

Mandatory Vaccination in Europe

Olivia M. Vaz, MPH,^a Mallory K. Ellingson, MPH,^b Paul Weiss, MS,^c Samuel M. Jenness, PhD,^a Azucena Bardají, MD, PhD,^d Robert A. Bednarczyk, PhD,^{a,b,e,f} Saad B. Omer, MPH, MBBS, PhD^{a,b,g,e}

abstract

BACKGROUND: Mandatory vaccination has been effective in maintaining high vaccination coverage in countries such as the United States. However, there are no peer-reviewed analyses of the association between mandates and both coverage and subsequent incidence of vaccine-preventable disease in Europe.

METHODS: Using data from the European Centre for Disease Prevention and Control and the World Health Organization, we evaluated the relationship between country-level mandatory vaccination policies and (1) measles and pertussis vaccine coverage and (2) the annual incidence of these diseases in 29 European countries. Multivariate negative binomial and linear regression models were used to quantify these associations.

RESULTS: Mandatory vaccination was associated with a 3.71 (95% confidence interval [CI]: 1.68 to 5.74) percentage point higher prevalence of measles vaccination and a 2.14 (95% CI: 0.13 to 4.15) percentage point higher prevalence of pertussis vaccination when compared with countries that did not have mandatory vaccination. Mandatory vaccination was only associated with decreased measles incidence for countries without nonmedical exemptions (adjusted incidence rate ratio = 0.14; 95% CI: 0.05 to 0.36). We did not find a significant association between mandatory vaccination and pertussis incidence.

CONCLUSIONS: Mandatory vaccination and the magnitude of fines were associated with higher vaccination coverage. Moreover, mandatory vaccination was associated with lower measles incidence for countries with mandatory vaccination without nonmedical exemptions. These findings can inform legislative policies aimed at increasing vaccination coverage.



Departments of ^aEpidemiology and ^bBiostatistics and Bioinformatics, ^bHubert Department of Global Health, Rollins School of Public Health, ^dDepartment of Pediatrics, School of Medicine, ^eEmory Vaccine Center, and ^fWinship Cancer Institute, Emory University, Atlanta, Georgia; and ^cHospital Clínic, Barcelona Institute for Global Health, Universitat de Barcelona, Barcelona, Spain

Ms Vaz conducted the literature search, created the figures, conducted data collection, analysis, and interpretation and was primarily responsible for the writing of the manuscript; Ms Ellingson assisted in the literature search, data analysis and interpretation, and writing and editing of the manuscript; Prof Weiss and Dr Jenness contributed to data analysis and interpretation and the editing of the manuscript; Dr Bardají assisted in data interpretation and the editing of the final manuscript; Dr Bednarczyk contributed to the data analysis and interpretation and the writing and editing of the manuscript; Dr Omer conceptualized and designed the study and contributed to data analysis and interpretation, writing, and editing; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Ms Vaz's current affiliation is Department of Epidemiology, Gillings School of Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC.

Ms Ellingson's current affiliation is Department of Epidemiology of Microbial Diseases, School of Public Health, Yale University, New Haven, CT.

Dr Omer's current affiliations are Department of Epidemiology of Microbial Diseases, School of Public Health; Department of Infectious Disease, School of Medicine; and Yale Institute of Global Health, Yale University, New Haven, CT.

WHAT'S KNOWN ON THIS SUBJECT: Outbreaks in Europe are in part due to decreased vaccine coverage. Vaccine mandates have been used successfully in countries such as the United States to establish and maintain high vaccine coverage; however, the impact of such laws in Europe is unknown.

WHAT THIS STUDY ADDS: In evaluating current vaccine mandates in Europe, we found that mandatory vaccination and the magnitude of fines were associated with higher vaccination coverage in European countries.

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Vaccination is 1 of the most useful tools for preventing infectious disease and reducing morbidity and mortality.¹ Availability of vaccines has had a substantial impact on rates of vaccine-preventable diseases across the world.¹ However, achieving high vaccination rates is challenged by less-than-optimal acceptance. In countries such as the United States and Australia, vaccine mandates, such as those requiring vaccination for entry into school, have been used to increase and sustain vaccination rates.^{2,3}

In Europe, mandatory vaccination policies are heterogeneous across countries. Countries vary not only in the presence or absence of a mandate but also in the implementation and enforcement of the mandates as well as in the consequences faced by individuals who fail to comply with their country's policy.^{4,5} Multiple countries in Europe, including France and Italy, have recently faced outbreaks of vaccine-preventable diseases, such as measles, and in response have changed their policies, whereas other countries are considering introducing immunization mandates.⁶⁻⁸ The effectiveness of these legal and administrative policies and their possible consequences has not been assessed in a peer-reviewed analysis. In the face of these changes, an evaluation of existing vaccine mandates in Europe could inform policy choices in Europe and beyond.

