

The Yellow-Green Government and the Thorny Issue of Routine Childhood Vaccination

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Abstract

During recent years, routine childhood vaccination has become a divisive and politically salient topic in Italy. During the spring of 2017, for example, the Lorenzin decree (No. 73 of 2017), which contained urgent provisions on vaccination prevention, divided public opinion and national political forces. In particular, both the League and the Five Star Movement immediately opposed the introduction of ten mandatory vaccinations. Moreover, the routine child immunization topic was once again at the centre of the political debate during the summer of 2018. The aim of this article is to present the contours of the problem relating to childhood vaccinations in Italy, and to reconstruct the current debate on mandatory vaccinations. It is not yet clear how the newly elected yellow-green government intends to tackle the problem: in the conclusions we will try to formulate some hypotheses.

Introduction

In the last few years, routine childhood vaccination has become a divisive and politically salient topic in Italy. During the spring of 2017, the Lorenzin decree (decree law no. 73), which increased the number of compulsory vaccinations, divided public opinion and political parties. Opposing the Lorenzin decree were, above all, the League and the Five Star Movement, the two parties currently in government.

When the Conte government took office in June 2018, the issue of childhood vaccination returned to the centre of the debate. Both the coalition partners are in favour of modifying the Lorenzin decree, but they do not seem to agree on the strategy to follow.

The League has always opposed the vaccination obligation and believes that information and persuasion strategy should be preferred over the use of obligations and sanctions: parents must be free to decide what is best for their children.

In relation to vaccines, the Five Star Movement has so far assumed an ambivalent position. Especially before the 2018 elections, several exponents of the Five Star Movement showed scepticism towards vaccinations, expressing opinions very similar to those of the 'no-vax' movement. After the elections, some leaders of the Movement instead issued more cautious statements: the Five Star Movement declares itself in favour of childhood vaccination, but believes that the provisions contained in the Lorenzin decree should be made more flexible and should differentiate from region to region.

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The aim of this article is to trace the contours of the problem related to childhood vaccination in Italy, and to describe the current debate on mandatory vaccinations. It is not yet clear how the newly elected yellow-green government intends to tackle the problem. We will try in the conclusions to formulate some hypotheses about it.

1. The problem: an overview of childhood vaccination coverage in Italy

Childhood vaccinations are considered among the most effective, and cost-effective, public health interventions to prevent infectious diseases [Ehreth 2003; Bloom et al. 2005; Andre et al. 2008; Doherty et al. 2016]. According to the World Health Organization, routine childhood vaccinations make it possible to avoid between 2 and 3 million deaths in the world every year due to diphtheria, tetanus, pertussis and measles [WHO 2017]. Nonetheless, over the past few years in Italy a substantial decrease in immunization coverage has been recorded [WHO 2017; EpiCentro 2018; Ministry of Health 2018]. The decreasing trend in immunization coverage is fuelled by the belief that vaccines are not effective and might instead cause serious adverse effects [Montanari Vergallo et al. 2018].

The decrease in vaccination coverage is a concern not only for non-immunized individuals, but also for society as a whole. As a matter of fact, so-called herd immunity is reached only when a high percentage of the population is immune to a given infectious disease. Once herd immunity is achieved, a given pathogen cannot spread further [Fox et al. 1971; Anderson and May 1985; Fine 1993; John and Samuel 2000; Fine et al. 2011]. Herd immunity is therefore a form of indirect protection against infectious diseases, since it also preserves the few individuals who have not been immunized [Fine 1993; John and Samuel 2000; Doherty et al. 2016]. World Health Organization recommendations [WHO 2013, 2014] indicate that herd immunity of some infectious diseases is reached when the vaccination coverage achieves 95% of each birth cohort. This is, for example, the case of measles.

