

Legal and ethical issues concerning the rejection of vaccines, and proposals for a necessary debate

Committee Members:

María Teresa López López (President)

Federico de Montalvo Jääskeläinen (Vice-president)

Carlos Alonso Bedate

Vicente Bellver Capella

Fidel Cadena Serrano

Manuel de los Reyes López

Pablo Ignacio Fernández Muñiz

Nicolás Jouve de la Barreda

Natalia López Moratalla

César Nombela Cano

Carlos M^a Romeo Casabona

José Miguel Serrano Ruiz-Calderón

Committee Secretary:

Victoria Ureña Vilardell

Index

1. Introduction and justification	4
2. The rejection of vaccines as a new social movement	6
3. Recognition of the right to protection of public health	8
4. The dual legal nature of public health	11
5. Vaccination as a public health policy	13
6. The absence of a legal vaccination duty in our legal system	14
7. When can a mandatory vaccination measure be adopted?	18
8. Parents' rejection of vaccination	21
9. Solutions to the social rejection of vaccines	22

Legal and ethical dilemmas regarding the rejection of vaccines and proposal for a necessary debate.

On 19 January 2016

The Committee, at the plenary session on 19 January 2016, approves the following report, in accordance with the provisions of Article 78 of the Law 14/2007, of 3rd July, on Biomedical Research, which establishes among the responsibilities of the Committee to issue reports, proposals and recommendations on relevant ethical matters for public authorities at the state and regional level.

1. Introduction and justification

Article 78 of the Law 14/2007, of 3rd July, on Biomedical Research, establishes in its paragraph 1, among other responsibilities of the Committee, “b) To issue reports, proposals and recommendations on matters that the Committee considers relevant related with the ethical and social implications of Biomedicine and the Health Sciences.” This competency is also stated in the Regulations of the Committee.

Under that competency, the Committee approved in its plenary on 6 October, the creation of a working group to address any legal and ethical issues that may arise related to immunization in Spain. Such proposal came in response to the concern expressed, by some Members of the Committee, about the current vaccines regulation and the possible deficits that our legal system may present to satisfactorily confront the refusal to accept this tool for promoting public health.

In recent days, the media has widely reported many cases showing risk situations for the community health caused by the parents’ refusal to immunize their children. We can thus remember the case that took place some years ago in Granada, when the Andalusian Health Service requested authorization from the Contentious-Administrative Court to proceed to vaccinate those children whose parents had refused to it under the framework of a measles outbreak.

More recently, media reflected the case of a minor who not having been vaccinated against diphtheria acquired the illness and died in a few weeks after not having any cases in the last decades in Spain.

Alongside those cases, the problem regarding vaccines is an issue that has long been concerning not only public authorities but also experts in Public Health. This is because after achieving one of the major successes in public health, they started now to realize that there is a negative position about vaccines among some sectors of the population. The reasons, as it will be later explained, are of different kinds, but what is of concern now is that they allow to predict that vaccines merit at least a reflection addressing what it can become a major collective health problem in the next years. The Spanish Bioethics Committee understands, from an ethical and legal perspective, the need to anticipate any issues, specifically when those are not yet identified, as it

will be seen later. A greater insight will allow us to make a calm and sensible deliberation.

This report thus originates from the public health risks that may arise from a future citizens' opposition to vaccines, and tries to find which might be, from an ethical and legal perspective, the better solutions to prevent that threat. On this regard, from a comparative view, there are different propositions in our environment that range from the implementation of a mandatory model of vaccination in the legal system, to types of economic incentives or equivalents (referred to as nudges in the Anglo-Saxon world, and which are becoming more relevant in the new public health policies) or the development of educational and informative measures to raise awareness among the population regarding the vaccines importance to the collective health.

Therefore, this reports aims to start a reflection about what has now become a further concern that goes beyond the particular mentioned cases that have appeared in the media. In any case, this is not just about offering concrete solutions but promoting, at least, the public debate regarding this public health problem and finding which the best solution may be, from an ethical and legal perspective.

As it will be seen throughout this exposition, although our legal system has not explicitly included the duty to vaccinate since it does not exist any specific legal norm which establishes that the public authorities can require their citizens to accept to be vaccinated, it is understood that there exists sufficient legal base to allow the competent public authorities to adopt the decision of mandatory vaccination, in the case of certain instances, and mainly in the case of epidemics. Nevertheless, outside the scope of epidemics, urgency or health need, such alternative shows many qualms.

In a sense, it implies a contradiction because if it really aims to avoid an epidemic, how can it be logically admitted to only implement a mandatory vaccination measure in the framework of an already widespread epidemic?

It is also true that a legal compulsory vaccination method creates a general incertitude regarding its real efficiency, and principally, regarding its effects in that part of the population who refuse immunization. Some sectors consider that the mandatory implementation of an immunization can provoke a worse reaction against vaccines.

On the other hand, the models based on educating and informing the people about the benefits of vaccines have failed in some countries. In this regard, the United States case is a paradigmatic one since using a permissive method based on education and information, it is now moving towards a system of compulsory vaccination.