In this study, we aimed to determine if (1) the vaccination rates for pertussis-antigen vaccines and measles, mumps, and rubella vaccines were associated with mandatory vaccination and the availability of nonmedical exemptions to these mandates; (2) the incidence of pertussis and measles was associated with mandatory vaccination and the availability of nonmedical exemptions; and (3) if the magnitude of the financial penalties faced by noncompliant parents was associated

with the rates of vaccination against pertussis and measles.

METHODS

Data Collection Methods

Analyses were conducted using publicly available data on vaccine mandate policies and vaccine rates by the first author. We focused our analysis on the 29 countries that were analyzed in the Vaccine European New Integrated Collaboration Effort (VENICE).⁹ This included the member states of the European Union (at the time of the study) as well as Iceland and Norway.⁹

Vaccination Rates

Vaccination rates were collected for 2006 to 2015 for measles and 2006 to 2016 for pertussis for these countries from the Global Health Observatory, a World Health Organization (WHO) collection of health-related statistics for its 194 member states.¹⁰ These were the most recent available data at the time the analysis was conducted. We elected to focus on measles and pertussis for multiple reasons. First, recent measles outbreaks have been 1 of the main drivers of policy changes in Europe. Both measles and pertussis have relatively high infectivity, meaning that even small changes in vaccine coverage can impact disease incidence. Lastly, both are diseases for which there is good surveillance of vaccine coverage and disease incidence. This country-specific information was compiled from reports by the health ministries or departments of WHO member states and was reported by the WHO on a global level. Immunization rates are collected as 1 of the Core Health Indicators used by the WHO. Although immunization rates are self-reported by the individual countries, the WHO does provide guidance and training to health systems on what and how to report.¹⁰

Measles and Pertussis Case Counts

Both measles and pertussis case counts were acquired from the WHO's centralized information system for infectious diseases. This system collects, analyzes, and presents data on infectious diseases in the WHO European Region, compiled from reports submitted by member states.¹¹ The population estimates used were from Eurostat, the statistical office of the European Union. These population statistics are provided annually by member states from the country's statistical authorities and are consolidated by Eurostat, which also ensures that the methodology is harmonized across countries to ensure comparable data.¹²

Vaccine Mandates

Information on whether vaccination was mandatory was obtained from a combination of sources. First, we used the VENICE 2010 survey, which indicated the 2010 status of vaccination requirements. The VENICE 2010 project surveyed experts working within immunization programs in participating countries. These experts were asked about the requirements for their country and were given a definition of "mandatory" and "recommended" to avoid misinterpretation.⁹ We then evaluated any changes in country-level vaccine mandate policies between 2010 and 2015 using the Vaccine Scheduler, a tool maintained by the European Centre for Disease Prevention and Control that presents the vaccine schedules of all countries in the European Union, including information on recommended versus mandated vaccinations.¹³

For those countries with vaccine mandates, we obtained additional information on the mandates and any available exemptions by conducting a review of country-specific vaccine policy on health ministry Websites. We collected information on the presence of nonmedical exemptions

and the potential penalties faced for noncompliance, including the amount of any financial penalties, from each country's health ministry Web sites and vaccine policy.^{9,13-20} For accurate comparison among countries, we transformed these financial penalties using Purchasing Power Parities (PPPs) on the actual individual consumption scale, calculated and provided by Eurostat.²¹ PPPs are a measure of how the units of national currency of a country compare in value to a standardized unit of currency and market, which Eurostat set as 1 euro in the EU. These PPPs were calculated and aggregated by using a set of annual prices for certain products and the breakdown of expenditure on gross domestic product (GDP) provided by participating countries.²¹

Data Analysis

All analyses were conducted by using SAS version 9.4 (SAS Institute, Inc, Cary, NC) and R version 3.3.3. We used multivariate models to conduct a longitudinal analysis of the association between different vaccine policies, vaccination rates, and disease incidence over time in the countries of interest.

