



## Commentary

## Mandatory vaccinations for children in Italy: The need for a stable frame

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Spoken words fly away, written words remain (Latin proverb).

On March 11, 2019 the indications for the 2018/2019 academic year regarding the vaccination requirements for children 0–16 years who attend educational and training institutions were put in place by the Italian Ministry of Health and the Italian Ministry of Education, University and Research [1]. In brief, children younger than six years can be turned away from nursery schools if they have not undergone mandatory vaccinations, while parents risk to pay a fine up to €500 if they send unvaccinated children 6–16 years to schools. Some parents opposed to vaccinations have announced on the social network that they will now withdraw their children from school. In anticipation of the National Vaccination Registry, a self-certification for the vaccination status of the students could be provided by parents until this date in Italy [1–3].

The broad implementation of childhood vaccinations in the second half of the 20th century has been one of the most successful public health policies, leading to the complete control or eradication of several severe infectious diseases. Mandatory vaccination policies had a pivotal role in the exceptional effects of pediatric vaccinations the past century. However, in addition to the benefits for the vaccinated person, the benefits of vaccinations in terms of public health rely on the assumption that vaccination coverage rates within communities consistently exceed the threshold for herd immunity.

Despite the long-lasting vaccination programs, the suboptimal vaccination coverage, for any reason, changed the landscape for some vaccine-preventable diseases in several European countries the past decade. This is the case of the recent measles epidemic in Italy, accounting for almost one quarter of the 12,066 notified measles cases and several deaths recorded in Europe during the large measles epidemic the past year [4]. In addition, following a steadily disappearance of subacute sclerosing panencephalitis in Europe the past decades, two cases were recently diagnosed in young children with measles in Italy [5]. In the modern era, parents who refuse their children vaccinations, render them susceptible to

the most severe outcomes, as the average age of patients has shifted from the first to the third decade of life, often in association with a more severe course or outcome [6]. A modeling study using data from outbreaks in the United States showed that the risk for a severe outcome has increased by 4.5 times for measles, 2.2 times for chickenpox and 5.8 times for rubella in a modern-day scenario compared to the pre-vaccination era [6].

Vaccine hesitancy (the reluctance or refusal to vaccinate despite the availability of vaccines) has been recognized by World Health Organization as one of the ten threats to global health in 2019 [7]. Italy is among the European countries with the highest levels of vaccine hesitancy, mainly because of concerns about vaccine safety and mistrust to public health authorities and other vaccination stakeholders [8]. The fragmentation of the regulatory framework for vaccinations the past twenty years also provided inconsistent messages about vaccinations to the general population in Italy. In response to the increasing vaccine hesitancy, the alarming decrease in vaccination rates below the threshold for herd immunity (from 90.4% against measles and rubella in 2013 to 85.3% in 2015) and the recent large measles epidemic, the Italian Ministry of Health passed the Decree Law 73/2017, raising the number of pediatric mandatory vaccinations from three (against diphtheria, tetanus and poliomyelitis) to twelve (plus against pertussis, hepatitis B, *Haemophilus influenzae* type b, measles, mumps, rubella, varicella, meningococcus serogroup B and meningococcus serogroup C) [2]. At the same time, the prohibition of enrollment of unvaccinated children to nursery schools and kindergartens was legally re-established, but it was not implemented until March 11, 2019 [2]. This law was innovated by the Law 119/2017, rendering ten vaccinations as mandatory (against diphtheria, tetanus, poliomyelitis, pertussis, hepatitis B, *Haemophilus influenzae* type b, measles, mumps, rubella and varicella) [3].

Similarly, France, a country with high rates of vaccine hesitancy and sub-optimal vaccine uptake rates against specific diseases, moved from a mandatory vaccination policy against three diseases (diphtheria, tetanus and poliomyelitis) to a mandatory vaccination policy against eight additional diseases (pertussis, *Haemophilus influenzae* type b, hepatitis B, pneumococcus, measles, mumps, rubella and meningococcus serogroup C) for all birth cohorts from January 1, 2018 onwards [9]. Children whose parents fail to comply to the new vaccination policy, are refused entry to nurseries,

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schools or camps [9]. This policy triggered a debate among public health scientists and other stakeholders in France, however preliminary results indicate significant increases in vaccine uptake rates against hepatitis B (from 88.7% in 2017 to 96.8% in 2018) and meningococcus C (from 43% in 2017 to 74.2% in 2018) and a more favorable attitude towards mandatory vaccinations among mothers of infants younger than 12 months [9,10]. According to a recent systemic review of studies mainly from Europe and North America, the majority of the population seems to be in favor of mandatory vaccination policies [11]. However, confidence towards health professionals and sources of information are key determinants of acceptance of mandatory vaccination policies [12]. Several European countries implement mandatory vaccination policies for the general population and health professionals (Maltezou et al; unpublished data).

