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SHORT PAPER

Impact of Mandatory Measles Vaccination on Coverage in Italy and the European Union: an observational study

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Keywords: Vaccination; Measles; Coverage; Mandatory
Parole chiave: Vaccinazione; Morbillo; Copertura vaccinale; Obbligatorietà

Abstract

Introduction. *Measles is a highly contagious disease, but it is preventable through vaccination. Despite the availability of measles vaccines, outbreaks continue to occur, due to factors such as vaccine hesitancy. In Italy, measles vaccination has been mandatory since 2017.*
Methods. *This study analyses vaccination coverage trends to assess the impact of this mandatory vaccination policy at regionjqal, national, and European Union levels.*
Results. *Results show a significant increase in measles vaccination coverage within Italy following implementation of the mandate, both at the national (+5,2%) and regional levels. However, the comparison of European countries with and without mandatory vaccination policies did not reveal statistically significant differences in coverage.*
Conclusion. *This suggests that while mandatory vaccination can improve coverage within a nation, additional strategies may be needed to address vaccine hesitancy and achieve herd immunity across broader geographical areas.*

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Introduction

Measles is a highly contagious viral respiratory disease caused by the Morbillivirus and preventable with vaccination (1). In Italy the measles vaccine was introduced in 1976 with different formulations, recommended in 1979, and mandatory since 2017 (2); despite this, there have been various measles outbreaks over the years (3). High levels of vaccination coverage are necessary to achieve herd immunity, reduce the incidence of this disease and prevent new outbreaks[1].

One of the main problems encountered in the last decade is the phenomenon of "vaccine hesitancy", often correlated with fake news or incorrect use of web information (4).

The World Health Organization (WHO) has set the goal of measles elimination, recommending a vaccination coverage of at least 95% with two doses (1).

In Italy, Law no. 119/2017 expanded the number of mandatory childhood vaccinations to ten, specifically including measles. This legislation mandates that proof of vaccination be provided for all children under the age of 16 seeking enrollment in state-operated educational institutions[2].

The National Vaccination Prevention Plan (PNPV) 2023-2025, in line with the indications of the previous plan (PNPV 17-19), recommends a two-dose measles vaccination schedule (12th month of age and 5th year) (5).

Evaluating trends in first-dose vaccine coverage levels during the five years preceding and following the implementation of mandatory vaccination is crucial to elucidate the law's impact on measles vaccination coverage.Additionally, this study seeks to assess the impact of mandatory vaccination policies on immunization coverage trends within the European Union by differentiating between countries with and without such mandates (6).

Materials and methods

Materials

Vaccination coverage rates at national level and for each European State were obtained through the ATLAS data collection tool, made available by the European Centre for Disease Prevention and Control (ECDC). This tool is based on data provided by the different member states through the European Surveillance System (TESSy) for infectious diseases Data updated to 2022.

Data on vaccination coverage for the different Italian regions were extracted from the reports available on the website of the Ministry of Health, calculated on the summaries sent by the Regions and PA.AA (7). Data updated to 2021.

Methods

Data on the mean measles vaccination coverage at 24 months in Italy were evaluated between 2013-2022. The coverage rates in 2013-17 were compared to 2018-22.

The mean regional vaccination coverage at 24 months was analysed between 2013 and 2021. To evaluate the impact of the mandatory vaccination law without the influence of the pandemic, 2015/16 was compared to 2018/19.

Ultimately, the mean coverages at 24 months in 2022 were compared between mandatory vaccination EU states and no mandatory vaccination countries.

Statistical analysis

The means of the groups defined above were calculated and compared using the Welch-corrected t-test for samples with unequal variance. Analyses with a p-value less than 0.05 were considered statistically significant.

The statistical analyses were conducted using the GraphPrism 5 software.

Results

Analyzing the Italian population in the period before the introduction of mandatory measles vaccination (2013-2017), the minimum vaccination coverage for the first dose was 85% in 2015, the maximum value 92% in 2017 with an average of 88.2% (SD 2.8). In the period after the introduction of mandatory measles vaccination (2018-2022), the minimum vaccination coverage was 92% in 2020, the maximum value 94% in 2022 with an average of 93.4% (SD 0.9).

Between the two analyzed groups, there was an increase on average of 5.2%, with statistical significance. ($p = 0{,}0163$; $df = 4$) (Fig. 1A).

