

## COMMENTARY

# The new Italian mandatory vaccine Law as a health policy instrument against the anti-vaccination movement

F. Chirico<sup>1</sup>

*Key words: Anti-Vaccination Movement, Health policy, Measles, Vaccination*

*Parole chiave: Movimento anti-vaccinista; Politica sanitaria; Vaccinazione antimorbillo*

### Abstract

*In Italy, the Parliament granted recently the final approval to a law introducing a long list of childhood vaccinations mandatory for preschool and school-age children. Before the approval, a vibrant public debate took place on the traditional media, in the social networks and among policymakers because of the so called “anti-vaccination movement”. In this paper, we discuss about ethical aspects and relationship between individual rights and public health. The role of social networks and the Internet is also essential to disseminate correct informations, influencing health behaviours and contributing to educating people about this major public health issue in a right way. Finally, new and specific educational programmes are needed in order to transmit the young generation the means to correctly understand scientific research about this controversial issue.*

### Background

According to the Italian Ministry of Health, Italy is experiencing a measles epidemic following a fall-off in vaccinations. During January-April 2017, around 1,500 cases of measles were reported in Italy, against some 840 in all of 2016 and about 250 in 2015. As a response to the outbreak, and in agreement with the 2010-2015 National Plan of Vaccinal Prevention, Italy's Parliament gave the final approval to a law introducing a slate of childhood vaccinations mandatory for preschool and school-age children (L. 119/2017, G.U. n 182, Aug 5

2017). Under this law's new requirements, parents must present proof of vaccinations to gain admission into preschools, day-care centers or elementary schools, whether public or private. Furthermore, parents of children of mandatory school age had to face administrative fines and suspension of parental rights by the local juvenile court in case of noncompliance (but the suspension was cancelled in the last formulation of the law). The requirements cover 10 vaccinations, including those being already mandatory such as polio, diphtheria, tetanus and hepatitis B, and new mandatory vaccines such as whooping cough, *Haemophilus*

---

<sup>1</sup> Health Service Department, State Police, Ministry of Interior, Italy

*influenzae* type B (Hib) measles, mumps, rubella and chicken pox (1).

## Discussion

### *The new Italian mandatory vaccine law and the anti-vaccination movement*

In Italy “no one can be compelled to undergo any medical treatment except as a specific provision of the law” (Article 32, c.2 Italian Constitution, December 27, 1947). Therefore, in Italy the medical treatment is mandatory only in specific situations: 1) when a person is considered under conditions of important psychic diseases; 2) at workplace when workers are exposed to occupational risks based on the risk assessment (“health surveillance”); 3) in emergency situations when the patient is unable to express his consent, regardless of the will of any relatives; and 4) in case of compulsory vaccinations. In this regard, Italy is one of the European countries where mandatory vaccination policies are ethically permissible, because the “Republic safeguards health as a fundamental right of the individual and as a collective interest” (Article 32, c.1 Italian Constitution, December 27, 1947). In Italy, vaccinations against polio, diphtheria, tetanus and hepatitis B were already compulsory, before June 2017. Following the recent so-called Lorenzin decree, which became law in July 2017, ten vaccinations (for polio, hepatitis B, tetanus, measles, *Haemophilus influenzae* Type B, diphtheria, mumps, rubella, pertussis, and varicella) became compulsory and free of charge for all children aged 0-16. According to the Italian law, the compulsory vaccinations may only be omitted or deferred in cases of proven danger to the health of the child, when specific clinical conditions, duly documented, are present. Finally, the National Health System is able to further offer as non-mandatory (but strongly recommended!) and free of charge vaccines for preventing

pneumococcal infection, rotavirus disease and meningococcal diseases by serogroups B and C. However, some Italian people have recently protested the new law. But, this protest is raising questions whether the people are really well-informed about the relationship existing between the potential benefits of a vaccine against the potential risk of an adverse event following immunization (AEFI) with vaccines. Indeed, although the Wakefield’s paper published in *The Lancet* was retracted and recognized as one of the most serious frauds in medical history (2, 3), the anti-vaccine movement has been gathering momentum, especially due to the influence of celebrities that have embraced the cause in debates shown on TV - a phenomenon that appears to have prejudiced the coverage of English and American immunization programs (4-6). This anti-vaccine movement claims a link between the measles, mumps and rubella (MMR) vaccination and autism that several epidemiological studies refuted (7, 8). Nowadays, politics seem to be following this movement. Indeed, social networks and the Internet have been gaining influence on vaccination coverage (9, 10); as a result, in order to lead in the polls, some politicians are in agreement with announcements disseminated in the media by the anti-vaccination movement. For instance, American newspapers reported curious news regarding USA President-elect Donald Trump’s scepticism about the safety of childhood vaccines (11). In Italy, the leader of a major Italian party, the 5-Star Movement, has drawn unfounded ties between vaccines and autism. Despite this, the Italian Health Minister, Beatrice Lorenzin, after judging it “grave and dangerous anti-scientific disinformation ... that in recent years has driven people not to get vaccinated” took action (12). Now, the Italian policy follows the example of vaccination policies in the US. But differently from US, the Italian law doesn’t allow parents to opt out on the grounds of “conscientious objection”

