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REVIEW

Towards the suspension of compulsory vaccination in Italy: balancing between public health priorities and medico-legal and juridical aspects

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Introduction

The vast majority of citizens living in Europe have significantly increased their life expectancy and quality in the last fifty years. This great result is mainly due to the improvement in both economic and social status of our societies, but also to the better general hygienic conditions after the II World War and to the parallel impressive scientific and medical progresses worldwide [1]. In particular, some of the best results in medicine during the last decades, unfortunately observed mainly in Western Countries, concern the field of prevention and control of infectious diseases (IDs), and mainly prophylactic vaccines have contributed to this [2]. It is well known that important IDs in term of morbidity and mortality, expanded worldwide in the recent past, have currently been eradicated or eliminated, such as smallpox, polio, diphtheria and other are under control as tetanus, hepatitis B infection (HBV), etc. [3-5]. In particular, children's health has mainly improved, obtaining the best advantages of well-planned vaccination strategies, being available national immunization schedules targeted for this age group in all Europe [6, 7].
Immunization strategies implemented all across the European Union (EU) Countries, to achieve and maintain over time high rates of vaccination coverages within the target populations, are variable, providing both compulsion and recommendation, free of charge and co-payment offer, incentives to parents (e.g. Austria) and to health-care personnel (Ireland and United Kingdom) and education and awareness-raising (e.g. Finland, Germany and The Netherlands) [8].
Following a current general attitude in Europe in the field of Public Health, aimed to abandon compulsory interventions for a number of preventive policies, in favour to an approach mainly based on health education and promotion and patient's self determination, a current attempt to suppress the compulsory offer of some vaccines of the national infant immunization schedule is growing up in Italy.

Current situation in Italy: public health issues

In Italy all the vaccines, which are considered as a Public Health priority, are included into a national infant and evolutive-age immunization schedule, being all offered following an active and free-of charge strategy, with the only exception of some relatively recent compounds (i.e., meningococcal and pneumococcal vaccines and varicella vaccine), depending by each single Regional determination [9]. In particular, the principal infant vaccinations are actually included in the Essential Levels of Assistance (LEA), that the Regions must guarantee to all citizens without any payment.
The vaccination offer is theoretically based on a mixed system in our Country, yet: four vaccines are defined as "compulsory" (against diphtheria, tetanus, Hepatitis B Virus, and Poliovirus), while the others are "simply" recommended (against measles, mumps, rubella, pertussis, H. influenzae type B, N. Meningitidis type C, St. Pneumoniae, varicella and papillomavirus) [10].
It is obvious, for the experts in the area of Preventive Medicine and Hygiene, that this dichotomy is a purely conceptual difference, to date: this is consistent with the facts that, differently from the dramatic epidemiological situation existing in Italy, during the fourties and fifthies, for some IDs, as tetanus, diphteria, polio, an analogous scenarios no more exists, and, as a consequence, no coercive catch-up by police is actually performed for individuals or parents, who express their dissent to the still existing "compulsory" vaccinations.
Nevertheless, during a recent past, vaccination coverages of the population for some of the recommended vaccines (i.e., against measles, mumps and rubella) have not been reached in an homogeneous way throughout our Country, particularly if compared to that obtained for the compulsory compounds [11-13].
In this view, the co-existence of a double system for the offer of current available vaccines could have encouraged doubts on the real value of some recommended vaccines of the immunization schedule, thus facilitating