This paper examines the impact of mandatory vaccination policies on regional vaccination coverage in Italy. Data from both before and after the introduction of the vaccination obligation (Law 119/2017) are analyzed to assess its effectiveness.

Prior to the implementation of the vaccination

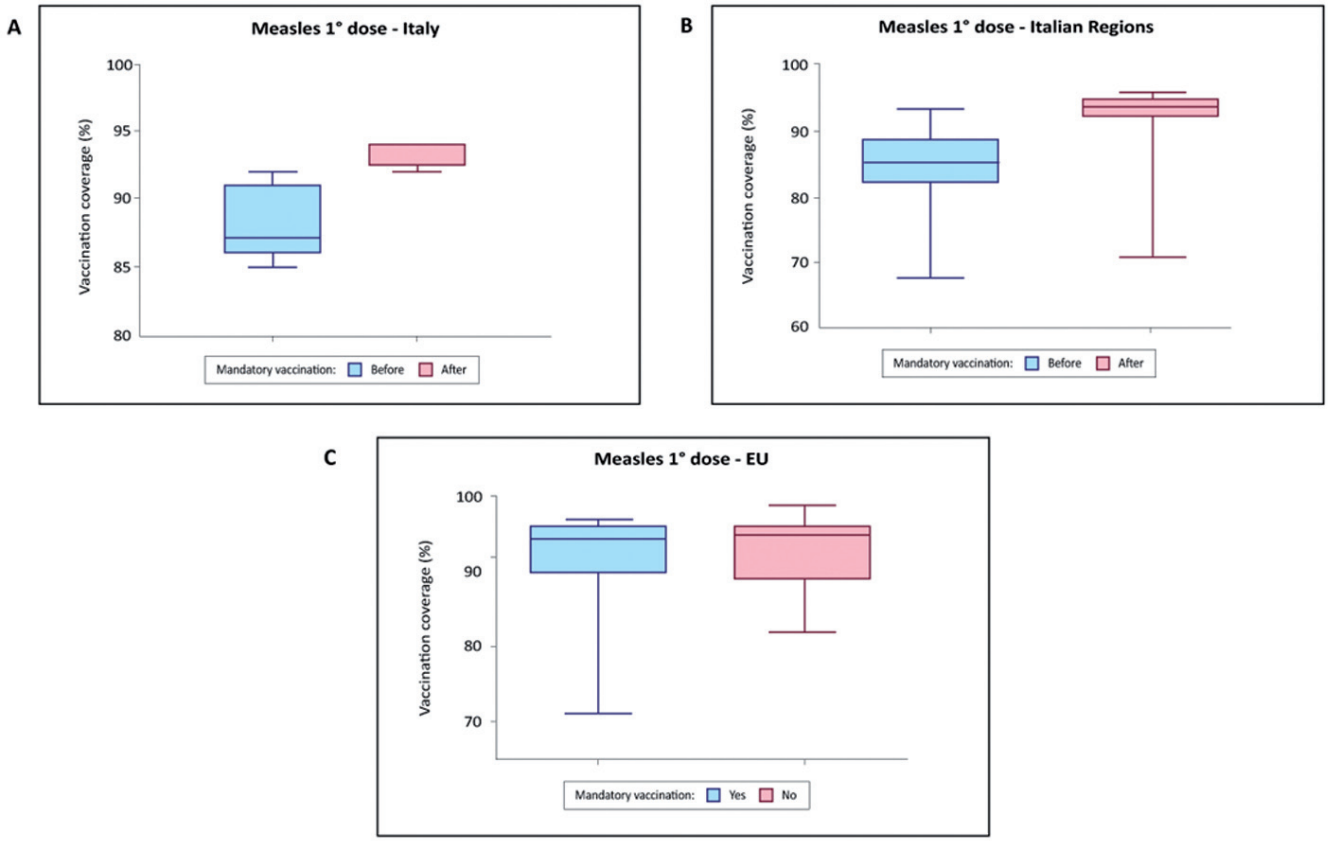

Figure 1 A - **Italian Vaccination Coverage Before and After Mandatory Law (2013-2022)**. This graph compares mean vaccination rates in Italy before (2013-2017) and after (2018-2022) the implementation of mandatory vaccination law (119/2017). B. **Regional Variation in Italian Vaccination Coverage** (2015-2016 vs. 2018-2019). This graph shows how mean vaccination rates differ across Italian regions before (2015-2016) and after (2018-2019) the introduction of mandatory vaccination law. C. **Measles Vaccination Rates: Mandatory vs. Non-Mandatory in Europe**. This graph compares mean measles vaccination coverage within European countries with and without mandatory vaccination policies.

