}} = K_{k+1} K_k \mu_k^{\{1\}}.
$$
 (7)

Using Eqs. [\(6\) and \(7\),](#page-2-1) the expected number of cases in the second generation of week  $k+1$  is

$$
\mu_{k+1}^{\{2\}} = K_{k+1} \mu_{k+1}^{\{1\}} = K_{k+1} K_{k+1} K_k \mu_k^{\{1\}} = K_{k+1}^2 K_k \mu_k^{\{1\}}.
$$
 (8)

From Eqs. [\(6\)](#page-2-1)–[\(8\),](#page-2-1) the relationship between  $\mu_{k+1} = \mu_{k+1}^{\{1\}} + \mu_{k+1}^{\{2\}}$  and  $\mu_k = \mu_k^{\{1\}} + \mu_k^{\{2\}}$  can be described as follows:

$$
\mu_{k+1} = \{K_{k+1}(E + K_{k+1})K_k\}(E + K_k)^{-1}\mu_k,
$$
\n(9)

where  $\boldsymbol{E}$  is an identity matrix.

To fit this transmission model, we modeled  $K_k$  as follows:

<span id="page-3-0"></span>
$$
K_k = R_k \frac{M'_k}{\rho(M'_k)},
$$
\n(10)

$$
M'_{k} = Q_{k}M = \begin{pmatrix} \alpha & 0 & 0 & 0 \\ 0 & \beta & 0 & 0 \\ 0 & 0 & \gamma & 0 \\ 0 & 0 & 0 & 1 \end{pmatrix} M,
$$
 (11)

where  $R_k$  represents the weekly effective reproduction number in week k,  $\bm{M}'_{{\bm k}}$  is the matrix that defines the effective contact structure among age groups, and  $\rho(\bm{M}'_{\bm{k}})$  is the largest eigenvalue of  $\bm{M}'_{\bm{k}}$ . In Eq. [\(11\)](#page-3-0),  $\bm{M}$  is the next generation matrix in Japan, as<br>estimated in our previous study (Jung et al., 2022), and  $\bm{Q}_t$  estimated in our previous study [\(Jung et al., 2022](#page-10-27)), and  $\mathbf{Q}_k$  is the matrix that represents the susceptibility of age groups 1–3 relative to that of age group 4. By modeling  $M'_k$  as in Eq. [\(11\),](#page-3-0) we assumed a similar contact structure to that in our previous study [\(Jung et al., 2022](#page-10-27)), while also allowing flexibility to capture changes in age-group specific susceptibilities. The parameters  $\alpha$ ,  $\beta$ ,  $\gamma$  in  $\mathbf{Q}_k$  were modeled as three-step functions to consider time-dependent variations in relative susceptibility:

$$
(\alpha, \beta, \gamma) = \begin{cases} a_1, b_1, c_1 & (\text{stepA} : \text{April } 14 \le k \le \text{July } 17) \\ a_2, b_2, c_2 & (\text{stepB} : \text{July } 24 \le k \le \text{August } 28) \\ a_3, b_3, c_3 & (\text{StepC} : \text{September } 4 \le k \le \text{October } 30) \end{cases} \tag{12}
$$

Step B mirrors the summer vacation period among schoolchildren, when their contact behavior is drastically different from the other two periods.

Assuming that variations in the weekly number of cases by age group are sufficiently captured by the Poisson distribution, the likelihood function for estimating the unknown parameters  $\theta = \{R_k, \alpha, \beta, \gamma\}$  is

$$
L(\theta; \mathbf{Y_k}) = \prod_{a} \prod_{k} \frac{\mu_{k,a} Y_{k,a}}{Y_{k,a}!},
$$
\n(13)

where  $Y_k = [Y_{k,1}, Y_{k,2}, Y_{k,2}, Y_{k,2}]^T$  represents the vector of the observed numbers of cases in week k. By minimizing the partitive logitudino due estimated the unknown parameters and derived the 95% confidence intervals negative loglikelihood, we estimated the unknown parameters, and derived the 95% confidence intervals (CIs) using the parametric bootstrap method.