Despite the recommendations of the World Health Organization, in the last few years vaccination coverage in Italy has not reached the recommended 95% threshold. For example, in 2016, coverage of the so-called 'hexavalent vaccines' – i.e., anti-polio, anti-diphtheria, anti-tetanus, anti-pertussis, anti-hepatitis B, and anti-type B *Haemophilus influenzae* – stood at around 93.4% as national average [Ministry of Health 2018]. Vaccination coverage, however, was not uniform all over the country: while some regions exceeded the 95% threshold, others were far below it [Montanari Vergallo et al. 2018]. The vaccination coverage for measles, mumps and rubella was much lower: as a national average, in 2016, coverage was around 87%, and no Italian region reached the recommended threshold of 95%. Moreover, the anti-chickenpox (varicella) coverage rate was around 46% as a national average. The data just reported are the consequence of a decrease in childhood vaccination coverage in Italy over the last decade or so. While the coverage rates for vaccinations included in the hexavalent vaccines were around 96.5% in 2006, from 2008 onwards the coverage rates have been decreasing. While measles, mumps and rubella vaccinations exceeded 90.5% of coverage in 2010, they were around 87% in 2016.

Finally, measles epidemics are a particular cause for concern. In fact, in the year 2017, the recorded cases of measles in the EU/EEA area were just under 14,500, of which more than a third were in Italy. There were 82 cases of measles per million inhabitants in Italy, compared to a European average equal to 28 cases per million [ECDC 2018]. In proportion to the population, only Romania and Greece report more cases of measles than Italy.

2. The Lorenzin decree law of June 2017

In May 2017, on the impulse of the Italian Minister of Health, Beatrice Lorenzin, the Gentiloni government approved a decree law containing ‘urgent provisions on vaccination prevention’. With the general aim of reversing the decline in immunization coverage, the Lorenzin decree (decree law no. 73) increased the number of mandatory vaccinations for children. The decree law was passed by the Council of Ministers on 19 May, and it was then signed by the President of the Republic on 7 June. The innovations introduced by the Lorenzin decree are described below.

COMPULSORY VACCINATIONS. Until decree law no. 73 came into effect, there were four mandatory vaccinations (against poliomyelitis, tetanus, diphtheria, and hepatitis B). By virtue of the Lorenzin decree the number of mandatory vaccinations was increased from four to twelve. The eight additional vaccinations were those against pertussis, *Haemophilus influenzae* type B (Hib), measles, rubella, mumps, chickenpox (varicella), meningococcus B and meningococcus C. Most of these were previously considered as merely ‘recommended’ by Italian legislation. These twelve vaccinations would have been compulsorily administered to all children born from 2017 onwards and would have become a mandatory requirement to access nursery schools and kindergartens.

ECONOMIC PENALTIES. In addition to the exclusion of children from pre-school educational services, the violation of the vaccination mandate would have also involved the application of pecuniary sanctions to be paid by defaulting parents. The economic penalties could have varied from a minimum of 500 euros up to a maximum of 7,500 euros.

EXEMPTIONS. The Lorenzin decree envisaged that two categories of children would be exempt from the vaccination obligation: 1) those already immunized as a result of natural illness (such as children who have already contracted the disease); and 2) those who are in specific clinical conditions that represent a contraindication to vaccinations (such as, immunocompromised children). Both exemptions should be attested by the family doctor.

PUBLIC COMMUNICATION CAMPAIGNS. The decree law attributed to the Ministry of Health the task of promoting initiatives of public communication to spread the culture of vaccination among the population. In particular, the Ministry of Health had to agree with the Ministry of Education on some awareness-raising initiatives for pupils and teaching staff in schools. For these initiatives, 200,000 euros were allocated for the year 2017.

3. The conversion law (and the main differences with the decree law)

In Italy, decree laws expire within sixty days unless converted into law by Parliament. As a consequence, the Lorenzin decree should have obtained the approval of both the Chamber of Deputies and the Senate by 6 August 2017.

During the examination of the conversion law in the Senate, several amendments to the original text of the decree law were approved within the 'Hygiene and Health' committee. The conversion law containing these amendments was voted on 20 July 2017. The votes in favour were 171, while those against were 63, with 19 abstainers. The Democratic Party, Alternativa Popolare and the Group for Autonomy voted in favour of the conversion law, as well as most of the Senators of Forza Italia, Ala-Scelta Civica, and art.1-Mdp. On the contrary, the League and the Five Star Movement voted against it.