obligation, regional disparities in vaccination coverage were evident. Lombardy registered the highest coverage rate at 24 months (93.4% in 2016), while the Autonomous Province of Bolzano had the lowest value (67.5% in 2016). Following the obligation's introduction (2018-2021), Lazio achieved the highest coverage (97.6% in 2021), while Abruzzo registered the lowest (62.1%). Molise exhibited the most significant increase in coverage in comparison to the 2013-2017 period (+11.6%). Conversely, Abruzzo experienced a decrease of 0.9%. In 2021, six regions and autonomous provinces attained coverage rates exceeding 95% (Fig. 2).

Comparing the coverage percentages at 24 months of all regions (Autonomous Provinces of Trento and Bolzano included) in 2015-2016 with those in 2018-2019, a statistically significant difference was obtained (mean 84.7% ± 0.97 vs 92.8% ± 0.7; $p < 0.0001$; df = 79). The median value in the period 2015-2016 was 85.2 with an interquartile range of 6.4 (82.2 - 88.5). In the period 2018-2019 the median was 93.5% with an interquartile range of 2.0 (92.3 - 94.3) (Fig. 1B).

The vaccination coverage for the first dose of measles in 2022 was analyzed by comparing 10 EU countries with mandatory vaccination (Bulgaria, Croatia, Czech Republic, France, Germany, Italy, Latvia, Poland, Slovakia, Slovenia) with 19 EU countries without mandatory vaccination (Austria, Belgium, Cyprus, Denmark, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Lithuania, Luxembourg, Malta, Romania, Netherlands, Norway, Portugal, Spain, Sweden) (Fig. 3).

Regarding the group with mandatory vaccination, the minimum coverage value was 71% (Poland) and the maximum value obtained was 97% (Germany, Czech Republic) with an average of 91.9%.