(13). Someone could object that such measures are coercive. Many laws can be considered as coercive, but nonetheless can be ethically acceptable by most people. For instance, isolation and quarantine are coercive measures that must sometimes be used in public health emergencies (13). Appeals to individual freedom cannot outweigh the importance of protecting public health. In the continuing tensions between individual rights and public health needs, it is critically important to demonstrate and justify that the action of protecting the public's health carries more weight and moral claim than that of the individual's liberty in rejecting the treatment (14). According to the Italian law, mandatory vaccination can be ethically justified because unvaccinated children pose a risk to the health and even the life of other children who cannot be vaccinated, and vaccination entails a very small (or nul) cost to parents and children. Indeed, the benefits of vaccination in terms of protection from infectious disease balance the costs and risk of vaccination (15). Indeed, an essential criterion of vaccine safety that regulatory authorities must establish is the risk/benefit assessment of immunization with a particular vaccine in a defined population (16). Data from the World Health Organization revealed that measles vaccination prevented an estimated 20.3 million deaths during 2000-2015 worldwide, making measles vaccine one of the best investment in public health (17).

Despite this, the anti-vaccine movement is still using pseudoscience and misinformation to support its claims, presenting false information as "scientific evidence" (18). As a consequence, the incidence of many vaccine-preventable diseases has been rising in recent years, even in countries with a high-standard of living and universal access to vaccines, such as the US, Europe and Australia. Paradoxically, in developing countries, the lack of vaccinations due to economic

reasons is leading to a huge burden in terms of child morbidity, disability and mortality, while in well-developed countries, where there are no economic troubles, the risk of vaccinating children is perceived as greater than the potential benefit. In Italy, the MMR vaccination was already included in the Italian National Vaccination Plan 2010-2015, but probably media and stakeholders were not paying enough attention to this topic in the public debate. Indeed, in 2014 in Italy MMR vaccination coverage was about 86-87% for the first dose, and only 82-83% for the second dose, with none of the 20 Italian Regions reaching the 95% vaccine coverage target (19). Indeed, given the highly contagious nature of measles, vaccination rates of 96% to 99% are necessary to preserve herd immunity and prevent outbreaks (20, 21). According to the National Institute of Health, in Italy the MMR vaccination coverage (national average) decreased in the period 2013-2015, from 90.4% (2013) to 85.3% (2015). As a consequence, between 1 February 2016 and 31 January 2017, the highest numbers of measles cases in Europe were reported by Romania (1,995) and Italy (1,020), accounting for 44% and 23%, respectively, of the European Economic Area cases in the 12-month period (22). To date (on July, 2017), the Italian Health Ministry has recorded more than 2,500 measles cases - already a tenfold spike from just two years ago. Measles is highly contagious and can cause serious complications, including pneumonia, blindness and encephalitis, and can be deadly. But even more shocking, the hexavalent diphtheria, tetanus, acellular pertussis, Haemophilus influenzae type B, poliovirus and hepatitis B (DTaPHib-IPV-HepB) combination vaccines, which were licensed and introduced in Europe in 2000 (22) to provide protection from these deadly diseases, has demonstrated in Italy an alarming downward trend in coverage (93.4% in 2015; 94.7% in 2014; 95.7% in

2013; and 96.1% in 2012). In April 2017, the measles outbreak prompted the Centers for Disease Control to issue a U.S. travel advisory for Italy, according to which getting measles vaccine has been suggested to be particularly important for infants 6-11 months of age (1 dose of measles vaccine) and children 1 year of age or older (2 doses of measles vaccine) (23). Further, the Italian health community had been also rocked by a scandal in northern Italy involving a nurse who claimed for years to have vaccinated children but had not. Moreover, Italy's highest court has recently issued a ruling that found no connection between childhood vaccines and autism, as alleged by a parent seeking legal relief, because the correlation has been widely dismissed by the scientific community. All that can explain why in Italy 10 preventable disease vaccinations are now mandatory. Vaccinations have made a great contribution to global health, eradicating smallpox and rinderpest, two major infectious diseases. This public health tool has been recognized as a formidable weapon against infectious diseases, producing a significant reduction in child mortality (24). However, due to superficial and influential media, the anti-vaccination movement is continuing to grow. Not only in Italy, but around Europe and the United States, parental fears about vaccines' safety have caused tens of thousands of parents to avoid vaccinating their children.

