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Health Reform Monitor

The 2017 Italian reform on mandatory childhood vaccinations: Analysis of the policy process and early implementation☆

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ABSTRACT

Background: The data on vaccination coverage for the year 2016 were a cause of concern for the Italian government. For some years, in fact, there has been a growing mistrust of vaccines in the Italy, and consequently vaccination coverage rates have been decreasing. The number of cases of measles has been particularly high.
Aim: The purpose of this article is to examine the content and the preliminary outcomes of the Lorenzin Decree, which was passed in 2017. This reform embodies a 'hard' approach to the issue of childhood vaccinations, based on their mandatory nature and on the intensification of the sanctions against non-compliant subjects.
Results: The Lorenzin decree provides for an increase in mandatory infant vaccines from four to ten. Following the reform, unvaccinated children are denied access to nurseries and kindergartens. Parents who do not have their children vaccinated are liable to pay a financial penalty. Data on the preliminary outcomes of the reform show an increase in vaccination coverage.
Conclusion: The Italian experience provides some policy recommendations, and could be a source of inspiration for European countries that are tackling vaccine hesitancy and declining vaccination coverage rates. At least for the short term, the 'hard' approach adopted by the Italian government is, in fact, bearing fruit, having reversed the negative trend in vaccination coverage rates.

1. The purpose of the policy idea

Before the 2017 reform came into force, four childhood vaccinations were 'formally mandatory' in Italy, which were: diphtheria, tetanus, poliomyelitis and hepatitis B. We use the expression 'formally mandatory' because, in reality, no type of sanction was enforced for parents who decided not to vaccinate their children. One of the twenty Italian regions, Veneto, had even transformed the four vaccinations from being compulsory to simply 'recommended'. In addition, before 2017, Italy was among the European countries with the lowest rates of confidence in vaccines (Larson et al. 2016; Siciliani et al. 2020). The lack of effective sanctions on one hand, and the growing vaccine hesitancy on the other, had over the years led to a progressive reduction in vaccination coverage rates (WHO 2017; EpiCentro 2018; Giambi et al. 2018; Ministero della Salute 2018; Montanari Vergallo et al. 2018).

The coverage rates for so-called 'hexavalent vaccines' – i.e., anti-polio, anti-diphtheria, anti-tetanus, anti-pertussis, anti-hepatitis B, and anti-type B Haemophilus influenzae – decreased, on a national average, from 96.5% in 2006 to 93.4% in 2016. Additionally, measles, mumps and rubella vaccinations – which exceeded 90.5% coverage in 2010 – dropped to around 87% in 2016. Measles epidemics, which were breaking out in Italy during this period, represent a particular cause for concern. In 2017, 82 cases of measles per one million inhabitants were recorded in Italy, whereas the European yearly average was 28 cases (ECDC 2018). In Italy in 2016, the vaccination coverage against measles was among the lowest in Europe (Rechel et al. 2018).

The Legislative Decree no. 73, containing 'urgent provisions on vaccination prevention', was approved in May 2017 by the Gentiloni government on the initiative of Minister of Health at that time, Beatrice Lorenzin (for whom the decree is named). Having the general aim of reversing the decline in immunization coverage in Italy, the so-called 'Lorenzin decree' embodies a 'hard' approach to the vaccine problem. The decree provides for an increase in the

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number of mandatory vaccinations from four to ten, and the tightening of penalties for the non-compliant.

The introduction of many mandatory vaccinations became a divisive and politically salient topic in Italy. The issue received heavy media coverage and attracted public attention even beyond national borders.

Actually, European countries can be grouped into two large families (Bozzola et al. 2018; Rechel et al. 2018; Paul and Loer 2019). On one hand, there are countries that impose mandatory childhood vaccinations. Countries such as Bulgaria, Croatia, Czech Republic, Hungary, Poland, Slovakia, and - for some time now - also Italy and France have followed the mandatory approach. On the other hand, there are countries that prefer to 'recommend' vaccinations, while keeping them voluntary in a formal sense. Instead, this strategy of imposing a formal obligation relies more on information and persuasion, appealing to parental responsibility (Rechel et al. 2018). The Nordic countries, Germany, UK, Netherlands, Austria, Ireland, Spain and Portugal are among the countries that adopt the voluntary approach to childhood vaccinations (Bozzola et al. 2018).

Therefore, the Italian experience is also of interest to policymakers in other countries since the Lorenzin decree marks a change in strategy and the transition from a looser to a decidedly mandatory approach.

