The reform of the Italian legislation on childhood immunization

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ABSTRACT

Upon the proposal of the Italian government, Law n.191/2017 has been enacted, meant to considerably raise the number of mandatory vaccinations, while leaving several others merely "recommended" (non-mandatory).
Such a reform has proven necessary in light of the latest epidemiologic data reflecting a steady decrease in the rates of immunization coverage in most Italian regions over the past few years, including mandatory vaccinations. Court rulings that held vaccinations may have caused autism, or even a child's death, have probably contributed to decrease in coverage.
Early interventions to mandate immunization had been put in place at the regional level, yet the Italian Government and Parliament have opted for a national piece of legislation devised to make mandatory vaccinations a requirement to gain access to the preschool system or day care services.
The authors elaborate on the reform's contents and shed a light on the medical, ethical and legal elements underpinning the mandate to immunize children. As a matter of fact, possible risks arising from vaccinations are rare, and largely offset by the benefits to both the children and society at large.
On the heels of the reform in question, the doctor-patient relationship is still at the forefront. In fact, citizens need to understand the value and usefulness of non-mandatory, recommended vaccines as well. Therefore, it appears necessary to improve the quality of vaccination counseling practices in childcare, but such activities need to take place within the framework of a broader strategy, centered on the fostering of a culture of prevention, backed by scientific research to the fullest extent possible.

Key words: immunization, legislation, mandatory vaccinations, doctor-patient relationship

INTRODUCTION

Vaccines represent an achievement in modern times. Unfortunately, over the past few years in several Western countries a substantial decrease in immunization coverage for the most common vaccines has been recorded, fueled by the belief that vaccinations have no real effectiveness, and might instead trigger potentially serious side-effects,

such as neurological alterations [1,2].

Italy is still one of few Countries, along with France, Greece and some Eastern European Nations, in which a mandate stands to immunize all newborns via a set of vaccinations. Until law decree n.73, 7th June 2017 came into effect [3], mandatory vaccinations amounted to four (against diphtheria, tetanus, poliomyelitis and hepatitis B). In fact, with the healthcare overhaul implemented through Law no. 833/1978, lawmakers have aimed to emphasize information and persuasion, rather than punishment. Therefore, vaccinations introduced at a later stage (for pertussis, meningitis, chickenpox, mumps, measles, rubella, *Haemophilus influenzae* type B conjugate vaccine, pneumococcal conjugate vaccine PCV13, meningococcal C conjugate, papilloma virus and chickenpox vaccines, etc.) were merely recommended, rather than mandatory.

By virtue of the above mentioned decree n. 73/2017, amended and ultimately enacted by the Italian Parliament via Law n.119, 31st July 2017 [4], the number of mandatory vaccinations was increased from four to ten, (anti-polio, anti- diphtheria, anti-tetanus, anti-hepatitis B, anti-pertussis, anti-type B Haemophilus influenzae, anti-measles, anti-rubella, anti-mumps and anti-chickenpox), whereas the remaining four, recommended vaccinations are: B meningococcal, C meningococcal, pneumococcal and rotavirus vaccines.

A set of data available have buttressed the need for an increase in the number of vaccinations mandated by law. Since 2013, Italy has witnessed a decreasing trend in immunization coverage as well, with the consequent "higher risk of large-scale outbreaks of diseases considered to be under control, and even a resurgence of diseases thought to have been uprooted in Italy" [5]. For measles, mumps, rubella, a 5% decrease in immunization coverage was recorded between 2013 and 2015, going from 90.4% to 85.3%. Coverage for meningococcal C stands at 76.6% [5]. In 2015, immunization coverage for poliomyelitis, tetanus, diphtheria, hepatitis B, has dropped to 93.4%, well below the 95% lowest threshold deemed safe by the WHO to create an effective herd immunity [5]. Such data confirm the existence of a significant downward trend in the rate of vaccinations for those diseases: coverage used to be 96.1% in 2012, 95.7% in 2013 and 94.7% in 2014 [5]. Only five Italian regions are placed above the WHO threshold for all of the above-mentioned conditions. Conversely, 14 regions do not reach the 95% threshold for any of the four same vaccination rates. (Table 1) [5].

