

Four Italian experiences on vaccination policies: results and lessons

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Abstract

Introduction. In 2018 the Council of Europe adopted a Recommendation on strengthened cooperation against vaccine preventable diseases. Among EU Member States, Italy has a long-lasting tradition of immunization policies implemented in the context of the National Health Service over the last forty years.

Methods. We identify, report and critically appraise four immunization strategies implemented in Italy in recent years and quantitatively assess their impact on coverage rates and other selected indicators.

Results. First: the regional law that suspended mandatory vaccination in the Veneto Region in 2007 to stimulate a proactive approach to vaccine uptake was not successful. Second: a strengthened political commitment started in 2014 brought to the release of an innovative and updated National Immunization Prevention Plan and to encouraging increase in vaccine confidence and vaccination uptake. Third: the success of social media influencers is exemplified by the case of Roberto Burioni, professor of microbiology, who in 2015 started a personal social media campaign to contrast anti-vaccinists. Fourth: The new 2017 Italian law extending mandatory vaccinations has successfully impacted on vaccine coverage which increased by more than 1% and 4% for polio and MMR vaccines, respectively, in the first six months since its entering into force, and has continued to raise in 2018.

Discussion. Our data and real-life case studies offer to the broader European public health community a solid basis for discussion and ground to evaluate similar policies implemented in different European settings, with the common goal to share best practices and promote the culture of immunization.

Introduction

In December 2018 the Council of Europe adopted a Recommendation on strengthened cooperation against vaccine preventable diseases focusing on improving vaccination coverage and supporting sustainable vaccination policies in the EU (1). Among EU Member States Italy, has a long-lasting tradition of immunization policies implemented in the context of the National Health Service (NHS) over the last forty years

(2). In fact since the establishment of the NHS in 1978 Italy has championed vaccine preventable diseases' control thanks to a successful combination of outstanding research outputs, the planning and implementation of visionary mass immunization programmes, the experience of its public health practitioners and decision makers, and a flourishing R&D sector. Nonetheless in recent times, Italy together with other neighboring countries (3, 4) has not been spared by general populations' growing

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hesitancy towards vaccines (5-8). As stated in the Council Recommendation, vaccine hesitancy is now considered a major public health concern, which effective control strategies are object of lively debate within the scientific community (9), but also matter of discussion at the civil society and political level (10-11). Here we identify, report and critically appraise four immunization strategies implemented in Italy in recent years with an effort to quantitatively assess their impact on coverage rates and other selected indicators: this with the aim of sharing best practices and lessons learnt, so as to create the basis for fruitful and constructive debate within the broader European public health community, united in its action to promote the value of vaccines in Europe (12).

Methods

We first outline and contextualize four key moments in recent Italian immunization strategies, we then assess the impact they had on general population vaccine confidence and uptake. For each of the four we provide details on normative and societal context and we identify parameters that might allow to quantify their impact, including immunization coverage data and media monitoring indicators.

Coverage data were provided by the Directorate General of Health Prevention (DGHP) of the Italian Ministry of Health (3). Coverage rates are calculated computing number of immunised subjects by resident target population, expressed as percentages. The 21 Regions and Autonomous Provinces report, on a year or semester basis, to the Ministry of Health on absolute numbers of immunised subjects and target populations. We have previously detailed reporting flows of immunization data in Italy from the local to the regional and national levels (3). Here we consider: 24 months of age coverage rates for poliomyelitis, used as a proxy for

hexavalent vaccine and 24 months of age coverage rates for measles-mumps-rubella (MMR), as well as influenza coverage rates in subjects older than 65 years (3, 4). Media monitoring data were derived from the most read Italian newspaper, "Corriere della Sera", screened to retrieve articles focusing on vaccines-related topics. We applied a media monitoring model previously described (13, 14) to quantitatively and qualitatively assess media coverage on vaccines and immunization-related topics. With regard to the impact of the debate on vaccinations on social networks, the number of monthly contacts was recorded on the most popular dedicated websites and social media groups.