Vaccination Rates and Associations With Vaccine Policy

A linear mixed-effects model was fit to estimate the association between the vaccination rates (outcome) and mandatory vaccination policies (primary exposure) in our countries of interest. We used an autoregressive correlation structure to account for within-country correlation over time. Using propensity score methods for covariate adjustment,^{22,23} we adjusted for the following covariates: percentage of the population living in urban areas, proportion of adults aged 24 to 65 with at least a lower-secondary education, GINI coefficient, universal health care service index, percentage of the population <14 years of age, and median age of

the country's residents. Covariate selection was informed by the existing literature on vaccine uptake and disease incidence as well as previous evaluations of the relationship between vaccine policy and disease incidence.²⁴⁻²⁸ The GINI coefficient represents the wealth distribution of the citizens of a country and is a commonly used measure of inequality.²⁹ The universal health care index combines 16 health service coverage indicators for reproductive health, maternal and child health, infectious diseases, noncommunicable diseases, and service capacity and access into a single metric.³⁰ The resulting regression coefficients comparing the presence of a mandatory vaccination policy, a nonmedical vaccination exemption, and a financial penalty were interpreted as the percentage point difference associated with each of these binary conditions.

Disease Incidence and Associations With Policy

We analyzed disease incidence for both measles and pertussis and the association between disease incidence and vaccine mandate policy for the years 2006 to 2015 (for measles) and 2006 to 2016 (for pertussis) for the countries of interest. To estimate the rates of pertussis and measles infections and associations with country mandates, a negative binomial model was fit with the assumption that the number of cases for each year was distributed as a Poisson random variable with mean μ and an offset for the population of the country. A negative binomial model was used to account for overdispersion. We used an autoregressive correlation structure to account for within-country correlation of the incidence of the disease over time. We used propensity score methods for covariate adjustment to account for demographic variables that have been previously shown to be associated with vaccine uptake.^{22,23} Incidence

rate ratios were derived from the models as a measure of association between incidence and the vaccination requirements of the country. Incidence rate ratios are interpreted as a relative difference in the incidence of the disease associated with the presence of vaccine mandates in a country.

RESULTS

Of the 29 European countries included in this study, 7 mandated vaccination (Fig 1 A and B).¹⁴⁻²⁰ Among these countries, only the Czech Republic and Latvia offered processes to acquire a nonmedical vaccination exemption.^{14,16} These processes required parents to either receive information (either online or through their health care provider) about vaccination or provide a written refusal of the vaccination as well as discuss the decision with their child's health care provider.^{14,16} In 6 of the 7 countries that had mandatory vaccination policies in place, if parents failed to meet the requirements of their country's regulations and requirements, they faced a financial penalty. Of these 7 countries, Latvia was the only one that did not have a financial penalty for refusing to vaccinate without obtaining a nonmedical exemption.¹⁶ In Latvia, health care providers are compelled to collect the signature of individuals who refuse vaccination and are required to inform the individual of the health consequences of failing to vaccinate.³¹

When adjusted to the euro, the country with the highest possible financial penalty was Hungary, where parents could face a financial penalty of up to 500 000 forints (~€1600 or ~\$1800) in 2016 if they failed to follow vaccination requirements.¹⁷ The country with the lowest financial penalty was Bulgaria, where parents could be fined a maximum of 300 lev (~€150 or ~\$170) in 2016 if they