#### 2.2.3. Counterfactual scenarios

<span id="page-3-1"></span>To allow counterfactual explorations of mask wearing, we parameterized the effective reproduction number using the mask-wearing rate. Extracting the impact estimate of mask wearing on secondary transmission from a published study ([Leech](#page-10-10) [et al., 2022\)](#page-10-10), we calculated the relative reduction of  $R_k$ , in week k,  $\omega_k$ , by

$$
\omega_k = \exp(-\lambda w_k),\tag{14}
$$

where  $\lambda$  is a constant that scales the effect of mask wearing on secondary transmission.

We then computed counterfactual (CF) scenario 1, in which mask-wearing coverage remained high even after February 8, 2023. In this scenario, we replaced  $w_k$  by  $w_k^{CF-1}$ , which is the same as  $\delta$  in Eq. [\(1\)](#page-2-2).

$$
\omega_k^{CF-1} = \exp\left(-\lambda w_k^{CF-1}\right) \tag{15}
$$

Using Eq. [\(11\)](#page-3-0), the effective reproduction number of this scenario was computed and input to the epidemic model to produce the CF scenario. That is, based on the idea of [Gavish, Yaari, Huppert, and Katriel \(2022\),](#page-10-28) we removed the effectiveness of mask wearing from  $R_k$  and instead multiplied the counterfactual effect, i.e.,

$$
R_k^{CF-1} = R_k \frac{\omega_k^{CF-1}}{\omega_k}.
$$
\n<sup>(16)</sup>

We explored three other CF scenarios in which the observed mask-wearing coverage decreased to be 75%, 50%, and 25% of the observed values, respectively. We calculated the mask-wearing coverage for each scenario as follows:

$$
w_k^{CF-2} = 0.75w_k \tag{17}
$$

$$
w_k^{CF-3} = 0.50w_k \tag{18}
$$

$$
w_k^{CF\_4} = 0.25w_k \tag{19}
$$

Using similar approaches to Eqs. [\(14\) and \(15\)](#page-3-1), the effective reproduction numbers for each scenario were computed. Once the epidemic curves had been computed, we multiplied the age-dependent CFR estimate by the cumulative number of cases per age group, allowing the expected number of deaths to be calculated. As a sensitivity analysis, we considered two different functions (linear and quadratic) for the impact of mask wearing on secondary transmission from a published study ([Leech et al., 2022\)](#page-10-10), and calculated the expected number of deaths with each function in the CF scenarios.

#### 2.3. Summary of assumptions

To formulate the model, the following assumptions were made. Assumption 1: the mask-wearing coverage declined exponentially after the recommendation was revoked. Assumption 2: the mean serial interval was 3.5 days and exactly two generations occurred within 1 week. Assumption 3: the effective reproduction number remained unchanged within any particular week. Assumption 4: the relative reduction in secondary transmission via mask wearing was a fixed, ageindependent function.

#### 2.4. Statistical software

All statistical and numerical analyses in the present study were performed using the JMP pro statistical software, version 17.0 (SAS Institute Inc., Cary, NC, USA).

#### 2.5. Data sharing statement

The sentinel surveillance data from Tokyo and estimated universal case counts were received after anonymization and are available as supplementary data.

#### 3. Results

From April 14 to October 31, 2023, there was a single epidemic wave (ninth wave). The estimated number of cases exceeded 7000 on August 28, the highest incidence during this period ([Fig. 1A](#page-5-0)). Once the mask recommendation was removed from March 13, mask-wearing coverage steadily decreased over time. [Fig. 1B](#page-5-0) shows that our toy model of mask-wearing coverage qualitatively captures the observed trend.

