

Commentary

Impact of mandatory law on vaccine hesitancy spectrum: The case of measles vaccine catch-up activities in Tuscany, Italy



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In July 2017 the Italian government passed a new law mandating ten vaccinations for children up to 16 years old [1]: diphtheria, tetanus, pertussis, hepatitis B, polio, *Haemophilus influenzae* type b (Hib), provided in the form of an hexavalent vaccine, and measles, mumps, rubella and varicella, provided either as MMR or MMRV vaccine, as foreseen in the strategic document on vaccine prevention (PNPV) endorsed by the Ministry of Health in February of the same year [2]. The policy was adopted, as part of the national response to a large outbreak of measles, to contrast the decline of vaccine coverage (VC). Since 2014, in fact, VC have decreased, leading to reduced level of protection in Italian population, in particular for measles, mumps and rubella vaccine (measles VC at 24-month of age was 90.4% in 2013, then ranging between 85.3% and 87.3% in the years 2014–2016) [3,4]. In Italy vaccination is actively offered free of charge to target population groups, including children, and administered by public immunization services, general practitioners and pediatricians operating within community health services, according to the PNPV [2] and regional immunization plans, leading to a certain degree of VC heterogeneity among Italian regions.

The introduction of mandatory vaccination in 2017 had an immediate impact on VC, due to the new requirement for school-aged children to have completed the vaccination cycles in order to attend educational services. As a result, measles VC at 24-month increased to 91.81% in 2017 (+4.58% vs 2016) and 93.22% in 2018 (+1.38% vs 2017; total increase +5.96%), although with regional variation [4] (Table 1).

While the impact of mandatory vaccination on VC is probably the most direct and well monitored outcome, we believe vaccine mandates may affect several aspects of vaccination programmes, which are often less stringently assessed and less often reported upon [5]. Additional effects of vaccine mandates may be probed within the framework of public health services organization and vaccine perception among general population [5]. These outcomes, in turn, may have an impact on VC, and influence the policy effectiveness.

Using data from a large Italian region, we investigated the impact of the 2017 mandatory immunization program on a broader spectrum of relevant outcomes, such as VC, organization of immunization service and catch-up activities, regional immu-

nization information system (rIIS) data quality and reasons for delaying/refusing immunization.

Tuscany is a region of central Italy, with approximately 3.7 million inhabitants, corresponding to the 6.2% of the national population. The historical VC trends in the region reflected those at national level, although with slightly higher VC rates. As shown in Table 1, the regional average 24-month VC for measles was 89.38% in 2016 and 95.32% in 2018, with a cumulative increase of +5.94%, equivalent to that registered at national level [6].

As part of PNPV implementation, and following the push provided by the mandatory law, regional health authorities carried out catch-up interventions to identify and actively offer mandatory vaccinations to unvaccinated/partly vaccinated children [3]. The impact of these efforts was assessed monitoring VC for the same birth-cohort at 24-month, 36-month and 48-month of age, with the latter indicator introduced in 2017 for this specific purpose [4]. In Tuscany, local health units (LHU) were responsible for catch-up activities and schools were also engaged to identify unvaccinated/partly vaccinated children and transmit the information to LHUs.

Catch-up activities resulted in a substantial increase in measles VC in the 2014 and 2015 birth cohorts, monitored through the abovementioned indicators. A respective increase of +5.65% and +1.75% was registered in Tuscany for the 2014 and 2015 birth cohorts, similarly to what observed at national level (Table 1). As a result, one-dose measles VC exceeded the World Health Organization target of 95%, for these birth cohorts.

During 2018, LHUs in Tuscany embarked on an intense activity of cleaning and updating the rIIS. Systematic scrutiny of the rIIS led to the identification of 1528 unvaccinated/partly vaccinated children, representing 6.6% of 23,321 children in the 2016 birth cohort in the region [6]. Information on the reasons for incomplete vaccination status was available for 1503 (98.4%). For a relevant number of children (206; 13.7%), administrative issues were at the origin of incomplete vaccination records, such as transfers out of the region, unknown residence or lack of individual vaccination records for recently arrived migrants (Fig. 1). While few were already vaccinated/immune, for a substantial number of children catch-up vaccination had been initiated by the end of 2018 (259; 17.2%). Reasoning along the vaccine hesitancy spectrum [7], temporary refusal, not traceable/contactable parents or those that did not attend the appointment with immunization services, could be