2. Political and Economic Background: The commitments undertaken by the Italian government at an international level

The Gentiloni government held office from 12 December 2016 to 1 June 2018. The Democratic Party, which was the main political force of this coalition government, enjoyed the support of the New Right Center led by Angelino Alfano and five other minor political parties belonging to the left and centre of the political spectrum. Since its rise to power, the Gentiloni government, and in particular, the Minister of Health, Beatrice Lorenzin, had to tackle the decline in vaccination coverage, which hindered attempts to meet Italy's international commitments. In particular, this refers to the guidelines set by the World Health Organization (WHO 2013, 2014), according to which herd immunity is attained by reaching a vaccination coverage of 95% for each birth cohort, with respect to certain infectious diseases, such as measles.

Moreover, Italy had assumed some formal commitments at an international level (Casula and Toth 2019). As stated in the European Vaccine Action Plan 2015-2020, for example, all 53 countries of the WHO's European region are required: 1) to preserve the status of a 'polio-free' country; 2) to control hepatitis B infections; 3) to eliminate the cases of measles and rubella; 4) to reach 95% coverage of at least three vaccinations by 2020, for diphtheria, tetanus and pertussis.

Despite these recommendations from the WHO, and the international commitments that had been made, the vaccination coverage in Italy did not reach the recommended 95% threshold in the years immediately preceding the adoption of the Lorenzin decree. As a consequence, in the first few months of 2015, Italy received a formal warning from the WHO because in Italy the vaccination coverage was at its lowest point for the last ten years, with cases of measles causing the most concern.

3. Health Policy Process

The decision to issue a legislative decree establishing broad vaccination requirements was made by Minister Lorenzin, after having been consulted by scientific consultants and collaborators. A decisive impulse came from the president of the Italian National Institute of Health (*Istituto Superiore di Sanità, ISS*) and the National Regions Conference.

After the Council of Ministers passed the legislative decree on 19 May, it was signed by the President of the Republic on 7 June. Given that Italian legislation requires that legislative decrees be converted into law by Parliament within sixty days of their enacting, the final approval by both Chambers – namely, the Chamber of Deputies and the Senate – was to be granted by 6 August 2017.

The original version of the legislative decree was subject to several amendments during examination in the Senate. The law was then finally approved on 20 July 2017, with 171 votes in favour, 63 against and 19 abstained. Concerning the main political forces represented in the Senate, the conversion law was supported by various parties as well as the Democratic Party, such as Forza Italia (the party formed by Silvio Berlusconi), among others. Instead, the Senators from the League (Matteo Salvini's party) and the Five Star Movement (*Movimento Cinque Stelle, M5S*), voted against it.

In order to prevent the 60-day expiration of the Lorenzin decree, no further changes were made to the text that was approved by Senate when the bill was transferred to the Chamber of Deputies. For the same reason, the Gentiloni government decided to cast a vote of confidence. Consequently, on 28 July, the draft passed by the Senate was then approved by the Chamber of Deputies as well, with 292 deputies in favour, 92 against and 15 abstaining. All the Deputies of the Democratic Party, most of the deputies of Forza Italia, as well as some minor centrist parties were in favor of the conversion law. Similar to what happened in the Senate, the conversion law was not supported by the Five Star Movement and the League.

4. The Content of the reform: Which Policy Instruments were used?

The traditional political science literature on policy tools (Linder and Peters 1989; Eliadis et al. 2005; Howlett, 2009; Capano and Lippi 2017) can provide a useful analytical means for better understanding the content of the Lorenzin reform. It is plausible to argue that the general strategy pursued by the Gentiloni government was a policy mix, based mainly on the use of regulation and coercion, through the introduction of new sanctions. Aside from these means, the government used persuasive tools aimed at promoting a culture of vaccination in Italy.

The main regulatory provision was the increase in the number of mandatory vaccinations from four to ten. In addition to the four vaccinations (for poliomyelitis, tetanus, diphtheria and hepatitis B), which were formally mandatory before the reform in 2017. The Lorenzin decree introduced another 6, for the following illnesses: pertussis, Haemophilus influenzae type B (Hib), measles, rubella, mumps, and chicken pox. In particular, the Lorenzin decree stated that all children born in 2017 or later were required to receive these ten vaccinations. The certification of vaccination would become an indispensable condition for the enrollment of children in kindergarten and nursery schools. In addition, the parents of an unvaccinated child would be charged a fine, ranging from 200 to 500 euros.

Children with health problems for which vaccination is contraindicated and those who have immunization as a result of natural illness would be exempt from the mandatory vaccination.

Within the reform package, regulation, coercion and financial penalties were combined with information dissemination and persuasion. The Lorenzin decree gives the Ministry of Health, in a combined effort with the Ministry of Education, the task of running campaigns and initiatives in schools regarding vaccine hesitancy. To contribute to the culture of vaccination in the Italian population, moreover, the Lorenzin decree provided a free-of-charge public health service of four additional vaccines (anti-meningococcal

B, anti-meningococcal C, anti-pneumococcal, and anti-rotavirus), which are not compulsory vaccinations, but simply 'recommended' by the Ministry of Health.