both anti-vaccination demands and the activity of the existing antivaccinal groups: this is particularly true in the worst case, in which the target population has not been correctly and adequately informed on the real equivalent low risks, in term of safety, and significant benefits, concerning protection, of both compulsory and "simply" recommended vaccines. This probably happened, even no one scientific evidence for spreading alarmist, and often consequent inaccurate information, concerning the field of vaccinology exists to date.
On the other hand, it is also important to consider, that a certain tendency not to comply with vaccinal obbligations also currently exists in Italy and could be, at least in part, explainable by the optimal control reached or the elimination of some vaccine-preventable diseases, such as diptheria, polio, tetanus and hepatitis B, letting some people to believe that the relative vaccines could be considered as unuseful and the risk to become infected null to date [13, 14].
In this context, a recent tendency to overcome the still existing double way vaccinal offer is gaining ground in Italy: this has also been supported by a precise statement by the last National Vaccination Plan 2005-2007, where administrative Regions were requested to provide equal offer and strength of recommendations for all the existing available vaccines inserted into the schedule [9]. In the above mentioned document, "a way towards overcoming the compulsory vaccination" is outlined, but specific criteria for a "future experimentation for its suppression" have been also clearly fixed and need to be met as prerequisites by Regions for starting the process, yet: namely, (i) the capability to maintain adequate vaccination coverages of the target population, (ii) the establishment of an effective informative system, structured in well organized vaccinal records, as well as the availability of accurate systems for (iii) the surveillance of both the vaccine-preventable communicable infectious diseases and the serious adverse events following vaccinations, including their clinical follow up [9].
All these items are well under discussion also within the National Vaccination Plan 2008-2010, currently in press.
In the meantime, some Italian Regions have already begun to adopt provisions to enable the exemption from the compulsory vaccination on their own territory, with an immediate effect [15-17]. For example, the Council of the Region of Piemonte approved, in 2006, the Plan for the Promotion of Vaccinations, that replaced the traditional distinction between compulsory and recommended vaccines, into a new one, between that "having priority" and "not having priority", based on the local epidemiological scenario and health-care burden, suspending the sanctions for evasion of the complusory vaccinations, in conformity with Law no. 689 of 24 November 1981 [18].
Even more interesting, the Veneto Region also started up a project for the suspention of the compulsory offer, beginning from the year 2008: availing itself of a recent provision of law [19], policy makers abrogated the sanctions associated with compulsory vaccinations, de facto eliminating the dichotomy between compulsory and recommended vaccines. This program was built in accordance to all the above mentioned conditions required by the Ministry of Health, in the National Vaccination Plan 2005-2007.

The medico legal and juridical aspects

Though the above mentioned examples represent brave experiences in the view of a probably inevitable and relentless change, it appears useful to focus on their constitutional legitimacy and on the observance of some medico-legal principles, which have rarely been sufficiently debated and taken into the right account, during the evolution of the process [20-25].
First of all, it is at least doubtful if such choice is admissible if taken only at a regional level, instead of at a national basis, which would have appeared, in our personal opinion, as a more homogeneous approach. In fact, in the field of Public Health, the general and best interest should always prevail on the personal view-point, particularly for matters concerning the whole community, as in the case of the prevention of trasmissible IDs. In fact, the achievement of the regional legitimate autonomy principle should also take into the right consideration the first priorities by the national level: consequently, even the regional law of Veneto was anticipated by the approval of the above mentioned NVP, it must be clear that a political-administrative agreement cannot be enough for jeopardizing a national provision of law.
From a strictly juridical view-point, quoting some sentences of the Constitutional Court, it is evident that the provision on compulsory or voluntary vaccination "responds to a community interest, as it concerns legislative choices of general character – omissis – that does not allow different regulations on the territory" [26]. On the basis of such principles, for instance, it has been declared unconstitutional a regional law, that regulated the informed consent for treatments using psychotropic substances on children and teenagers, saying that such matter concerns a fundamental principle of health safeguard, and must be therefore reserved for the national legislation. This trend also follows the indications of the Constitutional Court, regarding the clinical experiments on human beings and the donation and acceptance of blood and its components [27, 28].
Thus it is evident such matter should fall within the competence of the national legislation, at least with regards to its overall principles, being a question concerning the topic of "sanitary treatments", which are regarded as "compulsory", even not directly forcedly imposed. In this sense, Article 32, 2nd paragraph of the Italian Constitution foresees a reservation of the national legislation, because it can weigh on the fundamental human rights, such as health self-determination [29, 30]. In conformity with this, the legislation on compulsory vaccination is intended, in fact, to find a balance between the right to health of the individual and that of the community [31-37]. It is also helpful to remind that, in order to describe the complexity of the matter, that involves such thorny mix of interests, the Constitutional Court