[Fig. 2](#page-6-0) compares the observed weekly incidence by age group against the predicted number of cases in Tokyo based on our model. Our approach to modeling time-dependent transmission patterns before, during, and after the school summer holiday, as incorporated by our three-step function of relative susceptibility, successfully captures the overall age-dependent dynamics. The quantified next generation matrices are presented in Supplementary Table S3.

From the observed age-dependent patterns, it is possible to explore the causal impact of mask wearing on the epidemiological dynamics by modifying the mask-wearing coverage alone. [Fig. 3](#page-7-0) shows the epidemic curves for each CF scenario by age group. Only the weekly reproduction number was modified by the mask-wearing coverage (see Supplementary Fig. S1), and the counterfactual reproduction number was brought back into the model to yield the counterfactual number of cases. If the mask-wearing coverage had been maintained, the peak number of weekly new cases across all age groups would have decreased by 10%. Conversely, if the mask-wearing coverage decreased by 75%, 50%, or 25%, the peak numbers of weekly new cases would have increased to 113%, 125%, and 139% of the observed incidence, respectively.

Integrating the epidemic curve by age group gives the estimated cumulative number of deaths by scenario (see [Fig. 4\)](#page-8-0). If the mask-wearing coverage was maintained, the death count could have decreased to 3594 in Tokyo (95%CI 3521–3667). As the observed mortality was 4021 deaths, the reduced mask-wearing coverage was responsible for 427 additional deaths (corresponding to approximately 3700 additional deaths across the whole of Japan). Scenarios that assumed even greater reductions in mask-wearing coverage, by 75%, 50%, and 25%, yielded 4492 (95%CI 4412-4569), 5019 (95%CI 4934-5106), and 5608 (95%CI 5519-5699) deaths, respectively. A sensitivity analysis was carried out with respect to the relative reduction in

<span id="page-5-0"></span>

Fig. 1. COVID-19 incidence in Tokyo, 2022-2023 and mask-wearing coverage. (A) Sentinel-based weekly number of cases for Tokyo from week of October 3, 2022 to October 31, 2023. The count represents the sum of all notifications from sentinel medical institutes. Both daily incidence and weekly estimates of the sentinel report were available from October 3, 2022 to May 1, 2023; only the weekly sentinel report was available from May 8 to October 31, 2023. We then reconstructed the universal count of cases reported elsewhere [\(Okada et al., 2024\)](#page-10-19). (B) Observed mask-wearing coverage is shown as black dots; blue line shows estimated mask-wearing coverage with 95% confidence intervals in shaded area. We assumed that mask-wearing coverage declined following an exponential trend after the announcement that the mask-wearing recommendation was to be removed on February 8, 2023. These observed data are based on serial cross-sectional surveys.

the effective reproduction number as a function of mask-wearing coverage. The cumulative number of deaths in a CF scenario was computed using exponential, linear, and quadratic functions to describe the relationship between mask-wearing coverage and relative reproduction number. The form of this function did not have a considerable impact on the outcome (Supplementary Table S4).

### <span id="page-5-1"></span>4. Discussion

After transiting to the long-term management phase of the COVID-19 pandemic [\(World Health Organization, 2023](#page-11-1)), many countries discontinued universal mask mandates and recommendations. Along with a variety of policies that downgraded the handling rules of COVID-19, mask-wearing coverage declined from 97% to 69% in Japan by the week of October 30, 2023. Using a serial cross-sectional dataset of mask-wearing coverage along with the epidemiological estimate of the incidence of infection, the present study tackled the causal inference of mask wearing on the epidemiological dynamics of COVID-19. We have successfully shown that, if the mask-wearing coverage had been maintained at a high level (e.g., above 95%, as before) until October 2023, 427 lives could have been saved in Tokyo, corresponding to approximately 3700 lives across Japan. If the mask-wearing coverage had fallen even lower (to 25% of the actual value), there could have been an additional 1587 deaths in Tokyo, corresponding to approximately 13,000 deaths across Japan. This estimation was achieved by modifying the estimated effective reproduction number, specifying the preventive effect of mask wearing available elsewhere ([Leech et al., 2022](#page-10-10)), and computing the counterfactual reproduction number. As a result of this sensitivity analysis, we found that cumulative deaths did not differ greatly when using alternative functions to describe the relationship between mask-wearing coverage and relative reproduction number.