Data related to measles have alerted health care authorities. In fact, whilst in the year 2016 844 cases of measles were recorded, between January 1 and September 24 2017, already 4575 cases were reported [6].

Other European Countries, with health systems very similar to the Italian one, show higher percentages of vaccinated population but even in these Countries a

TABLE 1. Percentage of vaccinated population by Italian regions for Polio, Diphtheria, Hepatitis B and Tetanus (mandatory vaccinations before the June 2017 decree). Year 2015

Italian Regions	Polio	Diphtheria	Tetanus	Hepatitis B
Piemonte	95.2	94.9	95.4	94.6
Valle d'Aosta	93.4	92.9	93.6	92.6
Lombardia	93.5	93.4	93.6	93.2
Liguria	94.6	94.5	94.6	94.3
Prov.Autonoma Trento	92.8	92.7	93.1	92.1
Prov.Autonoma Bolzano	87.5	87.5	87.5	87.1
Veneto	91.3	91.3	91.8	90.8
Friuli Venezia Giulia	90.4	90.3	90.8	89.7
Emilia Romagna	94.0	93.8	94.3	93.5
Toscana	95.0	95.0	95.2	94.8
Abruzzo	95.7	95.7	95.7	95.7
Umbria	93.9	93.8	94.0	93.4
Marche	92.0	91.8	92.1	91.7
Molise	94.3	94.3	94.3	94.3
Lazio	95.3	95.2	95.3	95.2
Campania	91.3	91.3	91.3	91.4
Basilicata	97.8	97.8	97.8	97.8
Calabria	95.3	95.3	95.3	95.3
Puglia	93.8	93.8	93.8	93.8
Sicilia	91.9	91.9	91.9	91.9
Sardegna	95.1	95.1	95.1	96.0
Italy	93.4	93.4	93.6	93.2

negative deflection was recorded in line with the general trend. Perhaps this trend should be correlated with a decline in the population's attention and sensitivity to the vaccine theme and to the increased skepticism arising from doubts about possible damages induced by media [7]. The media have immense cultural importance and television in particular, being the most popular and widespread medium, is able to offer a degree of diversity unmatched by the print press and other media. The way the media construe world events molds our existences and the way we interact in society [8].

If we focus on the Health System of United Kingdom, that is very similar to the Italian one, we see that it has no compulsory vaccinations: Department Of Health (DOH) provides a recommended vaccine schedule. The British health system is very focused on general practitioners and their direct relationship with the patient based on trust, choice and openness: this architecture helps to reach high rates of vaccination coverage since the patient recognizes the scientific authority of his doctor and trusts him. In 2015 measles vaccination in UK reached 95%; polio, diphtheria and tetanus achieved 96% while rubella coverage was of 93% [7]. The Spanish National Health System, whose features retrace the Italian healthcare system as well, follows the political choice of no mandatory vaccinations and reaches coverage values that satisfy the WHO threshold of 95%. Measles and rubella vaccination percentage in 2015 reached 96%; polio, diphtheria and tetanus achieved 97%, as well as anti-Hepatitis B [7].

Clearly, if a majority of the population is immunized, herd immunity is created, by which a given pathogen cannot spread among the population anymore, thus ensuring that the relatively few individuals who have not been immunized are preserved anyway, given the low likelihood of such individuals encountering the pathogen [9, 10]. If immunization coverage decreases, a substantial risk arises of long eradicated infections remerging, and of others whose incidence had been going down growing again. As a matter of fact, owing to the migratory phenomenon populations are exposed to pathologies that had long disappeared from their territories [11,12,13].

The role played by court rulings

Several court rulings have contributed to a lower degree of trust, on the part of the public opinion, towards vaccinations. A ruling from the Milan courthouse n.4252, on 21st December 2007, contributed to alarming the parents: the judges identified a causal link between the sudden death of some children and the administration of vaccines [14,15,16].