After Senate approval, the bill passed to the Chamber of Deputies. To prevent the expiration of the Lorenzin decree 60 days after its approval, no further changes were made to the text, and the government opted for a vote of confidence. On 28 July, the same draft previously passed by the Senate was approved by the Chamber as well. The votes in favour were 292, while those against were 92, with 15 abstainers. As in the case of the Senate vote, while the Democratic Party, Alternativa Popolare, Ala-Scelta Civica and the majority of the deputies of Forza Italia and Art.1-Mdp voted in favour of the conversion law, the Five Star Movement and the League voted against. Sinistra Italiana and Fratelli d'Italia abstained.

3.1 Differences between the conversion law and the original text of the Lorenzin decree

As already mentioned, in the course of the examination in the Senate committee, the original draft of the Lorenzin decree underwent some substantial changes. The main differences between the two texts are as follows.

COMPULSORY VACCINATIONS: 6+4. The mandatory vaccinations would no longer be twelve as required by the decree law but ten, namely: anti-polio, anti-diphtheria, anti-tetanus, anti-hepatitis B, anti-pertussis, anti-Haemophilus influenzae B, in addition to vaccinations against measles, rubella, mumps and varicella. The compulsoriness of the last four is, however, to be reviewed every three years, based on data on vaccination coverage and any reported adverse reactions. Moreover, the conversion law made explicit that the compulsory vaccines also applied to unaccompanied foreign minors.

FOUR 'RECOMMENDED' VACCINATIONS. In addition to the ten mandatory vaccinations, four vaccines are considered 'recommended'. This means that the public health service will offer them free of charge, but without any obligation. The recommended vaccinations are now anti-meningococcal B, anti-meningococcal C, anti-pneumococcal, and anti-rotavirus.

SANCTIONS. The conversion law confirmed that compulsory vaccinations constitute a requirement to access kindergartens and nursery schools, but not for other degrees of education (such as primary and secondary school). The economic penalties which can be levied in case of failure to comply with the mandate were significantly reduced: by

virtue of the conversion law, the minimum penalty is now 200 euros, while the maximum fine is 500 euros (instead of 7,500).

EXEMPTIONS. As far as the exemptions are concerned, the conversion law confirms what was already stated by the decree law, namely that the following categories are exempted from the obligation: 1) children affected by health problems for which vaccination is contraindicated; and 2) children already immunized as a result of natural illness.

TASKS ASSIGNED TO AIFA. The conversion law attributes to AIFA (the Italian Medicines Agency) some tasks that were not mentioned in the previous decree law. First, AIFA is required to prepare an annual report – to be submitted to the Ministry of Health and then to the Chambers – on the outcomes of the vaccination programmes and on the impact of adverse reactions to vaccines. AIFA is also responsible for negotiating the prices of vaccines with pharmaceutical companies.

COMPENSATION FOR VACCINE DAMAGE. The conversion law includes some provisions, which did not appear in the decree law, regarding compensation for damage caused by vaccines. Approximately one and a half million euros are allocated for the years 2017 and 2018 to meet any compensation claims.

NATIONAL VACCINE REGISTRY. A final provision included in the conversion law is the establishment of a National Vaccine Registry within the Ministry of Health, with the aim of monitoring the implementation of the vaccination programmes. This would be a national computerized tracking system through which all vaccinated children are registered, as well as those not yet vaccinated, the doses and timing of vaccine administration, and any undesired effects recorded. For the realization of this national vaccine registry, 300,000 euros are made available (for the year 2018).

4. The parliamentary debate: favourable, sceptical and contrary parties to the Lorenzin decree

The main parties represented in the Italian Parliament were divided between those that supported the conversion law, and those that never shared its basic approach and voted against it. In addition, it is possible to identify a third group of parties who voted in favour of the conversion law, despite having shown scepticism towards the approach inspiring the Lorenzin decree.

