

Introduction of new and reinforcement of existing compulsory vaccinations in Italy: first evaluation of the impact on vaccination coverage in 2017

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In June 2017, a decree-law to increase the number of mandatory vaccinations from 4 to 10 for minors up to 16-years-old was issued in Italy. The vaccination coverage for 2017 showed a positive impact for all the vaccines, particularly for the measles, mumps and rubella vaccine at 91.6% for the year 2017, showing a 4.4% increase compared with 2016 (87.2%). Continued monitoring is needed to evaluate the medium to long-term effects of the law.

In June 2017, a decree-law (73/2017) was issued in Italy, stipulating that the number of mandatory vaccinations, for minors up to 16-years, would be increased from four to 10 vaccinations [1]. Vaccination against pertussis, measles, mumps, rubella (MMR), varicella, and *Haemophilus influenzae* type b (Hib) was added to the list of already mandatory vaccinations (diphtheria, tetanus, hepatitis B and polio). The Italian vaccination schedule is available from [2]. According to the law, all people who refused to be vaccinated could be subject to a fine, or children be denied attendance to education services until the age of 6 years.

Here, we report about the new law and its immediate impact on vaccination coverage (VC) in Italy and present data for 2017 collected at the beginning of 2018.

The decree-law in the Italian context

Over the past 15 years in Italy, there was a shift towards a voluntary approach to vaccination. Only four vaccines that were introduced in the past i.e. those against diphtheria (1939), tetanus (1963), polio (1966) and hepatitis B (1991) remained mandatory but penalties were not enforced for people refusing vaccination. Vaccines that were newly introduced in the vaccination programme e.g. those against pertussis, MMR, Hib, meningococcal disease and pneumococcal disease were only recommended. This approach aimed at achieving an

informed and voluntary consent based on the right to be protected against diseases for which safe and effective vaccines are available. Since 1999, there were no enforced penalties for those lacking mandatory vaccinations, and non-vaccinated pupils were still permitted to attend compulsory schooling or exams. However, school headmasters were obliged to report such cases to the local health authority and to the Ministry of Health (MoH) within 5 days. In Veneto, one of the 21 Italian Regions and autonomous provinces, the obligatoriness for the four vaccines was suspended in 2007 by a regional law [3].

However, since 2013, a steady downward trend in the uptake of both compulsory and recommended vaccinations was observed throughout the country, including the Veneto Region. This led to a drop in VC [4] below the 95% threshold recommended for polio and other vaccines by the World Health Organization (WHO) and by the Italian National Immunisation Plan (NIP), 2017 to 2019 [5].

Between 2013 and 2015, the decline in VC for MMR was particularly worrying: vaccination coverage fell by 5% from 90.3% to 85.2% at 24 months of age (Table 1). Such decline contributes to jeopardising the regional goal of elimination of measles and rubella in the WHO European Region. A slight increase in VC was observed in 2016 in some regions, but in January 2017, a severe measles outbreak occurred in Italy with 5,408 cases in 2017 and 805 cases in the first 3 months of 2018 [6], including eight deaths.

In April 2017, to extend the current vaccination obligations and make them enforceable the Italian Minister of Health initiated the preparation of a decree-law that usually has a faster path than an ordinary law. The decree-law was issued in June 2017 and passed by the

TABLE 1

Vaccination coverage by year and vaccine, Italy, 2011 – 2017

Vaccine	Number of doses	Year						
		2011	2012	2013	2014	2015	2016	2017
Vaccination coverage (%) at 24 months								
Polio	3	96.1	96.1	95.7	94.7	93.4	93.3	94.5
Diphtheria	3	96.3	96.2	95.8	94.7	93.4	93.6	94.6
Tetanus	3	96.3	96.2	95.8	94.8	93.6	93.7	94.6
Pertussis	3	95.8	96.0	95.7	94.6	93.3	93.6	94.6
Hepatitis B	3	96.0	96.0	95.7	94.6	93.2	93.0	94.3
Hib	3	95.6	94.8	94.9	94.3	93.0	93.1	94.2
Measles	1	90.1	90.0	90.4	86.7	85.3	87.3	91.7
Mumps	1	89.9	89.2	90.3	86.7	85.2	87.2	91.6
Rubella	1	89.9	89.2	90.3	86.7	85.2	87.2	91.6
Varicella	1	-	-	33.2	36.6	30.7	46.1	45.6
Meningococcal C	1	-	-	77.1	73.9	76.6	80.7	83.1
Pneumococcal 13v	1	-	-	86.9	87.5	88.7	88.4	90.8
Vaccination coverage (%) at 36 months								
Polio	3	-	-	96.3	95.7	95.4	94.1	95.1
Measles	1	-	-	92.3	90.7	89.2	88.0	92.4
Vaccination coverage (%) in their 7th year of life								
Polio	4	-	-	90.9	89.2	87.6	85.7	88.7
Measles	2	-	-	83.5	82.7	83.0	82.2	85.8

Source: Italian Ministry of Health.

Italian Parliament on 31 July 2017 with some modifications. The legislation was accompanied by operative documents and a media campaign to raise awareness among the general population on the importance of vaccination and to promote a stronger vaccination culture.

All the mandatory and the remaining recommended vaccines were offered actively and free-of-charge (as already established in the NIP) with a catch-up campaign for children up to the age of 16 years. This was applied to all vaccines except varicella, which is only mandatory for children born after 2016. All booster doses included in the NIP are now mandatory as well. A fine between 100 and 500 EUR has been established for unvaccinated children. Exception from vaccination can be granted if the child has acquired immunity following a natural illness or a child has a clinical condition representing a contraindication to the vaccination. Non-medical exemptions, for example, religious or philosophical beliefs are not accepted.