The most important take-home message from the present study is that removing the mask-wearing recommendation had a considerable epidemiological impact. We have shown that the population impact of mask wearing can be objectively analyzed by investigating the effective reproduction number in depth. Given the indirect effect of mask wearing, the causal inference cannot be achieved by directly investigating the incidence of infection, but rather by exploring the effective reproduction number in CF scenarios (as previously done to quantify the indirect effect of COVID-19 vaccination, e.g., [Gavish](#page-10-28) [et al., 2022](#page-10-28); [Kayano et al., 2023;](#page-10-29) [Watson et al., 2022\)](#page-10-30). To the best of our knowledge, the present study is the first to have successfully and quantitatively evaluated the actual policy of removing the mask-wearing recommendation in Japan.

An important caveat of developing such an evaluation path is that the realistic modeling of such an evaluation can (and should) be attained in real time, or at least in near-real time. That is, the proposed modeling method can be employed to predict in real time what will occur if mitigation measures are introduced, and policy makers can evaluate their own decisions by referring to the quantitative outcome in advance of the decision-making process. This type of approach could potentially act as a revolutionary pathway for evidence-based policy making in the future. At the minimum, any similar policy making could be accompanied by quantitative estimates of what the policy judgement is likely to induce. In the context of removing the mask-wearing recommendation in Japan, it should be possible for the population-level increase in the risk of infection (or death) to be quantified in real time, especially in advance of the decision or when the decision is announced to the public.

<span id="page-6-0"></span>

Fig. 2. Comparison between predicted and observed weekly number of COVID-19 cases from April 24 to October 30, 2023 by age group. (A) 0-19 years, (B) 20-39 years,  $(C)$  40-59 years, and  $(D) \ge 60$  years. Black dots represent the observed data; orange lines represent estimated numbers, and gray shaded areas show 95% confidence interval (which is relatively narrow) based on the parametric bootstrap method.

Additionally, selective measures may be considered in high-contact risk settings. It is known that some particular contact settings pose a high risk of transmission and may even lead to super-spreading events [\(Zhao et al., 2022\)](#page-11-5). Rather than simply issuing uniform policies across the country, implementing tailored policies, such as maintaining mask-wearing recommendations at least in high-risk settings (e.g., healthcare facilities), might be effective in avoiding future pandemics. To introduce such customized recommendations for each contact setting, quantitative evaluation using a model such as the one constructed in the present study could be valid.

We are not in a position to recommend mask wearing forever. One reason is that Japan is considered to have a higher level of cultural togetherness compared with Western countries [\(Gelfand et al., 2021\)](#page-10-31), and conformity to the social norm was the most prominent driving force for wearing masks [\(Nakayachi et al., 2020\)](#page-10-32). Countries with high levels of peer pressure are never regarded as healthy in the long run, and the mask-wearing policy had to be relaxed in some way in the context of the

<span id="page-7-0"></span>

Fig. 3. Weekly number of COVID-19 cases from April 24, 2023 to October 30, 2023 by age group. Black dots show the observed case count. Each line represents different scenarios with respect to mask-wearing coverage. Blue line shows scenario that maintained mask-wearing coverage at the 2022 level; other lines represent coverage of 75% (orange), 50% (gray), and 25% (yellow) of the observed values.

legal downgrading of COVID-19. More importantly, the dataset of mask-wearing coverage indicates that, even in the presence of peer pressure, mask wearing can decline substantially over the course of time following an announcement that the maskwearing recommendation is to be revoked. Thus, the policy impact of such an announcement was likely to have been enormous, and the present study indicates a critical need to base relevant decision-making on solid science that estimates the epidemiological impact. The correct decision on this matter applies not only to countries with identifiable peer pressure, but also to other locations with universal mask mandates, because mask mandate policies are known to be associated with the coverage of people practicing correct mask usage ([Goldberg et al., 2020;](#page-10-33) [Puttock et al., 2022\)](#page-10-34).