Finally, the reform in 2017 has assigned new competences to the Italian Medicines Agency (*Agenzia Italiana del Farmaco, AIFA*). According to the Lorenzin decree, AIFA must negotiate the prices of vaccines with pharmaceutical companies and monitor the impact of adverse reactions to vaccines as well as the outcomes of the vaccination programmes. In addition, an informative resource – the National Vaccine Registry – was established within the Ministry of Health. The purpose of the Registry was to record and manage information regarding all the vaccinated children, the administered vaccine doses as well as the possible undesirable effects of vaccines through a national computerised system.

5. Political parties and stakeholder positions

As was to be expected, the issue of mandatory vaccinations ended up dividing public opinion and the principal national political forces. The first objections by those who were against mandatory vaccination were raised, especially online, as early as when the initial rumours circulated in the press about the content of the decree. In June and July 2017, several demonstrations were held in favour of vaccination freedom in different Italian cities. Outside the Senate headquarters and later in front of the Chamber of Deputies, demonstrations and sit-ins were organized in order to put pressure on parliamentarians. Some Democratic members of parliament were attacked by some demonstrators, necessitating the intervention of the police forces. Minister Lorenzin and her staff were subjected to verbal attacks and threats.

In general, two rival coalitions emerged (Casula and Toth 2018). The first coalition, which was in favour of implementing new vaccination obligations, was led by the Ministry of Health and enjoyed the full support of the National Institute of Health, the Italian Medicines Agency, the National Health Council (*Consiglio Superiore di Sanità*) and the associations of paediatricians and family doctors. The Lorenzin decree was also supported by other medical associations and the majority of regional administrations, with the exception of only two regions – Valle d'Aosta and Veneto. In this regard, it is worth emphasizing that the latter also attempted to oppose the implementation of the Lorenzin decree by legal means, challenging the decree in Constitutional Court. However, the appeal advanced by the Region of Veneto was rejected by the Court in November 2017.

In addition to these regional administrations, the coalition that was opposed to mandatory vaccination was comprised of a multiplicity of small associations and informal groups. Compared to the coalition in favor of vaccinations, the opposing coalition was more heterogeneous, it lacked unitary leadership and it was organized mainly through social networks. Within the coalition against the Lorenzin decree, there were two distinguishing factions: the 'no-vax' versus the 'free-vax'. On one hand, the 'no-vax' supporters were extremely opposed to vaccinations since they considered them potentially harmful to health. On the other hand, the 'free-vax' supporters believed that, although they are safe, childhood vaccines should not be mandatory; the State should not interfere with the freedom of individuals to decide whether and how to get vaccinated.

Two rival coalitions also emerged in Parliament, with MPs divided between those who supported and those who were against the Lorenzin decree. The Five Star Movement and the League – the two main opposition parties – strongly opposed the Lorenzin decree. They were convinced that a strategy based on informative tools and persuasion would be more effective.

The positions of the stakeholders, and their respective political influence, are summarised in Graph 1 .

Graph 1 identifies the Ministry of Health and the National Institute of Health as the two main institutional actors which most promoted the reform, followed by the Democratic Party. Although in favour of the reform, the Italian Medicines Agency, associations of paediatricians and of family doctors were not able to take any lobbying action, which was, instead, picked up on by the anti-vaccination movement. The latter, in fact, through aggressive action, especially through social media, managed to put pressure on parliamentary debate. The 'no-vax' movement strongly influenced the positions of the League and the Five Star Movement, which were the major parties that voted against the reform. However, the main opposition parties were not successful in modifying the draft of the decree.

6. Preliminary outcomes

By looking at the vaccination coverage in Italy before and after the reform, certain preliminary outcomes come into view. Table 1 shows the vaccination coverage for mandatory and 'recommended' vaccinations during the period from 2010-2019, by considering the vaccination rate at the twenty-fourth month of life. While confirming a negative trend in the years leading up to the entry of the Lorenzin decree into force, the data shows a positive effect of this law. The choice to opt for a coercive measure is, in fact, increasing the vaccination rate in Italy, which in 2019, with 9 vaccinations out of 10, reached (or at least is very close to) the threshold of 95%. The lowest vaccination rate continues to be that for chickenpox (now approximately 90%), even though its vaccination coverage has increased in a significant way in recent years, which was previously around 45% before the Lorenzin decree entered into force.

Unfortunately, it is not possible to have a single national database capable of providing us, on a regional basis, with an accurate picture of the number and amount of penalties that have been imposed so far. However, an in-depth review of the main national journalistic sources reveals the persistence of some ño-vax enclaves(i.e. geographical areas in which anti-vaccine sentiments are more rooted, and in which vaccination coverage is lower than elsewhere). For example, some municipalities' data is available in which, at the beginning of the 2019-2020 school year, the following number of regularly enrolled but not vaccinated children were expelled from nursery schools and to whose parents an economic sanction was applied: 470 in Bolzano, 1,800 in Venice, 700 in Florence and 400 in Bologna.