The Rimini Court on 15th of March 2012, n. 148, [17] and the Pesaro Court on 11th of November 2013 [18] have validated a causal relationship (on scientific basis proven to be flimsy by several studies) [19,20,21]

TABLE 2. Percentage of vaccinated population, by Italian regions for Pertussis, Haemophilus influenzae B, Measles, Mumps, Rubella, Chickenpox, Meningococcal C, Pneumococcal conjugate (recommended vaccinations before the June 2017 decree)

ItalianRegions	Pertussis	Hib	Measles	Mumps	Rubella	Chickenpox	Meningo-coccal C	Pneumo-coccalconjugate
Piemonte	94.9	93.8	88.7	88.7	88.7	0.9	86.6	91.3
Valle d'Aosta	92.8	92.6	82.3	82.2	82.2	0.4	83.1	88.5
Lombardia	93.4	93.0	90.3	90.2	90.2	0.8	85.8	86.8
Liguria	94.5	93.9	81.5	81,32	81.49	10.57	79.65	92.80
Pr.Autonoma Trento	92.5	92.0	84.6	84.4	84.5	3.0	83.1	87.3
Pr.Autonoma Bolzano	87.5	87.2	68.8	68.8	68.8	4.2	63.1	81.7
Veneto	91.3	90.6	87.2	87.1	87.1	84.0	90.5	84.6
Friuli Venezia Giulia	90.2	89.6	82.0	81.9	81.9	67.0	84.1	81.0
Emilia Romagna	93.6	92.9	87.2	87.0	97.0	0.9	87.4	91.5
Toscana	95.0	94.6	88.7	88.7	88.7	78.2	90.9	92.9
Abruzzo	95.7	95.7	84.2	84.2	84.2	4.9	65,43	86.34
Umbria	93.7	93.4	87.5	84.2	84.2	4.9	85.7	90.3
Marche	91.7	91.5	79.9	79.9	79.9	2.8	76.9	88.0
Molise	94.3	94.3	77.4	77.4	77.4	47.7	68.1	92.6
Lazio	95.2	95.2	84.5	84.5	84.5	6.5	76.9	88.0
Campania	91,3	91.5	80.8	80.8	80.8	9.2	50.0	83.0
Basilicata	97.8	97.8	90.3	90.3	90.3	77.0	85.8	97.1
Calabria	95.3	95.2	84.4	84.4	83.7	53.0	67.9	88.7
Puglia	93,8	93.7	84.2	84.2	84.2	81.8	50.0	83.0
Sicilia	91.9	91.9	79.2	79.2	79.2	75.4	60.5	89.4
Sardegna	95.1	95.1	87.7	87.7	87.7	67.2	83.6	94.1
Italy	93.3	93.0	85.3	85.2	85.2	30.7	76.6	88.7

between vaccinations and autism [22,23,24].

The Rimini Court ruling was overturned in February 2015 by the Bologna Court of Appeals, [25] but going through databases it is easy to detect an increase in the rate of litigation arising from damages allegedly related to the administration of vaccines.

As for the risk of possible complications, it is certainly not to be underestimated: 2015 data show 7,892 [26]. Nevertheless, the Italian National Federation for the Orders of Doctors and Dentists, in a release published on 16th of July 2016, states that "vaccines have achieved a thoroughly reassuring level of safety, and current manufacturing technologies for vaccines having been in use for many years make their administration safe" [27]. Italian Medicines Agency data confirm that in 2015, with regards to diphtheria, tetanus, pertussis, polio, B hepatitis and B Haemophilus influenzae, reports of possible adverse side-effects were 68 for every 100,000 doses, of which 141 (14.3%) were severe. Yet, within such detections, the notion of severity is particularly wide-ranging. In fact, as many as 91 out of 141 adverse reactions were pyrexia and hyperpyrexia [28]. With regard to the vaccinations against measles, parotitis, rubella and chickenpox, only 641 cases were reported in 2015. Most of them (77%) were not severe. The rate of detection varied significantly according to whether the administration of the vaccines only covers the first three illnesses (45% of detections) or includes chickenpox too (18% of detections). In particular the rate of detections ranged from 15 per 100,000 doses of Proquad (for MPRC) to a maximum of 138 per 100,000 doses of Varivax (for chickenpox). Therefore, even those data highlight the degree of safety of those vaccines [28].

Scientific literature confirms that adverse events are rare and negligible, compared to the benefits relative to vaccinations. In fact, the risks inherent to the administration of vaccines are largely countervailed by the substantial hazard that some diseases might re-emerge and affect unimmunized individuals with a much higher frequency than the current one, in absence of a large-scale immunization campaign [29,30,31,32,33].