has significantly resorted to the category of the "tragic choices", meant as derived from the conflict between some values that assert themselves in such an absolute way that they could seem incompatible [38-40].
In this context, it is important to remind that also the Article 6 itself, letter a and b, Law no. 833/1978, expressly reserves to the State all administrative functions concerning the "international prophylaxis in maritime, flight, and border areas" and "the prophylaxis for infectious and contagious diseases, for which the compulsory vaccination and other quarantine measures are provided by law" [41]. Such practice is in conformity with the provisions of the novel Article 117 of the Constitution, amended by Constitutional Law no. 3/2001, according to which, the framework principles of sanitary matters, the fundamental ones, must be exclusively governed by the national legislation, whereas the regional legislation can only intervene in a complementary way.
In this regard, again the Constitutional Court has underlined that Regions can legislate on "sanitary care" matters only in conformity with the fundamental principles established by the State, to date [42]: as a successive ruling of the Constitutional Court confirmed, the regional law cannot, in fact, weight on the constitutionally safeguarded fundamental rights [43].
Besides, the fact that the law of the Veneto simply suspends and does not definitively repeal the compulsory vaccination does not seem to be enough appropriate for endorsing its constitutional legitimacy. Though the suspension itself has its own conceptual autonomy with respect to the repealing and to the derogation, it implies, however, that the legislator possesses the competence in the matter regulated by the law that he wants to suspend [44]. Besides, an open-ended suspension is bound to turn into a repealing. In fact, recently, the Constitutional Court declared illegitimate a regional law that ordered the temporary suspension of the veterinary vaccination campaign against the blue tongue, despite the decision of the Law Court who had ordered it in compliance with a EU directive.
This is logically explained because, if a different legislation at regional level is acceptable, the role itself of vaccination, that is prevention of the spread of a particular disease, would be completely neutralized: in fact, we have to remember that "viruses and other micro-organisms freely widespread and do not halt in front of regional borders" [45].
On the other hand, it is important to consider the Veneto experience as a pilot-project. Furthermore, Veneto have declared to guarantee, inside its regional work plan, all the vaccinations as LEA: in this context, it seems useful to highlight again that both compulsory and recommended vaccinations are currently included in this category of sanitary services, as per the decree of the Presidency of the Council of Ministers dated 29th November 2001 [46]. In addiction, from the preparation works on the law, it was evident that Veneto legislation have foreseen, as a first priority, to guarantee all the essential prerequisits reported in the last NVP 2005-2007, particularly, the achievement and maintenance of high vaccination coverages within the target populations, and the proper surveillance on the serious adverse events. It was also foreseen that the Council approved guidelines aimed at providing vaccinations actively and homogeneously on the whole regional territory, further assuring that an appropriate evaluation of the efficacy of the program (i.e., in terms of monitoring incidence rates of all the vaccine-preventabile diseases) should have been done by a technical-scientific committee, currently about to be constituted.
Nevertheless, in the view to speed up the process towards the suspension of compulsory vaccination in our Country, it still remains questionable if envisaging voluntary vaccination might influence the good level of the general sanitary service, if not in Veneto, possibly in other Regions, that have been demonstrated to be less virtuos, from the viewpoint of both personal and collective attitude towards disease prevention and health care safeguard. In particular, focusing on a personal viewpoint, with respect to the underage group "we cannot ignore the peril, arising from the lack of vaccination, hanging on a younger person, as it is no more a question of his/her self-determination, being underage, but of the parents, who have the faculty-duty to take all the appropriate measures and directives to avoid prejudice or real peril to the younger's health, being not feasible to allow parents a complete liberty, even in making such choices that could turn out to be seriously prejudicial to their child" [47].
Therefore, even if the cited regional experience of Veneto need undoubtely to be considered as a positive challenge for a more consciuos, ethical and modern Public Health approach for the prevention of IDs, some doubts still remain about the constitutional legitimacy of the law: thus, we believe such an important choice to suspend the compulsory vaccination should remain competence of the national legislation.

Discussion

It is indisputable that the improved hygienic and living conditions, supported by an important scientific progress, particularly in the medical field, have played a key role in averting the risk of diffusion of many dangerous epidemic IDs during the last half-century, at least in Western countries.
Particularly, in Italy, the so called compulsory vaccinations have played a crucial role in doing this, during the last decades: in fact, thank to this strategy, it was possible to reach and maintain high immunization coverage rates against the relative diseases, close to 100% in the selected target populations: as a consequence, the eradication, the elimination or, at least, the optimal control of some virulent infectious agents have been obtained. This was the case of smallpox eradication in the late seventies, that of the elimination of diphteria and of the control of both tetanus and hepatitis B, waiting for poliomyelitis, measles and rubella elimination and hopefully for their possible eradication, as planned by the WHO just in a next near future [48].