Finally, it should be also noted that the present debate will remain specially attached to the issues raised in the field of childhood immunization; particularly, when parents refuse to vaccinate their children. None of this detracts from the fact that the refusal of vaccination by health professionals will also be explained. Such refusal creates a fundamental problem in the people's development of attitudes against vaccination. As the Health Protection Agency of United Kingdom highlighted in an assessment report submitted as it was requested by the European Union, it is difficult to engage the public to get vaccinated when the professionals administering the vaccines question their benefits and/or are not getting immunized themselves. (vid. *Assessment Report on EU-wide Pandemic Vaccine Strategies*, Health Protection Agency, 25 August 2010, page. 112, in <http://ec.europa.eu>).

2. Immunization refusal as a new social movement

The discussion among vaccines involve a paradox. Vaccination constitutes the public health policy that has shown its greatest efficiency in the prevention of illnesses in the last decades (already in 2002, the World Health Organization estimated that vaccines could save more than 2 million lives per year), but, at the same time, it is one of the policies that generates more controversy in society. This is due to the success of vaccines regardless the decisions taken under recent sanitary crisis. It is precisely in those countries where vaccination rates have had the greatest achievements where vaccines are seen with higher mistrust. It seems that since many of the diseases that where devastating humanity the last few decades have been forgotten there is part of society who has the perception that vaccines are no needed. This is just a very profitable tool for the enrichment of the pharmaceutical industry. The main enemy of immunization is thus the success demonstrated by vaccines since they have made people believe some diseases have already disappeared.

Together with that, there are two more reasons that can be highlighted. The condition of preventive medicine (its implementation prior and after the existence of

the disease, for avoiding it), and the fact that the possible adverse effects are more echoed than statistical data that is very incomplete, which has been in the last few years informing about its clinical merits.

It is true that our country's overview allows us to conclude that we are not currently facing an issue of extremely importance. These are still minor movements while the immunization coverage rate reached every year is very high. Thus, immunization data in Spain reports, in example, that the lack of childhood vaccination does not mean a significant problem. In 2014, the percentage of children who had received the primary immunization series of vaccines recommended exceeded 96 % in all cases. A percentage that appears almost with no significant changes in the series since 2001. (Source: Ministerio de Sanidad, Servicios Sociales e Igualdad, Coberturas de Vacunación: Datos Estadísticos) Moreover, the percentage of children receiving recommended booster doses is close to 95 %.

The risk of increasing the refusal of vaccines in the near future is very likely considering the situation in other countries, and the fact that the immunization rate in the elderly has decreased significantly in the last few years (up to fifteen points in the last ten years), if we use the example of flu vaccination in the population aged over 65, with regard to the 70 % vaccination rate that had been reached a decade ago, today, this rate is 56.2 %. Such rate has been in the last ten years far from the recommended immunization rate by the World Health Organization and the European Union, which is 75 %.

Neither that example in the specific field of fighting against flu, nor what has been happening in other countries can be necessarily compared to the debate about childhood vaccination in our country. However, it cannot be denied that such rates, to which it could be add the low vaccination rate among health professionals, requires, at least, a discussion and, where appropriate, the adoption of political and judiciary measures that enable to cope with what it is still seen today as a mere risk and not a reality.

The recent case that happened before the summer of 2015 can be interpreted as a unique exception or as a preview of something that will inevitably arrived.

The anti-vaccination movement is not very relevant in our country in contrast to what happens, for example, in the United States, where there has been an increase of the rejection of vaccines in the last decades. That is why some studies highlight that, for example, in fifteen States the vaccination rate of MMR vaccine is below the 90 % population coverage. (EL AMIN et al, 2012)

In any case, it should be highlighted the fact that various countries have agreed to amend their legislation on vaccination (see California case after measles outbreak) or at least, they have started to debate about this issue (the case of The Bioethics Commission of Austria that decided to tackle the debate this Committee is discussing now).

3. Recognition of the right to protect the public health

The right to health protection is already proclaimed in Article 43.1 of our Constitution. However, this recognition has traditionally been underpinned in the struggle of curing diseases (healthcare aspect) in a more individual rather than collective domain. But, along with that objective, public health policies, for which the objective is not only to cure but also to prevent the disease, have begun for some time now—all that on the basis of the principle of comprehensive health care. Such idea is already included in Article 43.2 of the Constitution, when it states that it is the responsibility of the public authorities to organize and safeguard public health through preventive measures.

In the light of this, it can be concluded that the content of the right to protection of health is a two-pronged approach: on the one hand, it covers the field of the so called public health considering all the measures the State has to develop in order to preserve the health of its citizens; on the other hand, it comprises the actions to adopt in order to guarantee the health care that each citizen might need. In the first case, public authorities will primarily have the obligation to develop, it is, to develop effective policies to the protection of public health and the prevention of diseases. In the second case, they have the obligation to substantially give, it is, to make available to citizen health care resources to treat the disease.