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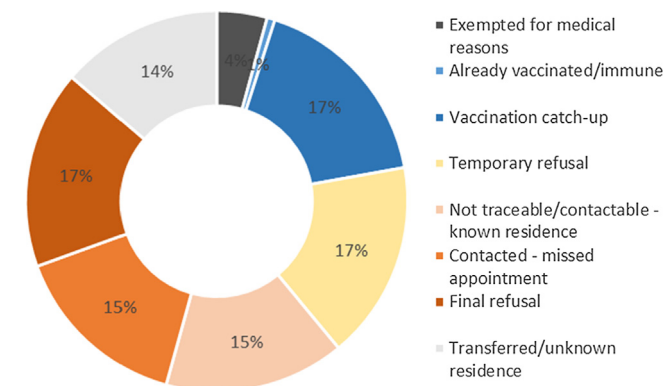
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Table 1

Measles vaccine coverage in Italy and Tuscany region, by birth cohort and year of data collection.

Birth cohort	Measles vaccine coverage 2018		Measles vaccine coverage 2017		Measles vaccine coverage 2016	
	Tuscany	Italy	Tuscany	Italy	Tuscany	Italy
2014	95.03%	94.93%	91.91%	92.4%	89.38%	87.26%
2015	95.26%	95.19%	93.51%	91.84%	–	–
2016	95.32%	93.22%	–	–	–	–

Source: Regione Toscana and Ministry of Health.

**Fig. 1.** Reasons for lack/incomplete immunization, birth cohort 2016, Tuscany, 2018 (n = 1503).

categorized as belonging to the vaccine-hesitant/vaccine skeptics population group. Altogether, children fitting these categories constituted the 47.3% (711) of the sample, and thus its largest quota, corresponding to the 3% of the entire birth cohort. Final refusal was 16.8% (253) of the sample, corresponding to 1.1% of the birth-cohort.

In recent years vaccine hesitancy has been monitored in Italy through standardized surveys on parents' attitudes. In 2016, 15.6% of the interviewed individuals were classified as vaccine-hesitant and 0.7% actively opposing vaccination [8]. In 2018, according to a new round of the survey, hesitant parents were 11.5% ($p < 0.001$) and anti-vaccine 0.5% (difference was not statistically significant) [3]. These data, in light of what we observed in Tuscany, may suggest that vaccine mandates may have pushed part of the hesitant parents to vaccinate their children without further delay. The remaining quota of vaccine-hesitant parents (6.6%) detected through the catch-up actions has been partially and progressively regained, allowing to reach the 95% threshold. Fully-refusing parents represent only 1.1% of the target population, in line with the evidence that strong anti-vaccine sentiment is present in less than 1% of Italian parents.

It has been argued that mandatory vaccination may boost anti-vaccine sentiments and determine an increase in vaccine-hesitant individuals in a given population [5,9]. However, this seems not to have been the case in Italy, where the heightened attention to vaccination following the mandatory law may have counterbalanced the spread of misinformation that characterized the earlier years [10]. In the Tuscany experience that we reported above, a strong anti-vaccine attitude affects about 1% of parents. The remaining quota of vaccine skeptic parents (about 3% of the target population) are those requiring a major effort by public health services to be engaged in order to ensure and maintain herd immunity.

While changes in attitude towards vaccination and vaccine hesitancy are key indicators worth monitoring alongside vaccine coverage, there are other significant outcomes of the mandatory law that are less easy to assess. Since the mandatory law became effective in 2017, regional and local health authorities in Tuscany and elsewhere in the country, have embarked in systematic review and validation of their rIIS, to verify entries, cleaning databases and

entering missing information. These activities have been essential to allow identification of the unvaccinated/partly vaccinated children for catch-up immunizations, but have also been instrumental for a substantial improvement of the completeness and accuracy of the rIIS. Besides, parents of unvaccinated children have been forced by the law to contact vaccination officers for undergoing vaccine counselling. As a result, more children have completed the recommended vaccination schedule, and health authorities can rely on their monitoring systems to assess the impact of the interventions and to better plan for future initiatives. Such efforts might be considered as a major outcome of the mandatory law. In our opinion, mandates did not only affect hesitant parents, but forced local health services to allocate more resources to immunisation activities and to be more effective as a whole.

When contemplating, planning and assessing mandatory vaccination policies, public health decision-makers should consider also the broader implications of such strategies, not only for the population but also for health services, as these may lead to a virtuous circle of improved quality, improved trust and enhanced vaccine resilience.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: [PL Lopalco, during the latest 4 years, received financial support in form either of research grants or personal consultation fees by GSK, MSD, Pfizer, Sanofi, Seqirus. The other Authors do not declare any potential competing interests.].

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