Results

An attempt to suspend mandatory vaccination

In 2007 one of the largest Italian regions, Veneto (4 million inhabitants), suspended with a regional law national-level mandatory immunization against polio, hepatitis B, tetanus and diphtheria for children (15). Suspending mandatory vaccines was intended with the aim of piloting an empowering approach to infectious diseases prevention which, combined with investments in health education campaigns, should have promoted a proactive approach to vaccine uptake. The Veneto regional initiative had been initially opposed by the Ministry of Health but was supported by a large share of the general public, as well as by the public health and pediatrics communities.

Here we assess the impact of such natural experiment (16) by comparing regional and national infant immunization coverage rates over time, before and after the adoption of the regional law. Figure 1 reports 24-month of age coverage rates for poliomyelitis over time (2000-2016), respectively in the Veneto Region and at the Italian national level. Although after the implementation

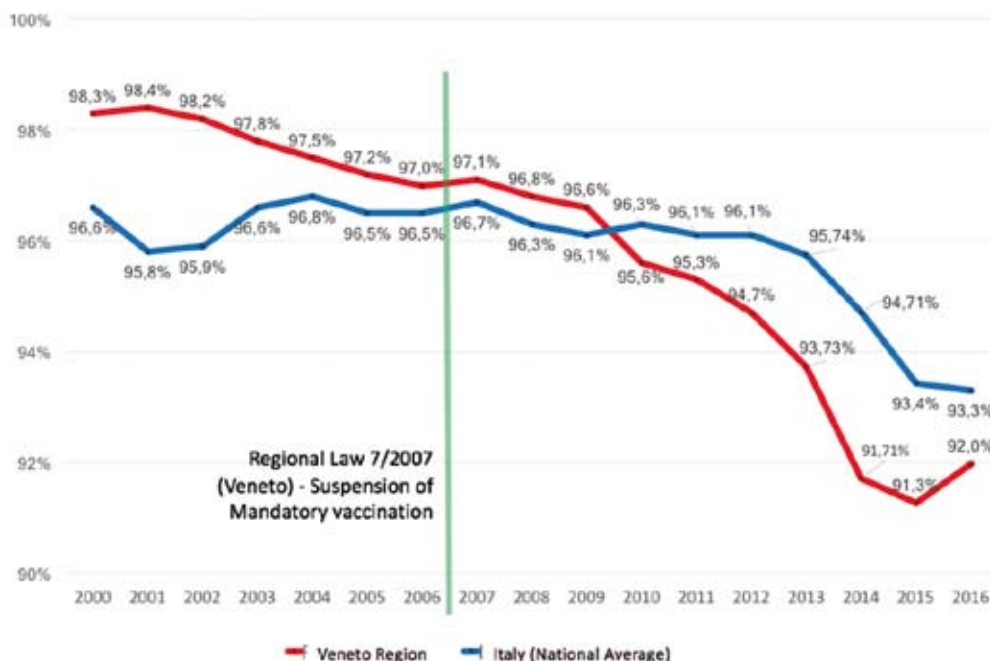


Figure 1 - Coverage rates in Veneto and in Italy, 2000-2016 (poliomyelitis, 24-months)

of the regional law in 2007 encouraging results were initially reported with no significant drop in coverage rates in Veneto, as compared to previous years, long-term data show for Veneto Region greater decreases in coverage rates (-5.0% for polio vaccine between 2006 and 2016), as compared to figures reported at the national level (-3.2% for polio vaccine in the same study period) and in other neighboring regions (3, 4). Overall, available data suggest the policy of suspending mandatory immunization to stimulate proactive vaccine uptake has not been successful.