Together with the constitutional provision, there are many other rules of procedure. Law 14/1986, of 25 April, General Health, enshrines in Article 3.1, as a

general principle of the system, the promotion of health and the prevention of diseases, and in Article 8, it considers the epidemiological necessary studies as a fundamental activity of the health system to more effectively guide the prevention of the health risks as well as the planning and evaluation of health. This should be based on an organised system of health information, surveillance and epidemiological action. Such provision is supplemented by the Law 16/2003 of 28 May, on the Cohesion and Quality of the National Health System, Article 11 of which includes public health benefits and, among those, the epidemiological information and surveillance, health protection, health promotion, disease prevention or monitoring and controlling possible health risks derived from the import, export or transfer of goods and the international passenger traffic, by the competent health administration.

It should be also added to those rules that the Organic Law 3/1986, of April 14th, on special measures related to public health (henceforth, Organic Law on special measures). This law contains a system of measures to adopt in situations of emergency or need for public health. Even though the law is extraordinarily frugal, it mentions the recognition, treatment, hospitalization and control measures.

Finally, we should mention the law 33/2011, of October 4th, on General Public Health. Such law constitutes an important novelty for our legal system and it satisfies a need demanded a long time ago including, more or less systematically, the regulation of public health. With this law, the citizens' right to health protection, as it enshrines the already mentioned Article 43, progresses towards its double purpose: health care and prevention.

In short, public health policies, in their modality of disease prevention policies, are one of the main challenges and achievements of medicine, and as such, they have been enshrined in our Constitution and in the laws designed to the development of the constitutional right to health protection as reflected in Article 43.

Furthermore, the Community legal order has already enshrined such policies of public health. In this regard, it can be seen Article 168 of the Treaty on the Functioning of the European Union, which provides that "*A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.*" Adding, after that "*Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental*

illness and diseases, and obviating sources of danger to physical and mental health.”

In similar terms, the Charter of Fundamental Rights of the European Union provides in its Article 35 that *“Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.”*

Moreover, this public objective of the promotion of the prevention policies has become more important and present as our healthcare system start to present financial problems because of the ever-increasing demand and the development of health technology. Therefore, it could be stated that the principle of distributive justice also operates in this field and it should be present in this debate. The autonomy that has largely prevailed at the bioethical debate needs to be refined not only in contexts in which the collective interest in its protection with the individual interest has to be met and combined, but, mainly, when health resources are more scarce and when the decision adopted by a citizen about health care (see, for example, rejecting a vaccine which may impede the development of a disease) affects the rest of the community.

Public health and diseases prevention constitute a constitutionally legitimate objective which can perfectly acts as the limit to the exercise of fundamental rights and, specially, to the right to refuse a medical treatment resulted from the right to physical integrity or indemnity as it has been recognized by our Constitutional Court, in its interpretation of Articles 15, 16 and 18 of the Constitution. In this regard, the General Health Law establishes in Article 11.1 that the citizens have the duty to comply with the general health-specific provisions, which are common to the whole population, as well as the specific provisions determined by the health services. In similar terms, Article 9.2 a) of the Law of patient autonomy provides that physicians shall be able to perform indispensable clinical operations in favour of the patients' health, with no need for the patient consent, when public health may be at risk due to health reasons established by the Law.

Moreover, the General Public Health Law states, in this regard, that citizens have the duty to collaborate in public health actions, in order to facilitate the development of such activities, and the duty to refrain from hampering, impeding or distorting its execution (Art.8).

4. The dual legal nature of public health

Public health presents, since the fundamental rights theory, a double dimension which endows it with a unique nature. On the one hand, public health can be configured as a real subjective right, whereby, citizens are provided with a series of benefits by public authorities. Those benefits are related to the right to health protection in a field that precedes and even transcend traditional healthcare welfare provision. Citizens would be able to demand public authorities an effective protection of their health which would be translated in the adoption of health surveillance and promotion, and disease prevention measures.

However, public health also transcends the individual rights and constitutes one of the main limits to individual rights, as an expression of the collective interest. In this way, we could state that public health comes from a real “right-duty”, so that the citizens would have the right to the protection of our health through the already mentioned actions of surveillance, promotion and prevention. But, at the same time, we have the legal duty to be subjected to those measures for the correct protection of public health as a collective interest.

Vaccines are an example of that dual dimension. Under the proclamation of the right to public health, citizens are provided with a provision right which basically involves access to vaccines recommended by the corresponding vaccination schedule, and, at the same time, they might also be subjected to the legal duty to properly vaccinate in order to avoid the spread of an epidemic to the detriment of the collective health.