Nowadays, the relatively recent availability of the combined polivalent formulations (i.e., in Italy, the hexavalent Diphtheria-Tetanus-Trivalent Acellular Pertussis-Hepatitis B-Inactivated Polio Virus-Haemophilus influenzae type B vaccine, and the trivalent Diphtheria-Tetanus-Trivalent Acellular Pertussis vaccine), containing togheter both compulsory and recommended vaccines, and their wide introduction as part of the routine national infant and childhood immunization schedule, have further contributed to optimize immunization coverages in our Country and all across Europe, de facto overcoming the conceptual Italian distiction between compulsory and recommeded offer. As a positive result of this, some vaccine-preventable diseases, for whom no compulsory offer have ever been established in Italy, such us that caused by H. influenzae type b, the first aethiologic agent of meningitis in infants at the end of the ninethies, have been definitively defeated [49].

As a matter of fact, it is also true that, in a recent past, the "simply" recommendation, in our Country, for some of the avaible vaccines could have created the misinterpretation according to that these important preventive tools would have been considered as of less value with respect to the compulsory ones: as a negative consequence of this possible misleading interpretation, acceptable immunization coverages have not been achieved in children since these last few years for some important Public Health transmissible IDs, such as measles, rubella or mumps, this translating into a significant delay in their possible control, still to date.

The example of measles is terribly paradigmatic of this. In Italy in 1979, measles vaccination was recommended for children aged >15 months. During the early 1990s, combined MMR vaccines were introduced, and in 1999, the recommended age of administration was lowered to 12-15 months. Even measles vaccine have been regularly incorporated into the routine childhood vaccination schedule, low immunization levels have been reached in children aged 12-24 months, since the mid of ninethies, resulting in only 56.4%, as reported by the ICONA national study, performed in 1997 by the National Institute of Health [11]. National vaccination coverage with 1 dose of MMR vaccine, by age 24 months, has remained inadequate also during the following years, as reported by the second ICONA study performed in 2003, with an estimated national coverage of 74% for the 2001 birth cohort [12]. So it is not surprising that a large oubreak, accounting for more than 40,000 cases aged under 15 years, with four measles-associated deaths and 594 hospitalizations occurred during January-July 2002 in Campania, where the vaccination coverages were estimated to be at 65% for the 1998 birth cohort [50]. Epidemics have continued to occur in Italy and throughout Europe, where the measles vaccine is part of the immunization schedules since at least 20 years: in particular, between 2006 and 2007, more than 12000 cases of measles in 32 European countries have been reported, 86% of which in Austria, Germany, Italy, Spain, Switzerland and Great Britain [51].

Following the above mentioned emergency, after a long period of inadequate vaccination coverage, Italy implemented a National Elimination Plan for Measles and Congenital Rubella in 2003, in order to reach the objective by 2010, according to the goals of World Health Organization (WHO) in the European Region: just thanks to this well organized and broad-spectrum preventive programme, both the observed increase of vaccination coverage, nearly 90% in 2005, and the strong commitment of the Italian public health service in the Elimination Plan suggest that measles control is approaching in Italy and its final elimination possible [52]. This approach is well in line with the recommendation by the WHO, in collaboration with UNICEF and other partners, to increase the awareness of the State Members on the importance of immunization and for improving the vaccination plans, as stated in 2008 [53].

Bearing in mind what said and now focusing on the main topic of our paper, even we consider as desiderable the actual tendency ongoing in Italy to overcome the compulsory offer of vaccinations, thus following a more consciuos, ethical and modern Public Health approach for the prevention of IDs, we also strongly believe that this might be successfully obtained only if performed at a national level, inside a well structured plan, coordinated by the Ministry of Health and Social Policies, in close collaboration with all the Regions. This will require the necessary time, yet. Otherwise, the risk of a re-emergence of some preventable IDs, nowadays kept under good control or elimitated following both compulsory or recommended vaccinal interventions, is still alarming real in our Country, even not necessarily in Veneto, if the immunization levels should decrease, as already reported in other geographical areas, such as East and central Europe, for some virulent diseases, in the case of diphtheria [54, 55] and whooping cough [56].