A Strengthened political commitment

In 2014 the Italian Government and the Ministry of Health adopted a strong political action of on immunization policies which resulted into the release of a new and innovative National Immunization Prevention Plan (approved in 2016 for the period 2017-19)

which introduced new safe and effective vaccines' programmes and extended immunization to selected target populations and at-risk groups (17, 18). The implementation of the 2017-2019 National Immunization Prevention Plan was coupled with other initiatives, including renewed governmental engagement with different stakeholders, including scientific societies and other technical bodies, strengthened health education and communication institutional campaigns around vaccines, and overall, the creation of a *momentum* around immunization at the political, scientific and societal level. We infer the impact of such strong political commitment analyzing: i) immunization coverage, ii) media coverage and iii) general population perceptions' around vaccines. Indeed, starting from 2015 at the national level, as well as in most Regional settings, an increase in vaccine coverage was reported, this after years of decreasing trends in both

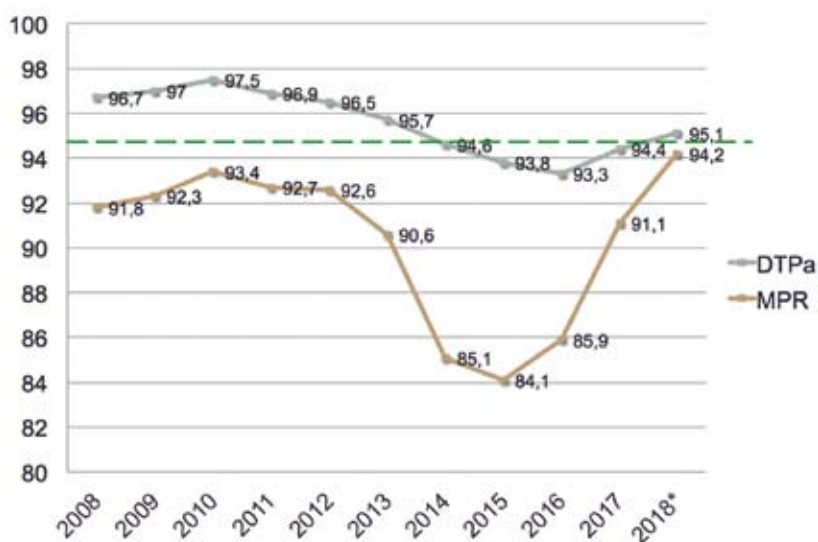


Figure 2 - Italy's 24 months of age coverage rates for poliomyelitis and measles vaccines (2011-2018)
 * Official data, Ministry of Health. For 2018 estimates based on available data from 5 Regions.

infant and adult vaccines coverage rates (3, 4). Twenty-four-months of age MMR vaccine coverage rose from 85.3% in 2015 to 87.3% in 2016 to 91.7% in 2017 (+7.5%) and anti-poliomyelitis from 93.4% to 94.5% (+1.2%) (Figure 2). Similarly, influenza coverage rates in elder populations increased by 8.4% from flu season 2014-15 (48.6%) to flu season 2017-18 (52.7%) (Figure 3).

Not only vaccine uptake showed reassuring trends but also, as emerges from media content monitoring, media focus on vaccines increased, and in a positive way. In fact, the number of general media articles talking about immunization-related topics published on “Corriere della Sera” increased from 2015 onwards and the large majority of them had a positive approach towards vaccines (19)



Figure 3 - Coverage rates for influenza in Italian elderly population (aged 65 or more), 1999-2018

Table 1 - News media articles on vaccines published on “Corriere della Sera” – absolute numbers per semester and by approach to vaccines

Period	N. of articles	(%) Negative approach to vaccines
Jan-Jun, 2015	35	11%
July-Dec, 2015	60	12%
Jan-Jun, 2016	33	15%
July-Dec, 2016	71	3%
Jan-Jun, 2017	221	13%
July-Dec, 2017	215	20%
Jan-Jun, 2018	108	13%

(Table 1). Along the same lines, the general population attitudes towards immunization changed from 2015 to 2018 with the share strongly against mandatory immunization decreasing from 18.6% to 8.1% and the share in favor of mandatory immunization increasing from 23% to 47.1% (20).