The Democratic Party, Alternativa Popolare and Ala-Scelta Civica were in favour of the introduction of the vaccination obligation. They immediately promoted public campaigns to raise awareness about the safety of vaccines and also the usefulness of herd immunity. Even though they share the approach of the Lorenzin decree, these parties positively welcomed the changes introduced during the Senate discussion, considering the amendments the result of a constructive parliamentary debate.

On the contrary, the Five Star Movement and the League are the main parties that had been opposed to the use of coercive measures since the presentation of the Lorenzin decree. In their opinion, the strategy to follow must rely on information and persuasion, not on obligation and sanctions. They thus required a ministerial information campaign to inform parents about the benefits and potential side effects of childhood vaccinations.

In this way, families would be given freedom of choice in deciding about the vaccination of their children.

Finally, Forza Italia, Fratelli d'Italia and Art.1-Mdp can be included in a third group of parties which, though initially sceptical towards the Lorenzin decree, finally voted in favour of the conversion law. They recognized that the parliamentary debate led to the introduction of relevant amendments that greatly improved the bill. In addition, they were aware that a rejection of the conversion law would have given their electorate the impression of being against vaccines.

5. The League's position on vaccination

The League's position on the issue of routine childhood vaccination has remained unchanged since the presentation of the Lorenzin decree. During the parliamentary debate, the League expressed opposition to the decree, accusing it of violating Article 32 of the Italian Constitution, as it infringes on the freedom of care of minors. For this reason, the League's parliamentarians voted against the conversion law. In particular, they declared themselves to be against the sanctions foreseen by the decree in the case of non-compliance with the vaccination obligation.

The national leaders of the League have repeatedly stated that they are supporters of the strategy adopted in Veneto. The latter is one of the two Italian regions (the other is Lombardy) currently governed by a League politician.

The Veneto Region, in accordance with regional law no. 7/2007, has abolished any form of vaccination mandate. This means that from 2007 to the approval of the Lorenzin decree, four vaccinations (anti-polio, anti-diphtheria, anti-tetanus and anti-hepatitis B) were mandatory in most Italian regions, but not in Veneto.

The advantages of the Veneto model have been repeatedly underlined by the president of this region, Luca Zaia (one of the most influential leaders of the League): *'Veneto is not against vaccines, but we are convinced that obligation is counterproductive, and leads to increased scepticism towards vaccines. Veneto is the only Italian region that does not provide mandatory vaccinations. We prefer to convince parents, leaving them free to choose. This is the strategy adopted in other 15 European countries, including Germany, Spain, the United Kingdom and many northern European countries'* (interview with Il Sole 24 Ore, 6 July 2017).

In Luca Zaia's opinion, the Veneto region model, based on the removal of the vaccination mandate and the elimination of any sanctions, should be extended to the entire nation.

This position continues to be supported by League members, as stated on different occasions by its leader, Matteo Salvini. The latter has publicly said that ten vaccines are *'too many'* and that the choice over whether or not to vaccinate children should be left to parents.

'Like many doctors, I believe that it is better to educate to vaccines than to oblige', said Salvini during an interview with the economic newspaper Il Sole 24 Ore (June 22, 2018). *'I vaccinated my children. Some vaccines save lives, but ten vaccines for some children are useless and even dangerous. I'm not anti-vaccination, but there are so many documented adverse reactions to vaccines. No child should be excluded from school or kindergarten'*.

The League's position against the vaccination obligation was revealed by a tweet released by Matteo Salvini on January 2018, in the middle of the election campaign. Salvini wrote: '*We will delete Lorenzin rules. Vaccines yes, obligation no*'. This tweet generated strong friction with Forza Italia and its leader Silvio Berlusconi, who expressed his total opposition to the opinion expressed by his coalition ally. This explains the decision not to include any reference to the issue of vaccines within the centre-right coalition's electoral programme for the March 2018 general elections (the League did not present its own separate electoral programme, but a unique coalition programme, together with Forza Italia and Fratelli d'Italia).