As public health tools, immunization should function in the difficult balance between individual and collective interests as a limit of them. GOSTIN presents an interest definition of public health law that makes us realize that collective dimension: “Public health law is the study of the legal powers and duties of the State, in collaboration with its partners (e.g., industry, health care, business, media, the community, and academy), to assure the conditions for people to be healthy, and the limitations on the power of the state to constrain the autonomy, privacy, liberty, proprietary, or other legally protected interests of individuals for the common good.” (GOSTIN, 2007)

That second perspective of the concept of public health, as a duty that should limit personal freedom, is precisely the most complex legal aspect, and yet, it is not recognized in the General Law of Public Health, which mainly meets public health as a provision being based on the freedom of choice. If public health as a legal expression could be considered in the “right-duty” category, it does not seem very consistent that the General Law of Public Health had omitted the second dimension of public health as a limit. As the Supreme Court has highlighted, it is known that public health as such does not constitute a real biological entity, but a verbal form to point out a non-permitted danger in the social order. (STS 7-XI-2000)

It is true that such dimension requires a special care and it cannot be compared to the public health as a right, mainly because it means the adoption of rights constraining measures, among others. Nonetheless, that should not cause the ignorance that without those measures, public health policies are to a large extent, deprived of its efficiency. Public health not only means that public authorities are compelled to develop the obligation to give or act, but also to invest citizens with faculties in order to request specific behaviors in defense of collective health from them.

In general, a public health model should be founded, from a legal point of view, in a proportionate relationship between the freedom of citizens and the collective interests. Thus, in short, since the central issue, both legal and ethical, in public health is to answer the question of to what extent it is admissible the establishment and promotion of State policies that, while they may have beneficial effects on the population, they usually affect the rights and freedoms of individual citizens. There are two reasons that make the answer to this question especially complex:

First, due to the risk that may be, intentionally or not intentionally, entailed behind the public policies of public health. We are obviously referring to the very reasonable possibility that such policies could end up in real paternalist practices, in which the State, for the benefit of a fully able person, adopts a decision that infringe his or her liberty, or even worse, when behind those public policies there is the idea of confronting a specific morality.

Secondly, due to the multiplicity of conflicts of different nature that can arise under those public health policies. Therefore, a global solution is very difficult, since it

should address the rights and values in conflict in each case. Those cases cannot be compared to other cases in which a subject refuse to undergo a genetic diagnosis test to predictably determine his or her predisposition to develop certain disease in the future, and, thus, to take the preventive and therapeutic measures, with the different case of the parent rejection to vaccinate their underage children.

However, it is also true that a full respect of personal freedom without addressing the common good is not only considered inadmissible in a social model such as ours, which has already surpassed the classic concept of the liberal state, but also it opposes the fact that the principal objective that the law has is to ensure the health of the community.

5. Immunization as a public health policy

Within the public health policies, immunization is especially relevant. The administration of vaccines for the prevention of communicable diseases has become one of the greatest successes of public health history. This is not just because it is the most efficient measure to prevent individual from certain infections but also because it has allowed the control and almost eradication of diseases representing a serious health problem.

Our legal system ensures vaccination through two measures: health care provisions, and epidemiological surveillance. Regarding the first procedure, due to its importance in public health and preventive medicine, immunization constitutes an allowance at expenses of the National Health System. Thus, the Royal Decree 1030/2006, of 15 September, establishing the common services portfolio of the National Health System and the procedure for its update, recognizes in its paragraph 3.1 of Annex II, the following preventive activity provision: immunization of all age groups, and risk groups, according to the current immunization schedule approved by the Interterritorial Council of the National Health System and the competent healthcare administrations, as well as those vaccines that might be recommended to the population in general or to risk groups, by specific situations that may recommend it.

Furthermore, the National Network for Epidemiological Surveillance also constitutes one of the main measures as a part of the protection of public health and, especially, with regard to the provision of vaccination. On this respect, we need to consider that the public provision of vaccination has a double character: an ordinary

one, related to the vaccines recommended by the corresponding vaccination schedules, and also extraordinary, in relation to those alleged outbreaks of vaccine-preventable diseases.

Finally, immunization is subject to specific quality conditions established by Law 29/2006, of 26 July, on guarantees and rational use of medicines and health products, for the denominated special medications.

6. The absence of a legal immunization duty in our legal system

The main problem that immunization might pose in terms of their effectiveness as a public health policy is whether a legal duty to vaccinate exists or not in our legal system. The rules regulating immunization in our legal system, although recognizing its particular relevance in the field of public health and individual and collective (epidemic) prevention of diseases, they do not include a legally binding clause.

It is true that it does exist an already outdated rule, the law 22/1980, of 24 April, modifying the Framework IV of the Framework law on National Health, of 25 November 1944, in whose single article declares that vaccines against smallpox and diphtheria, and against typhoid and non-paratyphoid infections, could be declared mandatory by the government when, due to the existence of repeated cases of those diseases or by the current or predictable pandemic situation, it may be considered appropriate. Regarding the rest of infections that already had totally or partially successful vaccination recognized methods, which do not constitute a risk, they could be recommended and, where appropriate, imposed by the health authorities.