Moreover, the Administrative Regional Tribunal of Friuli Venezia Giulia [34] has thrown out lawsuits from two families impugning a legislative order from the city council of Trieste. The families in question had argued that the risk connected to vaccines for such diseases was currently higher than that of being affected by the same diseases.

According to the Court: "this might hold true only in presence of a substantial percentage of the population being immunized", i.e. the so-called "herd immunity" effect. Furthermore, the judges contend, some children cannot get vaccinated on account of health issues, and if pathogens are spread partly because their schoolmates fail to undergo preventive practices, they risk falling seriously ill. Thus, individual interest, "however respectable and worthy of protection", must be superseded by the public interest. The Regional Administrative Tribunal also stresses how the obligation to get the four previously mentioned vaccines has never been repealed, but "some sort of conscientious objection has been allowed in that insofar as parents, contravening legal obligations, should choose not to immunize their children, such conduct does not entail adverse consequences in terms of their children being able to gain primary school enrollment". City governments put in place directives meant to prevent unimmunized children from enrolling in nursery schools or day care facilities. In such cases, failure to abide by the obligation to immunize children determines the parents' inability to enroll their children in pre-school [34].

Measures initially adopted at the regional level before the governmental and parliamentary interventions through law n.119/2017.

Interventions from the National government and Parliament have been anticipated by several local legislative initiatives. In fact, in 2007 the Region of Veneto suspended the vaccination mandate [35,36]. Nonetheless, the above-mentioned drop in immunization coverage has led the local authorities to put in place measures to swiftly ensure a rise in immunization coverage rates and guarantee the right to enjoy good health of both the children and the communities in which they live. The city of Trieste [37] and the region of Emilia Romagna [38] have resolved to ban enrollment of unimmunized children in nursery schools. The region of Tuscany is about to enact an even harsher piece of legislation banning from nursery schools and kindergartens all those children who have not undergone the whole set of childhood vaccinations laid out by the National Immunization Plan, and not merely the mandatory ones. Such a plan for the years 2017 through 2019 has introduced a new, free array of vaccinations, such as meningococcal vaccine B, as well as the possibility to sanction doctors who are opposed to them, or link them with conditions such as autism, despite the lack of scientific grounds to do so [39].

The Italian Government and Parliament enacted the above-mentioned reform in 2017. In addition to decuple the number of mandatory vaccinations, measures were introduced in order to facilitate the implementation of the "vaccination plan", such as the opportunity to make appointments for vaccinations for free in pharmacies, or mandatory negotiations on the price of vaccines, so as to prevent speculative practices with the Italian Medicines Agency. Such entity has also been tasked with laying out an annual report (in cooperation with the National Institute of Health and relying on an independent technical-medical commission) on the outcomes of the pharmacovigilance system and on data relative to the adverse side-effects provably associated with vaccinations [4].

Based on the legislation currently in place,

documenting the vaccinations administered will only constitute a requirement to access the pre-school system, but not for higher degrees of education. At the pre-school level, failure to produce such documentation in a legally timely fashion will cause enrollment to be invalidated [4].

Compared to law decree n. 73/2017, law n. 119/2017 has significantly reduced the penalties which can be levied in case of failure to comply with the mandate, from a maximum fine of 7,500 € [4].

In order to gauge the implementation of vaccination measures nationwide, the reform has instituted the National Vaccination Registry within the Ministry of Health [4].

Starting from 1st July 2017, the Ministry of Health will be promoting initiatives aimed at improving communication and institutional information to illustrate and foster greater awareness as to the new regulations within the decree, and to spread among the general population and health care practitioners a vaccination-oriented culture. Such initiatives will be carried out thanks to the contribution of general practitioners, pediatricians and pharmacists, in addition to counseling facilities for families. The Ministry of Health and the Ministry of Education, starting from the 2017/2018 school year, will be phasing in various training initiatives for educational workers and staff, and initiatives meant to raise awareness among student bodies about prevention measures and vaccinations, with the involvement of parents and health care workers associations. Projected outlays totaling 200,000€ for 2017 appear likely to fall short [4].

Ethical-legal basis of the immunization mandates.