6. The Five Star Movement and its ambivalence about vaccination

Similarly to the League, the Five Star Movement has also maintained a position against the Lorenzin decree. The parliamentarians of the Five Star Movement declared themselves against the sanctions envisaged by the Lorenzin decree and by the respective conversion law. To better understand the position of the Five Star Movement in relation to vaccinations, it is worth making a brief reference to the 'no-vax' movement.

THE NO-VAX MOVEMENT. For some years now, the movement in Italy against vaccination has become increasingly important. The so-called 'no-vax' movement initially developed on the Internet and on social networks, but later also organized public meetings, events, and supported the publication of some books against vaccines and vaccination obligations.

As the no-vax movement has no recognized leader and has fed on the web, it does not have a univocal and official position on the issue of vaccines. Different opinions and arguments coexist within the movement. In general, no-vax supporters believe that vaccines are potentially dangerous, and therefore childhood immunization should not be mandatory. Some believe there is a link between immunization and serious diseases, such as autism. Others believe that vaccines are part of a conspiracy orchestrated by pharmaceutical companies, and that the strategy of vaccination obligation is actually dictated by economic interests. Most believe that the State should not interfere with the freedom of individuals, and that the choice to vaccinate children belongs to their parents. According to some commentators, two factions can be distinguished within the movement: on the one hand are those who are properly 'no-vax' (vaccinations are harmful and must therefore be avoided); on the other hand are those who are simply 'free-vax' (vaccines are not dangerous, but they do not have to be mandatory).

The Five Star Movement is the party that appears to be closer to the anti-vaccination movement, but it is not clear whether the Movement belongs to the 'no-vax' faction or to the 'free-vax' one. The Five Stars seem to deliberately maintain an ambiguous position.

The official position of the Five Star Movement towards the thorny issue of childhood vaccination was recently made explicit by the leader of the movement, Luigi Di

Maio. He stated that the Five Star Movement is not against immunization, but rather the introduction of a vaccination mandate:

'I want to silence some unhealthy ideas about vaccines. Since I have been the political leader of the Movement, we have never been against it, we want it to be done. What we are not in favour of is linking obligation to school attendance, instead of introducing it when there is a risk of epidemics' (*Corriere della Sera*, August 13, 2018).

This clarification must be interpreted as Di Maio's willingness to respond to the accusations directed at the Movement of supporting and sharing the positions of anti-vaccination activists.

In May 2017, an article published in the *New York Times* accused the Five Star Movement of promoting an online anti-vaccine campaign, raising the fear of a link between vaccines and autism. Beppe Grillo, the founder of the Five Star Movement, responded to this attack by accusing the NYT of 'fake news', and claiming that 'there is no campaign promoted by the Five Star Movement against vaccines'.

Later, the Movement published on its blog a statement in which the official position of the movement on the subject of vaccinations was made explicit. The Five Star Movement declares itself in favour of vaccinations, and to make vaccines mandatory just in the case of a genuine epidemic emergency.

Moreover, the Movement is in favour of the creation of a national vaccine registry, through which immunization coverage would be monitored in real time at both national and regional level.

Despite official denials, the impression is that both during the 2018 election campaign and in the early months of the yellow-green government some members of the Five Star Movement have expressed opinions very similar to those of anti-vaccination activists.

The Five Star Movement seems deliberately ambiguous with regard to vaccinations: on the one hand, it reassures public opinion with moderate official statements (in favour of immunization), on the other hand it winks at anti-vaccination activists.

7. Health Minister Giulia Grillo and the 'flexible obligation'

With the establishment of the new yellow-green government led by Giuseppe Conte, Giulia Grillo, previously the Five Star Movement whip in the Chamber of Deputies, was appointed as Minister of Health.