Legal effectiveness and operability of that law is debatable. This means that a specific decision of mandatory vaccination could rarely be founded in that law. We will not get into detail explaining the factors that determine that lack of legal effectiveness since they are technical legal issues that exceed the purpose of this report. Although we could summarize the problem in the fact that the General Health Law foresaw in its final disposition 5 that, that specific article should be subjected to, along with other rules of recasting, regularization, clarification, and harmonization within eighteen months, a mandate that, even after more than 30 years, has not yet been fulfilled. Indeed, that is not necessarily undermining the effectiveness of the law, but it does allow to state that its effectiveness is already nuanced, pending to fulfill the mandate

imposed by the legislator. Moreover, a public decision regarding mandatory vaccination falls within the scope of the rights and freedoms of citizens, an area specially protected since it affects the physical integrity, so that a law including such faculty should be adopted as organic law, a characteristic that the hasty Framework Law of National Health lacks of.

Furthermore, apart from the problems arising from its effectiveness to be used as a legal framework to a mandatory vaccination decision, the cited Law 22/1980, includes two cases where vaccination is supposed to be mandatory: on the one hand, epidemics (repeated cases or epidemic status), and on the other hand, systematic vaccination. Regarding this last possibility, the norm appears less forceful on the possibility to impose it mandatorily (they could be recommended and, where appropriate, imposed).

Therefore, the vaccination legal regime in Spain is voluntary, which leads to generate situations such as, for example, the refusal by a minor and/or his or her parents of specific vaccines. From the own General Health Law, it follows that such voluntary nature regarding Article 28 provides that all preventive measures must attend the preferential principles of voluntary cooperation with health authorities and of no risk to life.

Moreover, the General Law of Public Health does not include any provision regarding the obligatory nature of immunization. Previously, on the contrary, such Law was founded on the voluntary nature of immunization. Thus, although in the first drafts of such law was included that (see Article 12.6) the special measures concerning public health that are binding are exempted from the need of consent, in the finally passed text there is not mention of that issue. Only Article 5.2 states that without prejudice to the duty to collaborate, the participation in public health actions will be voluntary, except with the provisions laid down in Organic Law 3/1986, of 14 April, Special Measures concerning Public Health.

Moreover, it should be recalled that the mentioned General Law of Public Health was not passed as an organic law, although partially organic, so it would not be constitutionally admissible to include norms concerning measures that affect directly and substantially the fundamental rights of the relevance of the physical or

psychological integrity, or freedom of ideology or religion. The Spanish Constitution stipulates that fundamental rights can only be limited through organic law. However, the text of this law should have been more clearly expressed regarding the value of vaccines as a fundamental tool of public health policies, without prejudice to remit such stipulation, concerning fundamental rights and public liberties affected to the previously mentioned Organic Law of Special Measures.

The Law of Patient Autonomy is coherent with the other mentioned laws. In its Article 9.2 a) refers to public health as a limit to the capability to refuse treatment. However, such provision requires the prior existence of a legal norm explicitly authorizing the interference in a person's integrity when it mentions that the health reasons allowing it should be "established by law", along with, a specific mention to the Organic Law of Special Measures.

Along with the voluntary nature of immunization, and in line with that principle, our legal system only establishes a recommended children immunization schedule, elaborated by the Interterritorial Council of the National Health System and which determines which are the vaccines every children need to receive from birth through 16 years old. Such schedule is complemented with the different schedules approved by the Autonomous Communities (Regions?), under their organizational and planning competencies of public health. Therefore, since it is a mere recommendation, parents can decide not to immunize their children without breaching the related national law.

It is true that some regional laws regarding education require, to access scholar centers, to certify that they have comply with the immunization schedule of the Community (Region?). However, such precautions do not imply a mandatory vaccination clause, but the consequence of the failure to comply with it is the non-admission in the corresponding center instead of a disclaimer decision of forced vaccination. The Court of Justice that have confronted such debate have accepted the public requirement of immunize a minor.

In this respect, it can be seen the ruling of the Contentious-Administrative Chamber of the Cataluña Superior Court of Justice, of 28 March 2000, that declared, literally, that the cohabitation in a social and democratic state governed by the rule of law includes, not only the respect of fundamental rights at the individual level, but also

that their exercise do not impair the right of the rest of the society who is governed by behavior patterns serving the general interest. Therefore, there is no breach of the right to education, as it can be proven by minor admission to school, but there is a failure to comply with some obligations whose aim is the prevention of diseases. When translated into practice, those obligations require to prove the systematic immunization regarding the age, which explains the idea of obtaining a herd immunity that, in addition to protect from infection non-vaccinated individuals due to individual contraindications, allows the elimination of the disease in a specific geographic area, and even at the global level. This case was about the decision adopted by a School Commission to cancel the registration of a student whose parents had decided not to immunize her, being that a necessary requirement to enter the school. Regarding the same issue, it can also be seen the ruling of the Contentious-Administrative Chamber of the La Rioja Superior Court of Justice, of 2 April 2002, that declares, in similar terms, that nothing can impede an alternative option and nothing can impose a vaccination decidedly rejected...[although]...the legal authority of the Administration to impose such requirement to anyone that want to opted to the kindergarten services cannot be unknown, rejecting the admission of children that do not comply with it, since the preventive measure applied is recommended for the health of all the members of the group.