Children until the age of 6 years must be fully vaccinated to attend preschool facilities (educational settings such as nursery, kindergarten, pre-primary school). Primary and secondary schools are used as filters to check the vaccination status of the children through the collection and review of their certificate of vaccination. This certificate is transmitted to the public vaccination services who is in charge of managing the entire immunisation process from the initial invitation

sent to the children (or caregivers) to the registration of vaccination in the local/regional computerised immunisation information system (IIS).

Vaccination coverage in 2017

In Italy, VC data are collected annually by the MoH from each of the 19 regions and two autonomous provinces [7] that use different computerised IIS to calculate the VC at regional/provincial level [8]. In all the regions/provinces, vaccinations are recorded in the IIS at the individual level at the time of vaccine administration. The 2017 data (as of 31 December 2017) were collected by the MoH using the same methodology as in previous years, to maintain comparability. There was no change in the methodology used to evaluate VC at the regional and provincial level. Data from all 101 Italian local health units are collected. The main limitation in the VC estimation in Italy is the availability of a reliable local population denominator.

Thus far, results show a positive trend in VC following the introduction of the decree-law for all the vaccines and birth cohorts. The VC at 24 months of age (birth cohort 2015) against polio, used here as a proxy of the hexavalent vaccine used in Italy, was 94.5%, a 1.2% increase compared with 2016. Eleven of the 21 regions have a VC over 95%. The VC for MMR was 91.6% for the year 2017, showing a 4.4% increase compared with 2016 (87.2%), and being over 93% in five regions. There was also an increase in recommended vaccinations, including pneumococcal (88.4% in 2016 vs 90.8% in

TABLE 2

Comparison of the vaccination coverage in 2016 and 2017 by birth cohort and vaccination, Italy

Vaccine	Number doses	Birth cohort	VC as 31 December 2016	VC as 31 December 2017
Polio	3	2014	93.3% at 24 months	95.0% at 36 months
MMR	1	2014	87.2% at 24 months	92.2% at 36 months
Polio	3	2013	94.1% at 36 months	94.7% at 48 months
MMR	1	2013	87.9% at 36 months	90.3% at 48 months
Polio	4	2010	85.7% in their 7th year of life	90.2% in their 8th year of life
MMR	2	2010	82.0% in their 7th year of life	86.8% in their 8th year of life

2017) and meningococcal C vaccines (80.7% in 2016 vs 83.1% in 2017).

The positive trend in VC for all the vaccines was also observed in other birth cohorts when comparing the VC for the same cohort one year later, showing the impact of the catch-up campaign in older children (Table 2).

Discussion and conclusion

An encouraging increase in VC was observed following the decree-law 73/2017. Vaccination was mandatory for all children, not only those who were due to be vaccinated at the time. Therefore, a catch-up campaign was necessary with a main limitation being the capacity of the vaccination services to perform all the immunisation required by the law. Due to this, the effect of the law is likely underestimated as its implementation only began in the second part of 2017. The requirement of a regular immunisation to attend preschool facilities and screening of certificates of vaccination at school most likely drew the attention of the parents on the importance of the vaccination.

The increase in VC between 2016 and 2017 (ranging from 0.9% for vaccination against tetanus at 24 months to 4.4% for MMR vaccination at 24 months) was most likely a result of the decree-law being brought into force and supported by the related communication campaign, which was amplified by the media. These probably increased the awareness of the population on the importance of vaccines and vaccination. Parents' reasons for their adherence to the vaccination should be evaluated in detail in further studies. However, there is still a small group of parents threatening a lawsuit against the law or are trying to delay the vaccination, making the normal process of active calling and pre-vaccination counselling longer and more difficult with a higher number of people not turning up at the appointment or bringing an exaggerated list of questions.

Results of a recent survey conducted in Italy estimated that 83.7% of parents were positive towards vaccination, 15.6% were hesitant and 0.7% were against vaccination [9]. This should be kept in consideration for further adjustment to the organisation of the vaccination services, because the number of hesitant parents

that could be convinced to vaccinate is relevant and could positively impact the VC.

The regions and the autonomous provinces in Italy are independent for health matters and consequently, the vaccination strategies and their implementation and thus VC vary between them. For example, in 2017 the VC for polio and MMR at 24 months ranged from 85.9% to 97.7% and from 71.8% and 95.3%, respectively [10].

Efforts have been taken from the local vaccination services to start the catch-up campaigns, but not all the work was accomplished in the last 6 months of 2017. However, the sustainability phase, expected for the year 2018 will be easier than the fast implementation carried out in 2017. However, in order to take full advantage of the law it will be necessary to maintain attentive on its implementation while continuing the communication campaign and improving healthcare workers' training. This will improve pre- and post-vaccination counselling to raise the awareness about the importance and the positive impact of the vaccination for the individual and the community health. A thorough evaluation of the effects of the law is expected to be done after three years.

Conflict of interest

None declared.

Authors' contributions

Fortunato D'Ancona proposed and draft the manuscript, contributed to the data analysis, prepared the tables.

Stefania Iannazzo proposed the manuscript, contributed to the data analysis, critically revised the manuscript.

Giovanni Rezza contributed to draft the manuscript and critically revised it.

Claudio D'Amaro, Francesco Maraglino, Walter Ricciardi critically revised the manuscript.

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