The success of social media influencers

We report the case study of Professor Roberto Burioni, a medical microbiologist and virologist who, in 2015, started a personal social media campaign to contrast anti-vaccinists, using Facebook and other social media to disseminate the science behind vaccines and disseminating scientific data to refute rumors about their dangers (21). With over 500,000 people following

his Facebook profile, Burioni has become a popular role model and influencer in the field of vaccines openly criticizing vaccines’ refusers and fighting fake news. He used a rather aggressive tone, claiming they are ignorant and that science is not a matter of democracy.

Although it is methodologically difficult to quantitatively estimate the so-called “Burioni effect” in influencing vaccines’ confidence, we report a drastic rebalance of the number of Italian social media pages supporting vaccines after 2015 (Table 2), suggesting his action on the web has been successful. In fact, as reported in Table 2 in 2015 Fakebook pages with the highest amount of contacts were anti-vax, while in 2018 pages with the highest numbers

Table 2 - Italian Most popular Facebook pages focusing on vaccines and vaccinations (In red anti-vax, In green:science-based and pro-vax) - Comparison April 2015 – January 2018)

Web site (04/2015) - N. of contacts Web site (01/2018) N. of contacts

Web site (2015)	N. of contacts	Web site (2018)	N. of contacts
Eugenio Serravalle	12,000	Roberto Burioni, MD	321,643
Autismo e danni da vaccino	4,800	Io vaccino	52,557
Vaccini basta	4,600	Eugenio Serravalle	27,643
Autismo e vaccini	4,100	Vaccini basta	21,010
Vaccinarsi	4,000	Autismo e vaccini	19,754
Rete informazioni vaccini	3,400	Vaccinarsi	19,095
FIMP prevenzione	2,600	Rete informazioni vaccini	18,716
Perché vaccino	2,200	FIMP prevenzione	11,212
Roberto Burioni, MD	0	VaccinarSi	10.642

contacts were those of supporting the scientific rationale of immunization.

The new law on mandatory vaccination

In 2017 Italy approved law n.119/2017 which makes 10 vaccines mandatory for children up to the age of 16 years, namely: diphtheria, tetanus, polio, hepatitis B – which were already mandatory – plus pertussis, haemophilus influenzae Type b, measles, mumps, rubella and varicella. More in details, the law requires children to be vaccinated for admission to childcare up to primary school and imposes monetary fines to family of unvaccinated children accessing primary school. The new law also includes the implementation of a national Immunization Information Systems and allocates dedicated resources for health education and health promotion interventions. (22-24).

The most recent data on vaccination coverage in Italy report, consistently throughout Italian Regions, a significant increase in 2017 following the entry into force of the law (14, 22, 25). At the national level vaccination coverage against polio was 94.5%, a 1.2% increase compared with 2016 with 11 Regions exceeding 95%. MMR coverage was 91.6% for the year 2017, showing a 4.4% increase compared with 2016 (87.2%). In the same period, there was also an increase in recommended vaccinations, including pneumococcal (+2.7%) and meningococcal C vaccines (+2.9%) (23). The increasing trend in vaccine coverage has continued in 2018 even if data are available only for 5 Regions representing about 50% of the Italian population (Lombardia, Veneto, Emilia-Romagna, Toscana and Puglia). Data confirm a positive impact of the law on coverage rates which increased for MMR and polio by, respectively, 3.1% and 0,7% after 2017 (Figure 2).

Discussion

In recent years, several studies, reports and position papers have been published on the alarming spread of vaccine hesitancy across Europe, on its characteristics (26), on its determinants (27-28), and on the need for all countries to take timely and effective initiatives to tackle it (1); but only few are the evaluations of interventions to control vaccine hesitancy; this is partly due to the difficulty of finding relevant indicators to quantitatively measure both vaccine hesitancy and the impact of interventions (29). In this paper we provide four real-life case studies of what has and has not worked to improve vaccine confidence and uptake in Italy. As for all operational research outputs we cannot infer straightforward causal relationships between policies and outcomes (i.e. vaccine uptake), neither we can exclude bias or confounding due to the various determinants that influence knowledge, attitudes and practice of immunization at the population level. We cannot even exclude different interpretations on some phenomena, as it has been done for the case of Veneto, still surprisingly considered as a positive experience by some researchers of that region (30). However, the availability of timely and good quality coverage data (which has few equals in Europe) make it possible to draw some partial conclusions on the four areas considered.