Unlike Spain, other countries, and among all, particularly the United States recognizes a mandatory vaccination law provision. Thus, since January 1998, all States have a legal system establishing mandatory vaccinations. Moreover, such vaccination model is controlled, with regard to minors, by the school, so that vaccination constitutes a necessary requirement to enter school (school-entry laws). In this sense, the school becomes a control tool used by the States in order to make parents comply with the immunization schedule.

This general regime is complemented by two exemptions to the mandatory immunization laws. The first one is that immunization is exempted for medical reasons, like the lack of immunocompetence, allergic background or the presence of certain underlying disease. In these cases, the exemption must be accompanied by the appropriate medical record. The second is the conscientious objection to mandatory vaccination for one reason or another. Forty-eight States allow religious exemptions,

and other eighteen allow ideological or philosophical reasons. In any case, States do not have any constitutional obligation to accept rejections not based on medical reasons. Moreover, another interesting fact is that vaccines are not free, not even when they are mandatory to enter school, but there are public programs which provides free vaccines for low-income families (Vaccines for Children Program).

Something similar to the issue of minors' immunization in Spain happens in the field of health professional immunization. It is either included in the General Law of Public Health, or in any other law, any express provision which allows imposition of immunization to health professionals. At least, this absence of the General Law of Public Health seems preferable than other provisions included in prior versions of the finally adopted legal text.

The occupational health laws neither include any provision allowing to impose immunization. Law 31/1995, on the Prevention of Occupational Risks, does not include anything on the matter, and the Royal Decree 664/1997, on the protection of workers from risks related to exposure to biological agents at work, only highlights that the corresponding vaccines should be made available to workers.

7. When can a mandatory immunization measure be adopted?

The lack of a specific compulsory clause does not impede that, in our legal system, individual or collective decisions of mandatory immunization can be adopted. In this line, there are sufficient mechanisms to make such a decision, although it is true that there is a certain legal vacuum regarding some of the issues where mandatory vaccination can be considered necessary.

First of all, it should be highlighted the legal system that establishes the Organic Law of Special Measures. This organic law gives, by itself, the necessary legal support to any measure adopted, as long as the rest of the constitutional requirements that lies under the authority that intends to affect the freedom and indemnity of a citizen are respected (specially, judicial intervention and the principle of proportionality).

Moreover, such regime is complemented by other provisions included in different norms. Among them, it can be highlighted the Law of Patient Autonomy that establishes, in Article 9, public health as an exemption to the right to reject a medical treatment undergone by a patient.

From the procedural point of view, the Law regulating the Contentious-Administrative Jurisdiction, in its Article 8.6, section two, assigns to the judges of that jurisdictional order the adoption of the corresponding measures: it will be up to the Judges of the Contentious-Administrative the judicial authorization or ratification for the measures that the health authorities consider urgent and necessary for public health and that imply the deprivation or restriction of freedom or of another fundamental right.

In any case, it is important to highlight that this legal regime that protects the collective health and that would allow to adopt a mandatory immunization measure is excessively disperse. It is a very scattered group and, at the same time, very heterogeneous, both by the meaning of the norms and by their legal status, and also, of course, by their historical framework, since they are rules created in very different times. The framework is, in conclusion, somewhat confusing.

Furthermore, another problem that presents such regulation is that it supports the adoption of those exceptional measures when there is a concurrence of an alleged case of urgency or health need (Article 1) —an undetermined legal concept that, although it fully fits with the compulsory immunization assumptions as a consequence of an epidemic, it does not seem as such with regard to other different cases, as the compulsory children vaccination provision provided in the corresponding immunization schedule (systematic immunization) or, even, the case of an outbreak. That means those cases in which vaccination does not pretend to undermine the effects of an already declared epidemic but to precisely avoid it to happen.

Therefore, it has to be distinguish between the compulsory immunization assumptions caused by the presence of an epidemic, that is, by a concrete risk for public health, from the assumptions that an immunization is needed to avoid, precisely, the potential risk of an epidemic (corresponding immunization schedule or outbreaks). And it is precisely here where the problem lies, since under the mandatory immunization regulation of our legal system there are two interpretations. A more stringent one, according to which, as we have been saying, it can only be adopted a mandatory immunization measure when it coincides the supposed cause of the epidemic. And a more flexible one that would also include other broader assumptions such as an outbreak, all of them, under the undetermined legal concept of urgency or health need. In any case, since they are measures that directly affect fundamental

rights such as physical integrity or liberty, it does not seem admissible to choose a flexible interpretation, not even when it concurs a collective interest of the constitutional relevance of the collective health.

Thus, it seems that our legal system has only established exceptional measures that would legally protect mandatory immunization in the first case and not in the second one.