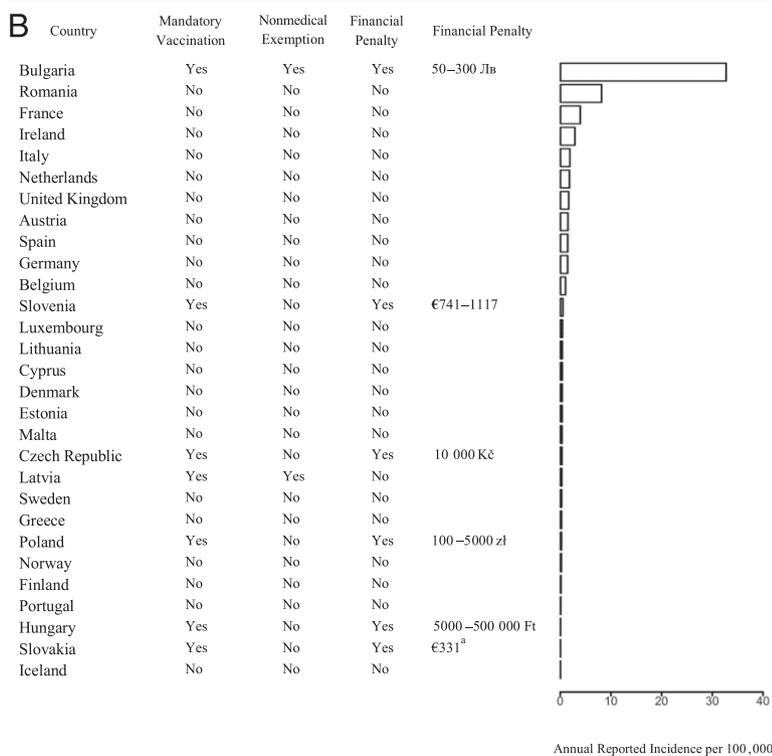
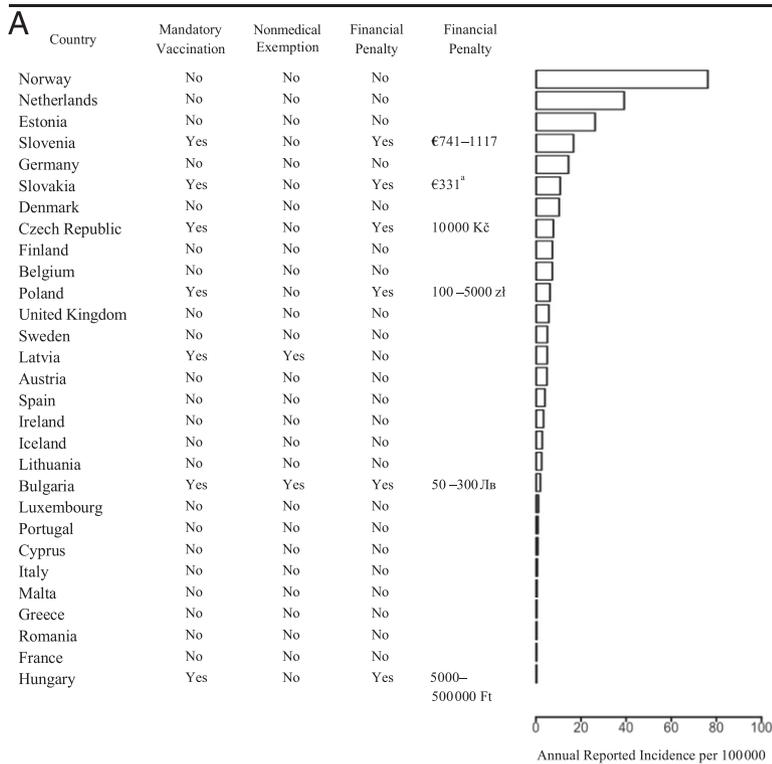


FIGURE 1

A, Annual reported incidence per 100 000. The mean annual reported pertussis incidence by country (2006–2016) among the entire population is shown. B, Annual reported incidence per 100 000. The mean annual reported measles incidence by country (2006–2016) among the entire population is shown. ^a Slovakia penalizes per parent, so if it is a 2-parent household, the total financial penalty would be €662. €, euro; Ft, forint; лв, lev; Kč, koruna; zł, zloty.

failed to comply with vaccination requirements (Fig 1A).¹⁷

Vaccination Rates and Associations With Vaccine Policy

Mandatory vaccination was associated with a difference of 3.71 percentage points for measles vaccination and 2.14 percentage points for pertussis vaccination when compared with countries that did not have mandatory vaccination (measles: 3.71 [95% confidence interval (CI): 1.68 to 5.74]; pertussis: 2.14 [95% CI: 0.13 to 4.15]; Table 1, Fig 2). Mandatory vaccination without exemption was associated with a difference of 3.80 percentage points for measles and 2.07 percentage points for pertussis vaccination (measles: 3.80 [95% CI: 1.23 to 6.37]; pertussis: 2.07 [95% CI: –1.74 to 5.89]).