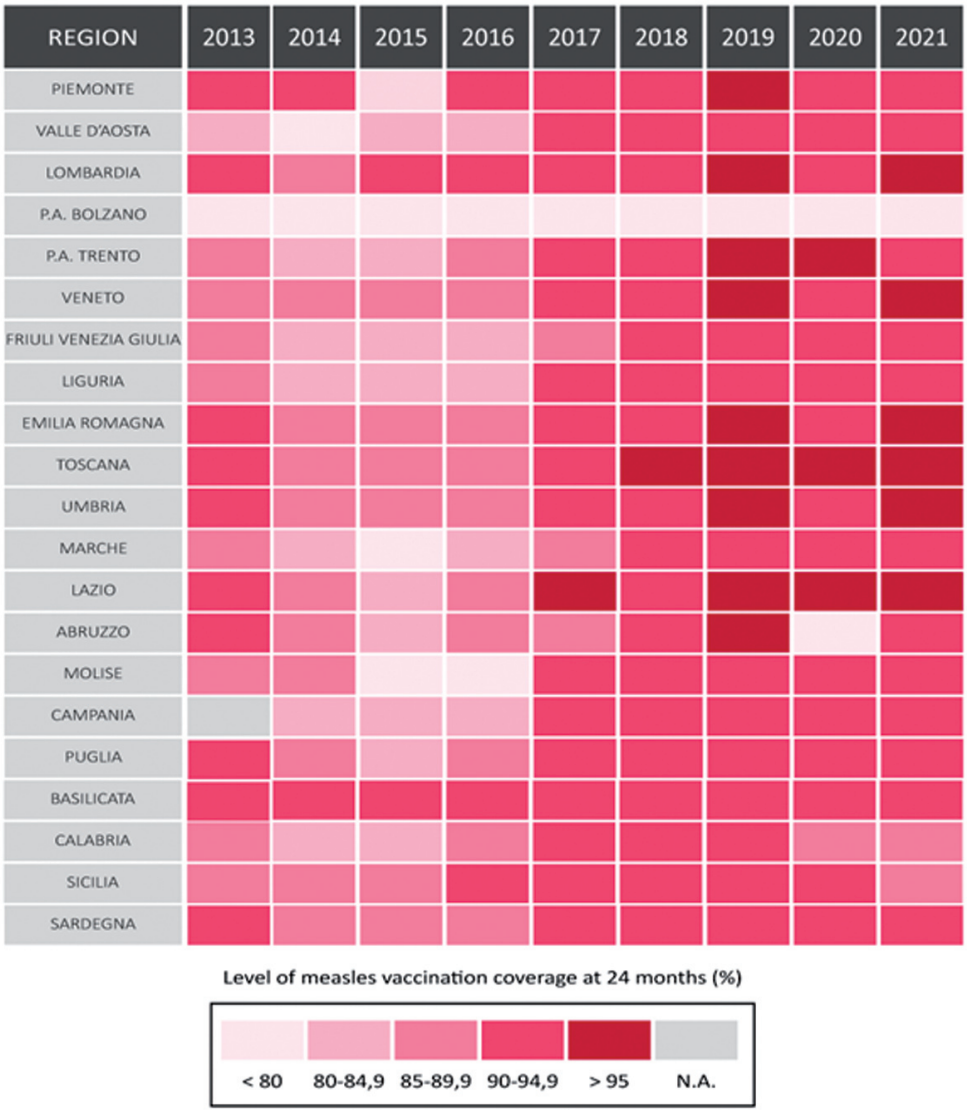

Figure 2 - Trends in coverage for first dose of measles vaccine (2013–2021) by Region/PP.AA.

The second group analyzed, without mandatory vaccination, showed a minimum value of 82% (Estonia) and a maximum value of 99% (Hungary) with an average of 92.7%.

The tests conducted did not show any statistical significance in the differences between the two groups. (p value = 0,7803; df = 13) (Fig. 1C).

Discussion and conclusions

The observed decline in immunization coverage and subsequent measles outbreaks within Italy during the 2015-2017 triennium (8) served as the impetus for the expansion of mandatory vaccination policies enacted through Law 119/2017.

The results show an improvement in the national average (+5.2%) during the five-year period 2018-2022 following the approval of the aforementioned law.

In 2020, in conjunction with the Covid-19 pandemic, there was a drop in vaccination coverage, with a subsequent realignment to pre-pandemic values in the period 2021-22.

In conclusion, this analysis offers further validation of the findings by Sindoni et al. regarding measles vaccination coverage between 2013 and 2019 (9).

The comparison at the regional level in the two years before (2015-2016) and after (2018-2019) the