In similar terms we can distinguish those cases in which there exists an effective risk to public health, this is, the healthcare of third parties, and those others in which the risk exclusively affects the own health of the individual concern. Therefore, albeit in the first case it could be accepted public decisions of mandatory vaccination due to the fact that it can exist a clear relation between, for example, the conditioned assistance to school and immunization, in order to avoid the transmission of an infectious disease in the school area. In the second case, such element is not present. This would be the case of the immunization against tetanus or human papillomavirus, in which there is not a risk-benefit relation between the health of the individual and the community.

Both in this last case of risk for the own health of the individual concerned, as in the previously commented one in which there is not an effective risk for the collective health, but a potential one (vaccines included in the systematic immunization schedule), mandatory immunization can only be justified by the provision in Article 9.2 of the Law of Patient Autonomy: a serious risk to human life or to the physical or physiological integrity of the subject, and the inability to make a decision since they are under-age. However, the enforcement of the Organic Law of Special Measures in these cases is not very well seen, due to the fact that the urgency or health need element does not concur.

Therefore, immunization in Spain is voluntary except in exceptional circumstances, such as an epidemic or, when a doubt, in outbreaks, in which there exist a legal mechanism to make it obligatory. Thus, this is proven, for example, by the judgment of the Chamber for Contentious-Administrative Proceedings of the National High Court of 29-IX-2010 when it affirms that apart from these cases (it refers to the mandatory immunization judgment regarding the individuals where it coexists a special relation of subjection —military and health professionals— or in very specific cases like

travels abroad prior the entry in Spain), it could be only justified as an extraordinary situation, covered by the Organic Law 3/1986 which exemptions the general principle of autonomy deducted from Article 10.9 General Health Law and Law 41/2002, of 14 November, not only about the patient, but as the citizen when is submitted to preventive treatment, in this case, an immunization.

8. Parental refusal of immunization

The case of the parental refusal to immunize their children presents an important nuance that allows, somewhat, to distinguish it from that of adults, usually, health professionals. The nuance comes from the fact that parents are adopting a decision in the exercise of their duty to protect their children, this means that it would be considered one of the cases designated by our legal system as a consent given to his or her representative (consent by representation). This determines that the decision-making capacity and, what interests us here, the treatment refusal (see, immunization) remains tempered.

Therefore, after the recent reform of Article 9 of the Law of the Patient Autonomy carried out by the Law 26/2015, of 28 July, on the modification of the system for the protection of children and adolescents, the cited precept provides in its section 6 that in the cases in which the consent must be given by the legal representative...the decision will be adopted according to the major benefit for the patient life or health, adding that those decisions that are contrary to those interests must be brought to the attention of the legal authority, directly or through the Public Prosecutor, in order to adopt the corresponding resolution, except that, by urgent reasons, it would not be possible to obtain the judicial authorization, in which case the health professionals would adopt the necessary measures to safeguard the life or health of the patient, protected by the justification causes of compliance with a duty, and the state of necessity. Then, section 7 provides that the provision of consent by representation would be adequate to the circumstances and proportioned to the necessities that must be attended, always for the benefit of the patient and respecting his or her personal dignity.

In the light of the legal framework of such recently incorporated law in our legal system that includes the criteria already foreseen by the Office of the Public Prosecutor in its Circular 1/2012 on substantive and procedural treatment of conflicts

regarding blood transfusion and other medical interventions of minors in case of serious risk, is highly questionable that a father would refuse to immunize his child when such treatment would mean a higher benefit for his or her life or health from a scientific point of view. Therefore, it can be claimed that after the approval of the new wording of Article 9.6 immunization can be provided even with the parental refusal. However, we should not consider the conflict resolved since other mechanisms should be promoted in order to avoid that such cases can be brought to justice, leading to a permanent conflict between health professionals and parents.

On the other hand, while the immunization coverage is still close to one hundred percent in the infant population, the so called *herd effect* might offset the effects on the collective health from the parental refusal to immunize their children. However, it cannot be either forgotten that if we legitimate that attitude, we might be precisely endangering the collective health since under certain coverage the risk of infection and even of an epidemic increases significantly. An option could be to exceptionally accept what it could be translated into a conscientious objection to a legal duty of immunization by ideological or religious reasons, and a very different one would be to claim that the parental refusal to immunize their children does not deserve a legal response, so that it has to be respected since there is not a real risk due to the current immunization coverage, when the generalization of such behavior would end up endangering the community. The affirmation that there is no need for a mandatory vaccination since there is a high immunization coverage lacks reliability.

9. Solutions to the social refusal of vaccines

The responses that the public policies and the law offer in relation to the promotion of the population vaccination are of different nature. Thus, according to the different models and experiences of the comparative law, such measures can be summarized as follows:

-Measures essentially based on the population education and information of the benefits of vaccines. Among such measures, those that allows the awareness of the population regarding the no elimination of certain diseases prevented just by immunization should be promoted. It is perceived that the population believes that certain diseases are eradicated when the truth is that those diseases are still existing but it does not have effects on people's health thanks to immunization efficiency. On

this regard, the greater the time distance is in relation to the epidemics that hit us some decades ago, greater has to be the effort of the public authorities to remind the importance of the immunization in the field of public health.