Among countries that impose a fine for noncompliance by parents, every €500 increase in the maximum possible penalty was associated with an increase of 0.8 points for measles vaccination coverage (95% CI: 0.50 to 1.15; $P \leq .0001$) and an increase of 1.1 percentage points for pertussis vaccination coverage (95% CI: 0.95 to 1.30; $P \leq .0001$).

Disease Incidence and Associations With Policy

For measles, Bulgaria had the highest incidence at 32.9 cases per 100 000 individuals per year (Fig 1B). Countries with mandatory vaccination experienced lower incidence rates of measles compared with countries without mandatory vaccination, although the 95% CI crossed the null (adjusted incidence rate ratio [aIRR] = 0.38; 95% CI: 0.13 to 1.16). Countries that had mandatory vaccination without the possibility of nonmedical exemptions did have 86% lower disease incidence than countries without mandatory vaccination (aIRR = 0.14; 95% CI: 0.05 to 0.36). The presence of a financial penalty was associated

TABLE 1 Association of Mandatory Vaccination, the Availability of a Nonmedical Exemption Option, and the Penalty of Noncompliance With Rates of Vaccination Against Measles (2006–2015) and Pertussis (2006–2016)

	No. Country-Years	Difference in Vaccination Rate, % (95% CI)	P
Measles			
Mandatory vaccination, yes or no	287	3.71 (1.68 to 5.74)	.0003
Mandatory vaccination without nonmedical exemption, yes or no	267	3.80 (1.23 to 6.37)	.0037
Financial penalty for noncompliance per €500	59	0.80 (0.5 to 1.15)	<.0001
Pertussis			
Mandatory vaccination, yes or no	316	2.14 (0.13 to 4.15)	.04
Mandatory vaccination without nonmedical exemption, yes or no	294	2.07 (−1.74 to 5.89)	.28
Financial penalty for noncompliance per €500	65	1.1 (0.95 to 1.30)	<.0001

All models are adjusted for GDP per capita, GINI, urban population, universal health care coverage, median age, percentage of the population <14 years of age, and education level.

with lower incidence rates of measles (aIRR = 0.14; 95% CI: 0.05 to 0.39).

Norway had the highest incidence of pertussis at 73.6 cases per 100 000 individuals per year (Fig 1A).

Pertussis incidence in countries that had mandatory vaccination was 70% lower than in countries that did not have mandatory vaccination, although the 95% CI crossed the null (aIRR = 0.30; 95% CI: 0.07 to 1.30). Countries with mandatory vaccinations without the possibility of nonmedical exemption had incidence rates similar to countries without mandatory vaccination policies (aIRR = 1.04; 95% CI: 0.18 to 6.32) (Table 2). The presence of a financial penalty was associated with lower incidence rates of pertussis (aIRR = 0.42; 95% CI: 0.18 to 0.98).

DISCUSSION

Mandatory vaccination policies in Europe were associated with higher rates of vaccination for both measles and pertussis. Although mandatory vaccination overall was not associated with a lower incidence of either measles or pertussis, when there was no option of a nonmedical vaccination exemption, the incidence of measles was significantly lower. Moreover, the presence of a financial penalty for nonvaccination was associated with a lower incidence of both pertussis and measles. Countries with a fine for noncompliance experienced incidence rates of less

than half that of countries without mandatory vaccination for both measles and pertussis. Among these countries with a financial penalty, a €500 increase in the maximum penalty parents could face for failing to comply with their country's vaccination regulations was associated with a 1.1% higher vaccination rate for pertussis and a 0.8% higher vaccination rate for measles.

Financial penalties could be an effective measure in a comprehensive mandatory vaccination program, although they need to accompany other measures, including a stable vaccine supply and vaccine education, to reach those who refuse to vaccinate. Financial penalties have been used in non-European countries, with some success. For example, in Australia, 6 months after the implementation of “No Jab No Pay” (a no vaccination, no family tax benefits program) in the beginning of 2016, “fully immunized coverage” of children at 1 year of age and 5 years of age had both reached record highs.² However, individuals who objected to vaccination were approximately twice as likely to reside in areas of higher socioeconomic resources. In this scenario, financial disincentives may not be adequate because those more likely to refuse vaccination may also have the ability to bear the consequences of the financial disincentives.³²