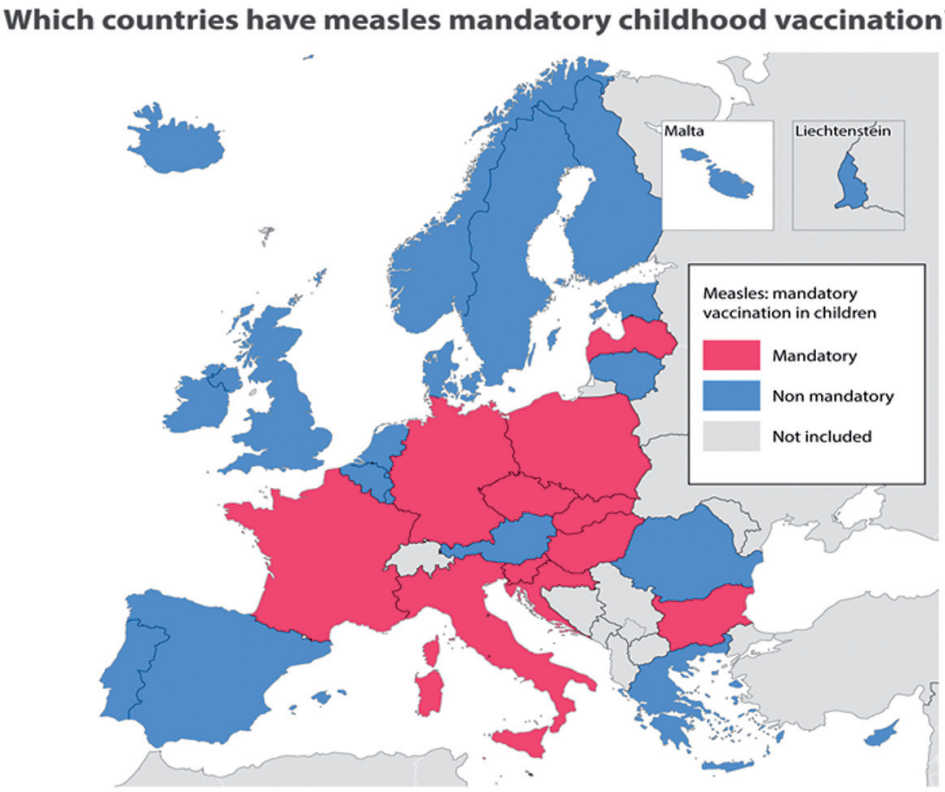

Fig. 3

introduction of Law 119/2017 showed a significant improvement in coverage at 24 months in most regions (+6% between 2016 and 2018), with 20 Regions/PA.AA. exceeding 90% coverage for the first dose. The average coverage increased from 84.6% to 92.8%, between the two periods. A reduction in the interquartile range was also observed in the period after the introduction of the obligation, suggesting that the law has allowed for the standardization of vaccination campaigns at the national level. In 2020, likely due to the pandemic, the average coverage decreased and only 3 regions maintained a coverage above 95%. In 2021 the situation improved, approaching the results of 2019.

In conclusion, the introduction of mandatory vaccination also had a positive impact on regional measles vaccination coverage and, despite some fluctuations, the general trend shows an improvement in coverage.

In 2022, the comparison between EU countries with mandatory measles vaccination and those without showed subtle differences in vaccination coverage. The group with mandatory vaccination had an average of 91.9%. The second group analyzed, without mandatory vaccination, had an average of 92.7%. The lack of statistical evidence between the means of the two groups could be influenced by several factors, such as data variability: although the means of the two groups seem similar, there could be a great deal of variability within each group.

Ultimately, from a statistical point of view, we cannot state that mandatory vaccination has a significant impact on first-dose measles vaccination coverage in European Union countries.

The European countries that express the greatest doubts about the safety of vaccines are those in Eastern and Southern Europe; those that are less skeptical are the countries of Northern and Western Europe, with the important exception of France and Italy, which show more negative feelings about the safety, efficacy and importance of vaccines among the population (10).

Country-level heterogeneities suggest that, while mandatory vaccination could be beneficial to improve coverage within an individual nation, additional strategies may be needed to address vaccine

hesitancy and achieve herd immunity across broader geographical areas.

Limitations of the study

This study possesses several strengths, notably its comprehensive analysis of mandatory vaccination policy impacts in Italy. However, certain limitations were encountered. Firstly, the inability to utilize second-dose data due to discrepancies created by the law's implementation skewed the analysis. Those receiving the second dose under mandate were not directly comparable to those with prior optional compliance. Additionally, the pandemic period presents a potential confounding factor, as it may have independently influenced vaccination coverage outcomes.

An additional limitation arises from the inability to analyze a full five-year period before and after the mandatory vaccination policy for all regions. Consequently, the analysis focused solely on data from the two years preceding and following the implementation of Law 119/2017.

At the European level, however, only 2022 was evaluated as it was not easy to evaluate the start date of the obligation for all European states.

Riassunto

L'impatto della vaccinazione obbligatoria contro il morbillo sulla copertura in Italia e nell'Unione Europea: uno studio osservazionale

Introduzione. Il morbillo è una malattia altamente contagiosa, ma è prevenibile attraverso la vaccinazione. Nonostante la disponibilità dei vaccini contro il morbillo, continuano a verificarsi epidemie a causa di fattori come l'esitazione vaccinale. In Italia, la vaccinazione contro il morbillo è obbligatoria dal 2017.

Metodi. Questo studio analizza le tendenze della copertura vaccinale per valutare l'impatto di questa politica di vaccinazione obbligatoria a livello nazionale, regionale e dell'Unione Europea.

Risultati. I risultati mostrano un significativo aumento della copertura vaccinale contro il morbillo in Italia a seguito dell'attuazione dell'obbligo, sia a livello nazionale (+5,2%) che regionale. Tuttavia, il confronto tra i Paesi europei con e senza politiche di vaccinazione obbligatoria non ha evidenziato differenze statisticamente significative nella copertura.

Conclusione. Ciò suggerisce che, sebbene la vaccinazione obbligatoria possa migliorare la copertura all'interno di una nazione, potrebbero essere necessarie ulteriori strategie per affrontare l'esitazione vaccinale e raggiungere l'immunità di gregge su aree geografiche più ampie.

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