It is not easy to understand whether the League and the Five Star Movement have a shared position on routine vaccinations. Regarding this issue, the 'government contract' is rather ambiguous. As stated in the 'contract for the government of change' signed by Matteo Salvini and Luigi Di Maio:

'With the aim of protecting individual and collective health, guaranteeing the necessary vaccination coverage, the issue of the right balance between the right to education and the right to health will be addressed, protecting pre-school and school children who may be at risk of social exclusion'. It is not clear what this means in practice.

In recently released interviews, the new Health Minister Giulia Grillo advocates the introduction of a 'flexible obligation', which should result in differentiated measures according to the rate of vaccination coverage registered at regional level.

As emphasized by the minister herself: ‘*There are regions which reach 97% of immunization coverage, and other regions with just 87%. Hence the need for a flexible obligation, the most rational thing to do*’ (interview with the La7 TV channel).

While waiting for the proposal for the ‘flexible obligation’ to materialize in a bill, so far the new yellow-green government has not approved any substantial changes to the Lorenzin decree. A recent ministerial circular (July 2018) envisages the extension of self-certification for the 2018-2019 school year (the possibility of self-certificating vaccinations was already envisaged by the Lorenzin decree, but only for the 2017-18 school year).

8. Conclusions: what will the yellow-green coalition government do about vaccines?

On the basis of what has been illustrated in the previous sections, it is natural to ask what measures the newly elected yellow-green government will adopt on the subject of infant vaccinations. At present, it is legitimate to hypothesize four alternative scenarios.

First option: to leave the situation as it is, without modifying the Lorenzin decree. The issue of vaccines, as we said, is politically delicate and divisive. One can assume that the majority of Italians are in favour of infant vaccinations: this emerges from some recent surveys [Observa 2017; Giambi *et al.* 2018] and it is shown by the fact that, even before the Lorenzin decree, the vast majority of Italian children received vaccines that were just ‘recommended’ (but not mandatory). Abolishing the Lorenzin decree could then turn out to be a boomerang: to pursue a no-vax minority, the yellow-green government could displease the majority of voters.

Second option: to introduce the principle of ‘flexible obligation’. It is not yet completely clear what the Minister Giulia Grillo intends with this expression. The logic should, however, be the following: the obligation to vaccinate children is introduced only when the immunization coverage (for a given disease) falls below a certain threshold of alarm (that of herd immunization). As soon as the coverage threshold is reached, the vaccination obligation can be removed. The decisions regarding the introduction or elimination of the vaccination mandate would be taken on the basis of the National Vaccine Registry data, which should allow the monitoring, in real time, of immunization coverage all over the country. The ‘flexible obligation’ principle should also include the possibility of adopting differentiated measures depending on the region.

Third option: return to the situation prior to the Lorenzin decree, repealing the latter. The situation before the decree provided for only four mandatory vaccinations (and not ten), without the sanction of the exclusion of unvaccinated children from kindergartens. Given the high number of cases of measles recently registered in Italy, some speculate that in this third option the mandatory vaccines could become five, including that against measles.

Fourth option: extend to the whole country the model adopted since 2007 by the Veneto region. This would mean approving a new law that transforms the ten currently mandatory vaccinations into ‘recommended’ (and therefore voluntary) ones.

It’s not easy at this stage to predict which of the four options will eventually be adopted by the yellow-green government. The decision could depend on the balance of power within the Conte government.

Matteo Salvini and the League seem to favour the fourth option, but maybe also the third one.

The Five Star Movement, on the subject of vaccination, may not share a common position. One faction (presumably a minority) of the movement seems close to 'no-vax' positions and considers vaccines dangerous: this faction is in favour of the fourth option (no mandatory vaccination). The majority of the Five Star Movement – among them the leader Di Maio and the Minister Grillo – have more moderate positions: they declare themselves in favour of vaccinations, and they seem to support the second option, that of 'flexible obligation'.

If the authors of this article had to bet a euro on one of the four options, we would perhaps bet on the first solution (to do nothing). In recent polls, both the Five Star Movement and the League have seen their popularity grow: intervening on a sensitive issue such as that of vaccines could prove to be an own goal, which could lead both coalition partners to lose consensus. Why would they risk that?

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