Some European countries are considering making vaccinations mandatory, including implementing financial penalties for noncompliance, even if they do not have a history of such policies. Italy and France have both made childhood vaccinations mandatory since the beginning of 2017 in response to decreasing vaccination rates and outbreaks of multiple vaccine-preventable infectious diseases, including measles, although the Italian mandate was later repealed.^{6,7} For countries with mandatory vaccination, there can still be outbreaks of disease due to the vaccination rate still not reaching the herd immunity threshold or geographic clusters of unvaccinated individuals.²⁴ The WHO Regional Office for Europe recently released a *Guide to Tailoring Immunization Programs*, offering a process through which to identify obstacles and motivators to immunization in areas of low vaccination rates and for how to design interventions tailored to meet those factors.³³

Previous examination of vaccine mandates in Europe via a nonpeer-reviewed analysis by the Action Plan on Science in Society Related Issues in Epidemics and Total Pandemics (ASSET) did not report a relationship between national policies on mandatory vaccination and vaccination coverage in Europe. Although the ASSET study examined most of the countries that were

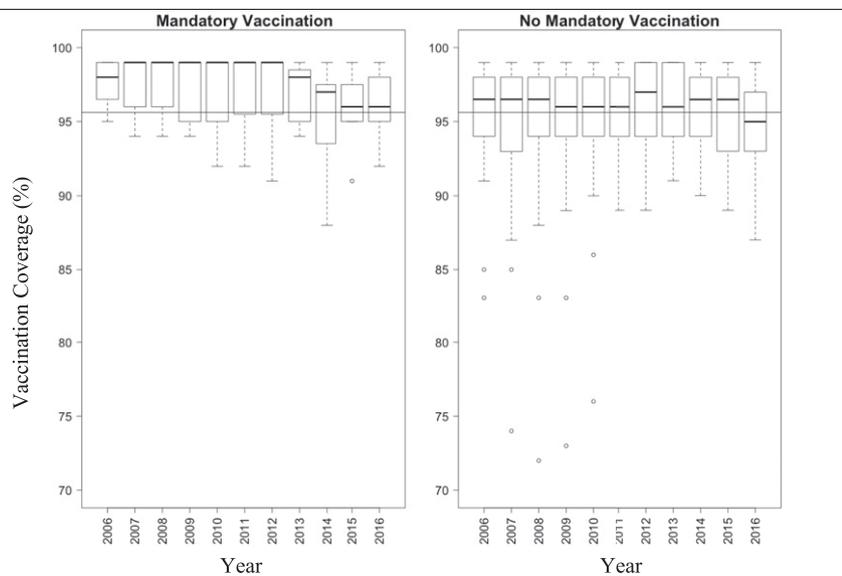
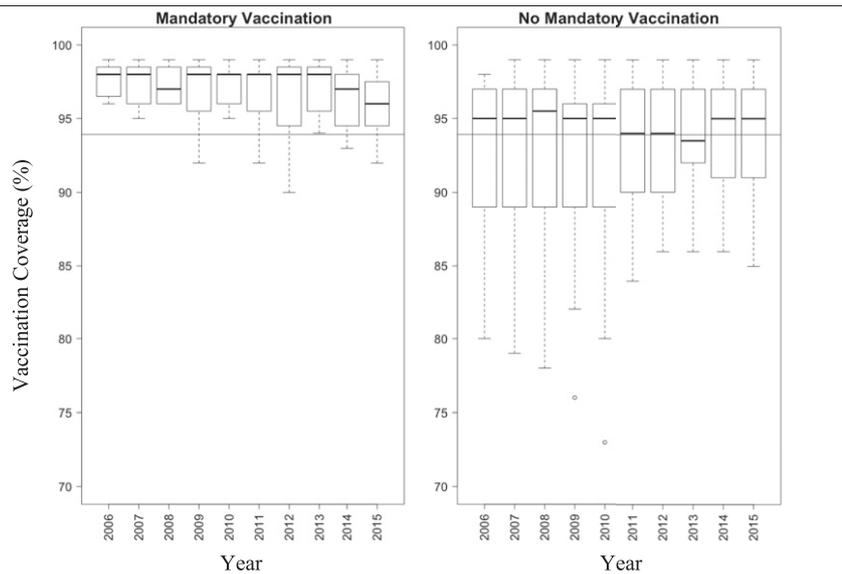


FIGURE 2

Median percentage and interquartile ranges of vaccination rates for countries with and without mandatory vaccination. ^a The horizontal line indicates the average vaccination rate across all countries and years included in the study.

included in our study, there are several differences between the ASSET analysis and our study. For example, whereas our study accounted for confounders in the regression models, the ASSET analysis ostensibly did not use adjusted models (because there were no adjusted analyses reported). Specifically, our study accounted for various factors that are associated

with vaccine uptake, including education level, distribution of wealth in the country, and health care accessibility. Moreover, our study also examined a longer period of time (2006–2016) than did the ASSET study (2007–2013), providing a higher statistical power for various analyses. Whereas the ASSET study only examined the presence of a mandate in a country as a binary

variable, we also examined the effects of allowing for nonmedical exemption on vaccine-preventable disease incidence and of the magnitude of a fine for noncompliance.