In this context, we also agree with other authors that the risk of importation of polio virus in our Country must not be absolutely underevaluated to date, on account of the continuos exchanges with both North African Countries, which are currently in danger of epidemics, due to their negative behaviour towards vaccinations, thus allowing the virus to pass into otherwise polio-free areas [13].

Thus, it is clear that the problem needs to be faced not only focusing on our national epidemiological scenario, in a individual manner, but also being aware that we are part of a larger community, that is the EU: as a consequence, the importance of a well structured vaccination system, on a national basis, directly lays in the possibility of largely minimising the risk of epidemics between neighbouring Countries. This risk is real, as reported by a Finnish study which pointed out a resumption of measles, mumps and rubella cases, though its eradication in 1996 and 1997, because of the increasing imported number of unvaccinated population [57].

At the same time, it is also to consider that also the political, social and economic changes, frequently taking place in the European area, i.e., following the Fall of the Berlin Wall, could play a crucial role in leading to a potential decline of the immunization coverages, as also already drammatically reported for diphtheria [55].

Furthermore, we are also sure that, as demonstrated for other preventive intervention all across EU, the current trend concerning Public Health policies seems to be in favour of an engagement in information and persuasion of the target populations, rather than in resorting to enforcement actions by law. This is crucial particularly in the field of primary immune-prevention of IDs, when vaccinal interventions are hypothesized to be planned as completely voluntary: in fact, the danger is that large groups within the population, and in particular that from degraded social environments and where the migratory phenomenon is more prevalent, will not be able to make a real conscious and informed choice. As outlined in a study made in Germany, such behaviour, due to many different factors (lack of information and motivation, structural deficiencies, etc.), would frustrate the hope of seeing the end of the previously cited preventable-IDs [58].

Where the principle of the individual self-determination will prevail, the suppression of the compulsory vaccination will necessarily envisage a global adequate information and awareness policy, aiming at improve compliance to vaccinations, thus maintaining optimal immunization coverages in target groups, the first essential tool to assure, and hopefully improve, the control of all vaccine-preventable IDs in the next future.

On the other hand, although, in our Country, vaccinations are routinely administered through a well-established and organized network of public frameworks, homogeously located in the territory, as part of the National Healthcare System, it must be underlined that, a certain degree of heterogeneity concerning both the immunization strategies with available preparations and their offer conditions (active and passive offer, free of charge and payment/co-payment offer, etc.) still persist, at both the regional and the local level.

As a consequence, in order to reach the ambitious aim of the suppression of the compulsory vaccinations, a further improvement at both the political and organizational level, togheter with a real cultural and social shared policy are necessary, as it is foreseeable that the immediate suppression of the compulsory vaccination "ope legis" could, at least in part, harm the whole vaccination system, which could not be still complitely prepared for this radical change to date, at least in some areas of the Country.

If a proven and well settled organization within the public health vaccination network is of fundamental importance, as abundatly said, the other cornerstone on which any suspension program should be based on is, in our opinion, the active and broad partecipation of the population in it, at all social levels, which obviously foresees an adequate mass information and health education and promotion campaign. This successful approach has been already demostrated both in the recent Measles and Rubella and HPV National vaccination Plans, where also an open and constant dialogue with the media about the rational of the immunization strategy and the safety and the efficacy of the adopted vaccines have been provided.

Thus, the entire process towards the suspension has to be bound to enhance the sense of responsibility of both the parents, whose freedom of choice need to be granted, and the health-care workers, increasing their individual awareness with respect to all decisions concerning health, which means a further step towards the self-determination regarding both therapeutic and prophylactic choices, in a way towards the abandon of the so-called "paternalistic medicine".

The realization of the pilot project in Veneto could, therefore, represent an important and foresighted "test bed" of the capacity to reach such a modern and revolutionary aim, in conformity with the national objectives of the current NVP. This could represent the first virtuos experience to take as a model for similar projects, to be performed also by other Regions, towards the mid-term suppression of the compulsory vaccination all across the Country.

Nevertheless, what the Region of Veneto has proposed and realized further needs to be reviewed in the light of those principles of juridical and medico legal nature, that have been discussed above.

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