<span id="page-8-0"></span>

mask wearing coverage at the end of obserbation period(%)

Fig. 4. Counterfactual mortality estimates with different mask-wearing coverages from April 24, 2023 to October 30, 2023. Each bar shows the cumulative deaths from April 24, 2023 to October 30, 2023, according to different mask-wearing coverages. Each color block with numbers represents the cumulative number of deaths by age group, i.e., those aged from 20 to 39 years (blue), 40–59 years (orange), and  $\geq$ 60 years (green).

There are several questions regarding this type of estimation study with substantial indirect effects. For instance, if a surge of incidence occurs because of lower mask-wearing coverage, people may refrain from continuing high-risk contact, so the actual epidemic size may not be as large as calculated by the counterfactual model. This notion is correct in the sense of the quantitative prediction of actual scenarios, but the causal effect of mask wearing should be clearly separated from the issue of risk-avoiding behaviors associated with risk awareness. Similarly, if there is a surge of cases in hospitals, healthcare facilities may be overwhelmed by the caseload pressure. In this scenario, a decreased admission rate may elevate the case fatality risk, and we may therefore underestimate the mortality impact. This notion is likely to be true, but the causal inference of maskwearing coverage has nothing to do with caseload pressure. Thus, the causal inference of mask-wearing coverage should strictly handle only the mask-associated effects of the counterfactual reproduction number.

Three technical limitations must be discussed. First, our empirical data were limited to Tokyo, because the incidence estimate was only available from a restricted number of prefectures. Tokyo is the city with the greatest ascertainment capacity, and thus, the incidence data from Tokyo are considered to have captured the age-dependent transmission dynamics most precisely. Second, any components of the effective reproduction number other than mask wearing, e.g., human mobility and vaccination coverage, were not scientifically decomposed. The estimation was carried out during the post-vaccination period, and thus, we did not fully describe the effective reproduction number mathematically. This reinforces the importance of the assumption that the effective reproduction number should be multiplied by (1 – the mask-wearing effect). Third,<br>the estimation was carried out after the primary series of vaccination. If the estimation had bee the estimation was carried out after the primary series of vaccination. If the estimation had been carried out at a different time (e.g., pre-vaccination period), the indirect effect of mask wearing could have been far greater than presented. The indirect estimate of mask wearing thus remained a dynamic value.

#### 5. Conclusion

Despite the important limitations outlined in Section [4,](#page-5-1) we firmly believe that the present study successfully estimated the impact of removing the mask-wearing recommendation in Japan. If the mask-wearing recommendation had not been discontinued, an additional 3700 lives could have been saved during the ninth wave across the whole of Japan. If the maskwearing coverage had declined to 25% of the observed coverage, there could have been 13,000 additional deaths. Our proposed models could greatly help science-based policy making in the future.

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# Ethical approval statement

The sentinel surveillance data from Tokyo were received after anonymization and are available as supplementary data. Because the present study used only openly accessible data, ethical approval was not required owing to the nature of our study.

#### CRediT authorship contribution statement

Mayu Nagata: Writing  $-$  review & editing, Writing  $-$  original draft, Visualization, Validation, Methodology, Investigation, Formal analysis. Yuta Okada: Writing  $-$  review & editing, Methodology, Investigation, Formal analysis. Hiroshi Nishiura: Writing  $-$  review & editing, Supervision, Methodology, Conceptualization.

#### Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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#### Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.idm.2024.08.002>.

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