7. Conclusion

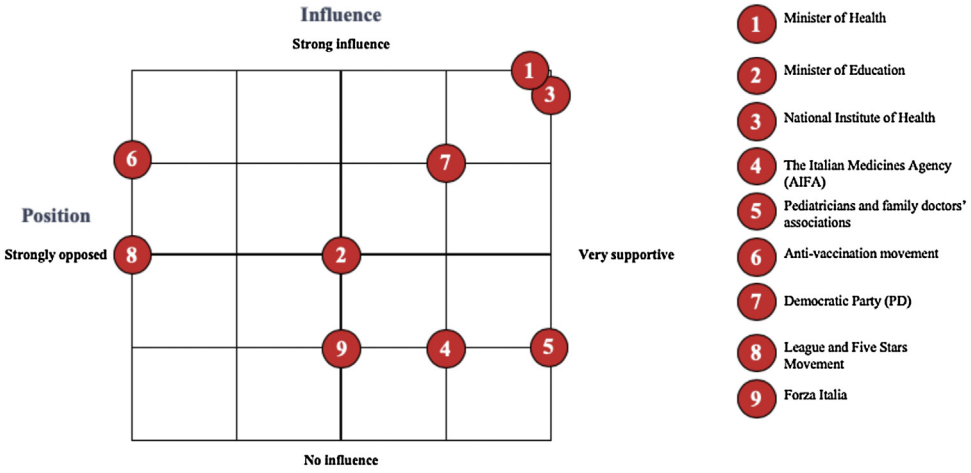
Italy's latest reform for increasing childhood vaccination coverage rates can also provide lessons to other countries that are facing vaccine hesitancy and declining vaccination rates. Italy has opted for a 'hard' approach, based on the mandatory nature of vaccines and the tightening of sanctions. Alongside the regulatory and coercive measures, the Lorenzin decree also implemented the use of informative tools and the promotion of awareness campaigns.

The adoption of the Lorenzin decree was made possible thanks to a favorable situation of international pressure, support from the medical-scientific community and agreement in parliament between the government coalition and some members of the opposition. The 'hard' approach adopted by the Gentiloni government aroused resistance and protest from some of the opposition parties and movements opposed to mandatory vaccination. However,

Table 1
Vaccination coverage (2010-2019) - Vaccination on the 24th month.

	Mandatory vs. not mandatory before decree law no. 73/2017	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
diphtheria	Mandatory	96.4	96.3	96.2	95.7	94.7	93.3	93.6	94.6	95.1	95.0
tetanus	Mandatory	96.4	96.3	96.2	95.8	94.8	93.6	93.7	94.7	95.1	95.0
pertussis	Not mandatory	96.4	96.3	96.2	95.7	94.6	93.3	93.6	94.6	95.1	95.0
poliomyelitis	Mandatory	96.3	96.1	96.2	95.7	94.7	93.4	93.3	94.6	95.1	95.0
hepatitis B	Mandatory	95.8	96	96	95.6	94.6	93.2	93	94.4	94.9	94.9
Haemophilus influenzae type B (Hib)	Not mandatory	94.6	95.6	94.8	94.9	94.3	93	93.1	94.3	94.3	94.9
measles	Not mandatory	90.6	90.1	90	90.3	86.7	85.3	87.3	91.8	93.2	94.5
mumps	Not mandatory	90.6	90.1	90	90.3	86.7	85.2	87.2	91.8	93.2	94.4
rubella	Not mandatory	90.6	90.1	90	90.3	86.7	85.2	87.2	91.8	93.2	94.5
chickenpox	Not mandatory	n.a.	n.a.	n.a.	30.7	36.6	33.2	46.1	45.6	74.2	90.5

Source: EpiCentro (2020)



Graph 1. Positions of stakeholders and influence at a glance.

these protests did not prevent the approval and implementation of the decree.

Two years after its entry into force, the Lorenzin decree seems to be working. According to the data available so far, a considerable increase in vaccination coverage has been recorded up to now.

Following the 2017 reform, Italy has become - at least at the European level - one of the countries that most embodies the 'mandatory' approach to childhood vaccinations. The Italian example could be followed by other countries. France, for example, taking a cue from the Lorenzin decree, has also decided to increase the number of compulsory vaccinations (from 3 to 11) beginning in January 2018 (Paul and Loer, 2019). And other countries are considering whether to make certain vaccinations mandatory, particularly the measles vaccine (Siciliani et al. 2020).

Declaration of Competing Interest

The authors report no declarations of interest.

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