There are a few limitations to our study that should be considered. First, this study is ecological in nature; therefore, we cannot draw a direct link between individual vaccine refusals and vaccine policies. However, given that policy is implemented at the population level, a country-level analysis is an appropriate way to evaluate the potential impact of a policy. Second, although the WHO's Global Health Observatory and the centralized information system for infectious diseases are the best available sources for immunization rates and disease incidence, both are reliant on reporting by physicians and officials in each country. For disease incidence, case counts rely on individuals seeking medical care in the case of disease, their physician reporting the case to the local health authority, and these local health authorities properly reporting these cases to the national health ministry or other entities who would eventually report to the WHO or the European Centers for Disease Control. However, this is true for countries with mandates and without; therefore, the associations in our analysis are likely to be an underestimate due to nondifferential misclassification. Similarly, although we conducted a review to identify the best available sources of information on country-level vaccine policies, it is possible that we either did not or were unable to find all details on a given policy. Therefore, we were unable to account for a lag in effect that a change in policy may have. Additionally, there is also the possibility that the availability of nonmedical vaccination exemptions as well as the magnitude of the financial penalties faced by those who fail to comply were measured by using information that might not have reflected the entire period studied.

TABLE 2 Association of Mandatory Vaccination, the Availability of a Nonmedical Exemption Option, and the Penalty of Noncompliance With the Incidence of Measles (2006–2015) and Pertussis (2006–2016)

Mandatory Vaccination	No. Countries	Pertussis ^a Incidence Rate Ratio (95% CI)	Measles Incidence Rate Ratio (95% CI)
No mandatory vaccination	22	Reference	Reference
Mandatory vaccination	7	0.30 (0.07 to 1.30)	0.38 (0.13 to 1.16)
Mandatory vaccination without nonmedical exemptions	5	1.04 (0.18 to 6.32)	0.14 (0.05 to 0.36)
Monetary fine			
No mandatory vaccination	22	Reference	Reference
Mandatory vaccination and monetary penalty for noncompliance	6	0.42 (0.18 to 0.98)	0.14 (0.05 to 0.39)

^a Models are adjusted for GDP per capita, GINI, urban population, universal health care coverage, median age, percentage of the population <14 years of age, and education level.

Using resources from 2006 to 2018, we were not able to find any indications that any countries substantively changed their mandatory vaccinations from 2006 to 2016.^{7,9} Lastly, both vaccine coverage and disease incidence are complicated outcomes dependent on a number of factors. We either did not or could not account for all possible factors that may influence this relationship, such as the geographic proximity of the selected countries or overall population size, instead choosing to prioritize those factors that had been previously associated with these relationships in the literature.

CONCLUSIONS

Although our findings support the use of mandatory vaccination and financial penalties to ensure the maintenance of the necessary high vaccination rates, our analysis involved existing mandates. The introduction of new mandates should be accompanied by careful surveillance of the impact on both vaccine acceptance and disease outcomes. Vaccine mandates shift the balance of convenience in favor of vaccination and, when accompanied by robust vaccine safety assurance and vaccine communications programs, have the potential to play a substantial role in decreasing the

negative impacts of vaccine-preventable diseases.

ABBREVIATIONS

aIRR: adjusted incidence rate ratio
 ASSET: Action Plan on Science in Society Related Issues in Epidemics and Total Pandemics
 CI: confidence interval
 GDP: gross domestic product
 PPP: purchasing power parity
 VENICE: Vaccine European New Integrated Collaboration Effort
 WHO: World Health Organization

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Address correspondence to Mallory K. Ellingson, MPH, Yale Institute for Global Health, 1 Church St, Suite 340, New Haven, CT 06510. E-mail: mallory.ellingson@yale.edu

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