*Perspectives about vaccinations in Italy: The role of social networks and the Internet*

Across the world, policymakers should produce 'evidence based' rather than ideological decisions. An important issue concerns how scientists can communicate science to policy makers. This aspect is an increasingly complicated task in the current political climate. According to a Report (25), there is very limited evidence of "what works" to turn scientific evidence

into policy. This is because scientists think about how to produce the best possible evidence rather than how policymakers use evidence in complex policymaking systems. Evidently, there is a cultural gap between scientists and policymakers. However, the role of social networks and the Internet is essential, because they are easily accessible to everyone, and one of the greatest problems with using the web for health-related searches is that there is no formal system for editing information published on the web, and there is no peer review of information (26). Indeed, vaccine sceptics have recognized that social media are powerful channels for propagating information as well as misinformation and anti-vaccine websites have proliferated (27). Social networks are well-established means of influencing health behaviours and outcomes, contributing to educating people about major public health issues (28). Probably, in the next future, new and specific educational programmes carried out by schools are needed in order to transmit the young generations the means to correctly understand scientific research. In this way, according to the new Italian law, the Ministry of Health is committed to carry out a campaign for the education of the population about the importance of vaccinations; during the 2017-2018 academic year, the Health Ministry, together with the Ministry of Education, Universities, and Research, will promote initiatives for the training of teachers and students on the subject of vaccinations and parents' associations will also be involved in the campaign (19). We hope that these measures will be sufficient and Italy's mandatory vaccine law will be adopted by other developed countries.

**Declaration:**

The author declares no conflict of interest. There is no source of financial support. The manuscript was not submitted elsewhere.

## Riassunto

### *La nuova legge Italiana sulle vaccinazioni obbligatorie come strumento di politica sanitaria contro il movimento anti-vaccinista*

In Italia il Parlamento ha recentemente approvato una norma di legge che introduce una lunga lista di vaccinazioni obbligatorie infantili per i bambini in età scolare e prescolare. Prima dell'approvazione ha avuto luogo un intenso dibattito pubblico sui media tradizionali e sui social networks e tra i decisori politici a causa del cosiddetto "movimento anti-vaccinista". In questo lavoro vengono discussi gli aspetti etici e la relazione tra i diritti individuali e la salute pubblica. Il ruolo dei social networks e di Internet sarebbe essenziale per diffondere informazioni corrette, influenzando i comportamenti riguardanti la salute e contribuendo all'educazione delle persone su questa importante questione di salute pubblica nel modo migliore. Infine, nuovi e specifici programmi educativi sono necessari per trasmettere alle giovani generazioni i mezzi per comprendere in modo corretto la ricerca scientifica su questo tema controverso.

## References

1. Law No. 119 of July 31, 2017. Urgent Provisions on Vaccine Prevention. *Gazzetta Ufficiale Repubblica Italiana* No 182, Aug 5, 2017.
2. Godlee F. The fraud behind the MMR scare. *BMJ* 2011; **342**: d22.12.
3. Sathyanarayana Rao TS, Andrade C. The MMR vaccine and autism: Sensation, refutation, retraction, and fraud. *Indian J Psychiatry* 2011; **53**(2): 95–6. doi: 10.4103/0019-5545.82529.
4. Smith MJ, Ellenberg SS, Bell LM, Rubin DM. Media coverage of the measles-mumps-rubella vaccine and autism controversy and its relationship to MMR immunization rates in the United States. *Pediatrics* 2008; **121**(4): e836-e843.
5. Speers T, Lewis J. Journalists and jabs: media coverage of the MMR vaccine. *Community Med* 2004; **1**(2): 171–1.
6. Vasconcellos-Silva PR, Castiel LD, Härter Griep R. The media-driven risk society, the anti-vaccination movement and risk of autism. *Cien Saude Coletiva* 2015; **20**(2). doi: 10.1590/1413-81232015202.10172014.
7. Taylor B, Miller E, Farrington CP, et al. Autism and measles, mumps, and rubella vaccine: No epidemiologic evidence for a causal association. *Lancet* 1999; **353**: 2026–9.
8. Dales L, Hammer SJ, Smith NJ. Time trends in autism and in MMR immunization coverage in California. *JAMA*. 2001; **285**: 1183-5.
9. Smith A, Yarwood J, Salisbury DM. Tracking mothers' attitudes to MMR immunisation 1996-2006. *Vaccine* 2007; **25**(20): 3996-4002.
10. Mason BW, Donnelly PD. Impact of a local newspaper campaign on the uptake of the measles mumps and rubella vaccine. *J Epidemiol Community Health* 2000; **54**(6): 473-4.
11. Edwards-Levy A, Delaney A. Americans aren't with Donald Trump on vaccines. *The Huffington Post* [Newspaper on the Internet]. 2017 Jan 19. Available from: [http://www.huffingtonpost.com/entry/donald-trump-vaccines-poll\\_us\\_58812730e4b096b4a230a361](http://www.huffingtonpost.com/entry/donald-trump-vaccines-poll_us_58812730e4b096b4a230a361). [Last accessed: 2017, Jul 27].
12. Ravagli M. Amid Measles Outbreak, Italy Makes Childhood Vaccinations Mandatory. *Kunc* [Weblog]. 2017 Jul 03. Available from: <http://www.kunc.org/post/amid-measles-outbreak-italy-makes-childhood-vaccinations-mandatory>. [Last accessed: 2017, Jul 27].
13. Giubilini A. Italy has introduced mandatory vaccinations- other countries should follow its lead [Internet]. 2017 Jun 2. Available from: <https://theconversation.com/italy-has-introduced-mandatory-vaccinations-other-countries-should-follow-its-lead-78576>. [Last accessed: 2017, Oct 2].
14. Goodman RA, Hoffman RE, Lopez W, Matthews GW, Rothstine MA, Foster KL, eds. *Law in public health practice*. Oxford, NY: Oxford University Press, 2007.
15. Chirico F. Vaccinations and media: An on-going challenge for policy makers. *J Health Soc Sci*. 2017; **2**(1): 9-18. doi 10.19204/2017/vccn1.
16. World Health Organization (WHO). Balancing efficacy and safety. Available from: <http://vaccine-safety-training.org/balancing-efficacy-and-safety.html>. [Last accessed: 2017, Jul 27].
17. World Health Organization (WHO). Measles. Available from: <http://www.who.int/mediacentre/factsheets/fs286/en/>. [Last accessed: 2017, Oct 2].
18. Osborne H. Why are anti-vaxxers so persuasive? Pseudoscience, misinformation and healthy behaviour. *International Business Times* [Newspaper on the Internet]. 2015 Nov 03. Available from: <http://www.ibtimes.co.uk/why-are-anti-vaxxers-so-persuasive-pseudoscience-misinformation-healthy-behaviour-1527034>. [Last accessed: 2017, Oct 2].