The aim of the 2017 laws was to address the alarmingly lowering vaccination coverage rates among children in Italy. Preliminary results have been positive up to now, compared with the recent past where vaccinations were almost uniformly provided in a voluntary basis [13]. Indeed, although the 2017 laws caused numerous controversies, in practice their implementation enabled the vaccination of hundreds of children who would not get vaccinated because of the choice of their parents. However, the self-certification of the vaccination status of children by their parents was inconsistent and not in the same line with the 2017 laws about mandatory vaccinations. In practice, the self-certification provided a legal ground for several parents who refuse vaccinations for their children to surpass the mandatory vaccination policies. False certifications have been provided by vaccine hesitant parents in several occasions. The self-certification policy contributed to the backwards and forwards of vaccination policies in Italy the last twenty years. Given the confusion that the self-certification imposed on the attitudes and practices of parents towards vaccinations and in anticipation of the National Vaccination Registry, we recommend its definite withdrawal and replacement by a vaccination certification by health professionals. However, vaccine hesitant parents may seek advice from vaccine hesitant health professionals. A telephone survey among 1712 general practitioners in France found that 11% were moderately vaccine-hesitant and 3% were highly hesitant or opposed vaccinations [14]. In France, checking the vaccination status of young children is the responsibility of the personnel of nurseries, schools and camps. The difficulties to assess the vaccination status of children and to have reliable real-time data at the national level emerged the past years in several European countries. National vaccination registries are urgently needed to guide public health interventions. In the meanwhile, the state and public health authorities should fulfill their obligation to protect the most vulnerable people, considering

the recent tragedy in Europe of losing several tens of lives from measles, for which safe and effective vaccines are available for several decades.

### Declaration of Competing Interest

The authors declared that there is no conflict of interest.

### References

- [1] Ministry of Health, Ministry of Education, University and Research. Subject: vaccination requirements relating to minors aged between zero and sixteen who attend educational, training and educational institutions – new guidelines for the 2018–2019 annual school. Available at: <<http://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2018&codLeg=64928&parte=1%20&serie=null>> [last accessed: March 17, 2019] [in Italian].
- [2] Decree-law 7 June 2017, n. 73, containing "Urgent provisions concerning vaccination prevention" G.U. General Series, n.130; 7 June 2017. Available at: <<http://www.gazzettaufficiale.it/eli/id/2017/08/05/17A05515/sg>> [last accessed: March 17, 2019] [in Italian].
- [3] Law 31 July 2017, n. 119. Conversion into law, with amendments, of the decree-law 7 June 2017, n. 73, containing urgent provisions regarding vaccination prevention. Official Gazette General Series, n.182; 5 August 2017. Available at: <<http://www.gazzettaufficiale.it/eli/gu/2017/08/05/182/sg/pdf>> [last accessed: March 17, 2019] [in Italian].
- [4] European Centre for Disease Prevention and Control. Monthly measles and rubella monitoring report. March 2019. Available at: <<https://www.ecdc.europa.eu/sites/portal/files/documents/measles-monthly-report-march-2019.pdf>> [last accessed: March 17, 2019].
- [5] Masnada S, Zuccotti GV, Bova SM, Gatti H, Morabito V, Santarone ME, et al. Re-emergence of SSPE: consequence of the decline of adherence to vaccination programmes? *Eur J Paediatr Neurol* 2019;23():338–40.
- [6] Fefferman NH, Naumova EN. Dangers of vaccine refusal near the herd immunity threshold: a modeling study. *Lancet Infect Dis* 2015;15:922–6.
- [7] World Health Organization. Ten threats to global health in 2019. Available at: <<https://www.who.int/emergencies/ten-threats-to-global-health-in-2019>> [last accessed: March 17, 2019].
- [8] Giambi C, Fabiani M, D'Ancona F, Ferrara L, Fiacchini D, Gallo T, et al. Parental vaccine hesitancy in Italy – results from a national survey. *Vaccine* 2018;36:779–87.
- [9] Cohen R, Gaudelus J, Leboucher B, Stahl JP, Denis F, Subtil D, et al. Impact of mandatory vaccination extension on infant vaccine coverages: promising preliminary results. *Med Mal Infect* 2019;49:34–7.
- [10] Vaccine boosters. *Nature* 2018;553:249–50.
- [11] Gualano MR, Olivero E, Voglino G, Corezzi M, Rossello P, Vicentini C, et al. Knowledge, attitudes and beliefs towards compulsory vaccination: a systemic review. *Hum Vaccin Immunother* 2019;1–14. <https://doi.org/10.1080/21645515.2018.1564437> [Epub ahead of print].
- [12] Gualano MR, Bert F, Voglino G, Buttinelli E, D'Errico MM, De Waure C, et al. Attitudes towards compulsory vaccination in Italy: Results from the NAVIDAD multicentre study. *Vaccine* 2018;36:3368–74.
- [13] Ministry of Health. Subject: Vaccination coverage at 24 months, 36 months and 5–6 years of age (per 100 inhabitants) by Region and by antigen. Available at: <[http://www.salute.gov.it/portale/news/p3\\_2\\_1\\_1\\_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=3633](http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=3633)> [last accessed: March 17, 2019] [in Italian].
- [14] Verger P, Collange F, Fressard L, Bocquier A, Gautier A, Pulcini C, et al. Prevalence and correlates of vaccine hesitancy among general practitioners: a cross-sectional telephone survey in France, April to July 2014. *Euro Surveill* 2016;21(47). pii: 30406.