In conclusion, the nudge method, adopted in the Veneto Region, did not give the positive results expected; or, at least was not successful in encouraging proactive vaccine uptake and contrasting vaccine hesitancy. A reinforced political commitment, at the national level gave encouraging results and contributed to stimulate the public debate on the topic and a greater dissemination of scientific information, countering the spread of fake news (31). On the other hand the discussion around vaccines moved out from the scientific community and was highly exploited during the 2018 national electoral

campaign. Last but not least, the so-called “Burioni effect” was more difficult to assess. Notwithstanding the great impact on the web and the inversion of trends between scientific information and fake news, it is difficult to quantify the effect of Burioni’s action on the general population; the antivaxxers didn’t change opinion but most likely it had a positive impact on the hesitant people, contributing to promote the value of immunization (32, 33). Last in time, but now least, we fuel the debate around mandatory immunization, instrumental to public health action, reporting the positive affect it had in Italy on regional and national -level vaccine uptake and suggesting coercive interventions might be pivotal to maximize societal benefits when population wellbeing is put at risk by decreasing vaccine confidence (21). As we present the case of Italy, we report and assess the impact of different immunization policies and social phenomena on vaccine uptake and, more in general, on population attitude and practice of immunization. We believe our data and real-life case studies offer to the broader European public health community a solid basis of discussion and ground to evaluate similar polices implemented in different European settings (34), with the common goal to share best practices and promote the culture of immunization.

Lavoro effettuato nell’ambito della ricerca “*Analisi delle ricadute sanitarie e delle componenti sociali sulla popolazione e sul personale sanitario dopo l’estensione degli obblighi vaccinali in Italia*” affidata all’Accademia Lombarda di Sanità Pubblica con un contributo non condizionato di Sanofi SpA.

Conflicts of interest

None declared

Riassunto

Quattro esperienze italiane di politiche vaccinali: risultati e commenti

Introduzione. Nel 2018 il Consiglio d’Europa ha adottato una Raccomandazione sulla cooperazione contro

le malattie prevenibili dal vaccino. Tra gli Stati membri dell’UE, l’Italia ha una lunga tradizione di politiche di immunizzazione attuate nel contesto del Servizio sanitario nazionale negli ultimi quarant’anni.

Metodi. Abbiamo identificato, riportato e valutato criticamente quattro strategie di immunizzazione che hanno riguardato l’Italia negli ultimi anni e valutato quantitativamente il loro impatto sui tassi di copertura e su altri indicatori selezionati

Risultati. Primo: la legge regionale che ha sospeso la vaccinazione obbligatoria nella Regione del Veneto nel 2007 per stimolare un approccio proattivo all’assorbimento dei vaccini non ha avuto successo.

Secondo: un rafforzamento dell’impegno politico avviato nel 2014 dal piano nazionale di prevenzione vaccinale ha incoraggiato l’aumento della fiducia nei vaccini.

Terzo: il successo degli influencer sui social media è esemplificato dal caso di Roberto Burioni, professore di microbiologia, che nel 2015 ha avviato una campagna personale sui social media per contrastare gli anti-vaccinisti.

Quarto: la nuova legge italiana del 2017 che ha esteso gli obblighi vaccinali ha avuto un impatto positivo sulle coperture, aumentate di oltre l’1% e 4% rispettivamente per i vaccini contro la polio e l’MMR nel 2017 ed è proseguito nel 2018.

Discussione. I nostri studi di casi reali e di dati offrono alla comunità scientifica solide basi per la discussione e per valutare politiche simili introdotte in contesti diversi.

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