The Oviedo Convention, enacted in Italy through Law n. 145/2001, has reinforced the principle of self-determination in the realm of healthcare, hence any medical treatment may be delivered solely upon free and informed consent on the part of the patient [40]. Proper balance between such principles has been established by the art. 32 of the Italian Constitution, which states that "no one may be compelled to undergo any kind of medical procedure, except under the provisions of the law" and that "such laws may in no way breach the limits that define human dignity and respect" [41]. Consequently, vaccinations may not be unilaterally imposed by the government without approval from the Parliament and no compulsory health care treatment may violate the principle of respect of every human being. Such a scenario may come real if, for instance, a mandate on any kind of immunization stemmed from interests other than the safeguard of individual and collective health.

From their perspective, parents who opt out of a given vaccination exercise their right to choose in what they consider to be their child's best interest, alarmed by the possibility that a given vaccination might irreparably harm his or her health, thus bringing about an outcome contrary to the stated one, protect their wellbeing.

However, it should be kept in mind that their "right" to forgo any given vaccination influences the epidemiological dynamics of diseases, which could be eradicated by means of immunization. Hence, the parents' right and duty to rear their children according to their own deeply held values and beliefs, based on what they consider to be their child's best interest, may not warrant any decision which could pose a danger for the community at large. If, for instance, parents refuse to immunize their child against measles, their free choice contributes to the failure to achieve such a degree of coverage as to eradicate the disease. Such a disease may in fact spread not only among those who have opted out of vaccination, but among those who have not been immunized due to a medical condition (e.g. several types of immunodeficiency) or children too small to be vaccinated [42,43,44]. It should be taken into account that along with parents' right to choose, there exists a minor's right to be shielded from potentially deadly diseases, i.e. his or her right to be safeguarded if the parents' choice may result in harm to his or her health. "The minor is [...] "jure proprio" holder of the right to health exercised through the parents, who are the legal representatives." "Parents are not free to decide about the health of a child as their own, but they act as legal representatives and must respect the principle of the child's pre-eminent interest, without letting prevail personal choices and opinions." [45] According to the National Committee for Bioethics, "vaccinations fall under parental responsibility according to the child's best interest and the right to be vaccinated". The refusal of vaccinations "results in an increase in the risk of children attending multiple environments (hospital, school, gymnasiums, swimming pools, public and private playgrounds, etc.) which become risky because of the refusal", and put "serious danger to the most vulnerable subjects who for medical reasons cannot be vaccinated [46]. The United Nations Convention on the Rights of the Child sets forth that "States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health (Art. 24) [47]. According to the UNICEF's Minority Health Code, every child has the right to be "vaccinated to prevent infectious diseases with high-frequency, penetration and risk of sequelae, in a manner appropriate to his/her health" (Art. 7) and "to be protected from all forms of violence, physical and moral negligence, maltreatment and exploitation, including traditional practices prejudicial to his health and practices of physical constraint" (Art. 15) [48]. Moreover, an uptick in the amount of compulsory vaccinations may be instrumental in safeguarding orphaned children or those children growing in dysfunctional families, who would not otherwise undergo merely recommended vaccinations. In this regard, although the Italian Code of Medical Ethics of 2014 does not specifically refer to vaccinations, it does state that "doctors must safeguard a minor, in particular when they realize that their living

conditions and environment are unfit to ensure his or her health, dignity, and an acceptable quality of life" (art. 32) [49,50]. Thus, if pediatricians ascertain non-compliance with vaccination mandates, they are required to take steps in order to preserve the child's health.

Such considerations are not meant to deny that vaccination mandates are compatible with parents' rights and freedom of choice. It is just as manifest that individual and public health cannot be the only element worthy of protection, but it must be weighed against the protection of parental rights. Yet, in that regard, it seems possible to strike the right balance through sound and thorough information. In fact, the vaccination mandate may not be perceived by parents as an imposition, provided the the information provided enable them to understand that vaccinations have the best risk-benefit ratio. Besides, even after the reform comes into full effect, parents will still retain a margin of freedom, since several important vaccinations will remain non-mandatory.