19. World Health Organization Regional Office for Europe. 4th meeting of the European Regional Verification Commission for Measles and Rubella Elimination (RVC): 26-29 October 2015, Copenhagen, Denmark. Geneva: World Health Organization, 2016. Available from: <http://www.euro.who.int/en/health-topics/communicable-diseases/measles-and-rubella/publications/2016/4th-meeting-of-the-european-regional-verification-commission-for-measles-and-rubella-elimination-rvc>. [Last accessed: 2017, Oct 2].
20. Measles Outbreak. *JAMA Pediatr* 2015; **169**(5): 494-5. doi:10.1001/jamapediatrics.2015.0384.
21. Plans-Rubió P. Evaluation of the establishment of herd immunity in the population by means of serological surveys and vaccination coverage. *Hum Vaccin Immunother* 2012; **8**(2): 184-8.
22. European Centre for Disease Prevention and Control (ECDC). Surveillance and Disease data. Available from: [http://ecdc.europa.eu/en/healthtopics/measles/epidemiological\\_data/pages/annual\\_epidemiological\\_reports.aspx#sthash.7kUjVhBp.dpuf](http://ecdc.europa.eu/en/healthtopics/measles/epidemiological_data/pages/annual_epidemiological_reports.aspx#sthash.7kUjVhBp.dpuf). [Last accessed: 2017, Oct 2].
23. Centers for Disease Control and Prevention (CDC). Measles in Italy. Available from: <https://wwwnc.cdc.gov/travel/notices/watch/measles-italy>. [Last accessed: 2017, Oct 2].
24. Greenwood B. The contribution of vaccination to global health: past, present and future. *Philos Trans R Soc Lond B Biol Sci* 2014; **369**. doi: 20130433.
25. Langer L, Tripney J, Gough D. The Science of Using Science Researching the Use of Research Evidence in Decision-Making. London: EPPI-Centre Social Science Research Unit UCL Institute of Education University College London; 2016 Apr. Available from: <http://www.alliance4usefulevidence.org/assets/Science-of-Using-Science-Final-Report-2016.pdf>. [Last accessed: 2017, Oct 2].
26. Chirico F. "Predatory Journals" or "Predatory Scholars?" The Essential Role of the Peer Review process. *Int J Occup Environ Med* 2017; **8**(3): 186-88. doi.10.15171/ijoem.2017.1082
27. A case of junk science, conflict and hype. *Nat Immunol* 2008; **9**: 1317. doi. 10.1038/ni1208-1317.
28. Christakis NA, Fowler JH. *Connected: The Surprising Power of Our Social Networks and How They Shape Our Lives*. New York: Little Brown, 2009.

Corresponding author: Francesco Chirico, M.D., Via Umberto Cagni, 21 20162 Milano, Italy  
 e-mail: medlavchirico@gmail.com