In conclusion, in the face of such conflicting interests, and factoring in the undisputable difficulty to draw a line between individual and collective rights, we contend that not only does a State have a right, but a duty to promote immunization practices as well. Even the National Bioethics Committee on 22 September 1995 stated that the government has the right and the duty to promote vaccinations considered essential by the international scientific community, not only through information campaigns and Health education, but if necessary with other more incisive ways. In addition, each solution adopted may be equally acceptable, in order to achieve the purpose, that is a sufficiently extensive vaccine practice to protect both individuals and the whole population from significant contagion risks [51,52].

The importance of the doctor-patient relationship

The legislators' increasing the number of mandatory vaccinations does not in any way discount the importance of a sensible and forthcoming doctor-patient relationship. In fact, numerous important vaccinations are still non-mandatory. Furthermore, since compliance with vaccination mandates is not a requirement for enrollment in primary schools or following stages, a solid discourse between doctors and patients is essential in order to help parents appreciate the importance of vaccinations, thus increasing coverage.

A survey by Censis under the conditions abrogated by the 2017 reform has highlighted a far from positive picture: 79% of parents claim to know what the vaccination schedule is, but only 5.6% have been able to indicate correctly the number of vaccinations currently mandatory; more than 25% indicated as compulsory vaccinations that are, in reality, merely recommended [53]. Against such a backdrop, it is essential to seek moments of mutual listening, in order to further informed consent [54,55]. Pediatricians, as well as physicians who administer vaccines, have a moral duty to provide the parents with timely, updated information on vaccines, devoid of any personal opinion or bias, but rather backed by the best, most sound medical research available [56,57]. It is necessary to establish a relationship based on mutual trust, prompting parents to voice their doubts while providing them with any helpful informational resource available [58] It is incumbent upon the pediatrician to expound on vaccinations in as an understandable a way as possible, to explain any possible or even likely complications inherent to the disease meant to be prevented, expected benefits, as well as risks, of vaccination. It is important for healthcare professionals to inform parents of any professional opinions opposed to vaccinations, while pointing out a possible lack of scientific substantiation for such opinions. It is also key to point out the need to take into account the risks possibly arising from the failure to vaccinate a child, affecting the child as well as the community at large, since such risks fall within the risk-benefit assessment through which an informed decision whether to consent to the vaccination can be made. Lastly, pediatricians need to get through to the families the key concept of herd immunity and its implications in terms of relevance to the community, as well as the importance of achieving prescribed coverage and keeping it unaltered, within a broader vision of policy-making aimed at furthering the prevention of infectious diseases.

Only upon completion of the above mentioned informational pathway, which entails a calm, focused approach as well as an appropriate timeframe, parents will be enabled to make an informed, fully aware decision on whether to consent to the vaccinations or turn them down [59].

Since it is difficult to conceive that every pediatrician is able to provide such detailed information, it is necessary for the Ministry of Health to lay out information protocols tailored to each vaccination, so as to ensure the exact amount and quality of the information to be provided to the patients. Otherwise, there is a risk that people's freedom of choice may be affected by a higher or lower degree of competence and availability of single pediatricians.

CONCLUSIONS

At current trends, the vaccination coverage is low enough to compromise the herd immunity effect incrementing the risk of re-emerging of some nearly eradicated diseases. Law n. 119/ 2017 only partly solves the problem, because the above-mentioned vaccinations are mandatory to gain access to the preschool system for very small children, whereas parents of children of elementary school age or older, it will be enough to pay a 500€ fine to dodge the mandate. Consequently, constant screening is therefore crucial in guaranteeing the capacity to intervene in a timely fashion if abnormal dynamics should come

into being, threatening to compromise the herd effect. It is therefore necessary to undertake any effort needed to build up trust in immunization within the public as well as in the medical community, but primarily to raise awareness of the risks posed by dwindling immunization coverage. To that end, media outlets play a key role: newspapers, television, the internet as well as schools, in addition to specific, targeted national campaigns crafted in accordance to the segments of society they seek to reach. In that regard, it is advisable to mount informational, multilingual campaigns geared towards immigrants as well.

However, without a growth in the culture of healthcare workers towards vaccinations, it is hard to achieve consistent and persistent results also in the general population [60]. And in this field, there is evidence that the Continuing Medical Education has a crucial role [61].

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