Some studies consider that within the education and information strategies, those that focus on informing the population about the high vaccination rate that we have been achieving in our country regarding to minors during the last years can be very effective , so that this can allow parents to be aware of the low risk of the negative effects and the benefits of the *herd effect*. (SERPELL et al, 2006)

In the same vein, it is important that the public authorities in coordination with scientific societies and professional groups develop strategies, procedures and techniques that allow the health professionals that are facing those parental refusals to immunize their children to confront and resolve them with legal certainty.

Moreover, in Australia children immunization is guaranteed by the combination of a voluntary clause with the prohibition of the children to go to school when they have a vaccine preventable disease, which force parents to request days of unpaid leave to the detriment of their wage income.

In other countries in Europe, such as Latvia, immunization is voluntary but parents need to sign an information document in which they assume the possible consequences that may derive from their decision, for both their children and for third parties.

-Measures based on mandatory vaccination models. This is the common situation for the majority of the countries in Eastern Europe, in some of which, the debate is not about questioning the obligation of immunization but the lack of universalization of such a provision that is not yet accessible to the whole population. Some studies consider that the foundation of mandatory vaccination in such countries that oppose the voluntary principle present in the majority of Western Europe lies in the idea that epidemics are still close in time, so that the population is yet very aware of the value that vaccines provide in the fight against an illness.

In countries such as the United States of America, the policies based on the information, promotion and incentives have been replaced over the last years by

coercive measures, according to which, parents are forced to vaccinate their children, and the health workers can be exposed to the loss of their job if they do not accept to be vaccinated, mainly, in certain healthcare areas where there is a higher infectious risk (emergency room, floor, operating room, etc.) Some authors highlight that traditional information and promotion vaccination policies are doomed to failure. (Lugo, 2007) Campaigns based exclusively on education or promotion are considered to provide minimal changes in the immunization rates, especially, in the field of health professionals, by requiring more studies measuring the results of the combination of different policies.

From a strictly ethical perspective, it has been noted a general principle that governs healthcare professions and that would inform in favor of the vaccination of such professionals, the principle of *primum non nocere* (no-harm).

Which of the described measures can be considered more adequate from a legal and ethical perspective?

Obviously, the principle of proportionality requires to adopt the less coercive measures when the goals to be achieved are the same (in legal terms, this refers to the subprinciple of necessity). Thus, from clearly coercive measures like mandatory vaccination, priority should be given to the promotion of information and incentive measures.

However, we believe that this does not detracts from the fact that a complete system of measures should not be legally created in our legal system in a way that the recourse of each one of them, bearing in mind to which extent they affect individual freedom, should be made in a proportional way, according to the circumstances of each case.

In this regard, the lack of a norm that allows to promote a public mandatory immunization measure outside the concrete cases of epidemics seems, *prima facie*, as a deficit of our legal system, especially, addressing the recent experiences of our neighbor countries, and, in some cases, those happened in our own territory. Therefore, it seems appropriate that along with the measures implementation of education, information and promotion of a people's favorable behavior regarding immunization as a main public health policy, it could be imposed, in specific cases,

mandatory vaccination, for example, when the immunization rate show a decrease so that the *herdeffect* could disappear without the need to wait for an epidemic or an outbreak to happen. The Nuffield Council on Bioethics (United Kingdom) in a 2007 report considered that there are two circumstances in which such measures could find a further justification: when they are serious and highly contagious diseases, and when eradication is possible with the adoption of the measure.

On the other hand, it would also be important to promote the principle of transparency in the field of immunization, and that the public authorities continue working with the support of scientific societies and professional groups in order to determine which the essential vaccines for the collective health really are, measuring with strictly objective criteria the risks and benefits, so that the decision is determined by scientific and public health criteria, excluding commercial, demagogic and opportunistic interests. Defining and establishing a unique immunization schedule without territorial differences, except for those specific cases with geographic or population needs, seems an indispensable measure to avoid that the differences and discussions among the Autonomous Communities (Regions?) are seen by the population as an expression of the absence of a truly scientific and undisputable criterion.

Moreover, it is also important to focus most of the efforts on the vaccination of health professionals. The principle of *primun non nocere* or of no-harm that govern the relationship between patient and health professional affirm that the refusal of those professionals does not seems acceptable from an ethical and legal perspective.

The promotion of the vaccination of those professionals should not be underpinned in merely organizational or professional performance criteria, but instead, in the already mentioned principle that the health professional, above all, cannot harm the patient, and by refusing immunization it can be stated that he or she is doing it since they are not taking simple measures to avoid it.

Together with those actions, public authorities should continue to work in other important measures such as the coordination of the immunization schedules of the Autonomous Communities (Regions?), avoiding alterations or divergences among them; the adoption of information mechanism to avoid health warnings not scientifically

founded regarding vaccines, which end up causing a social concern that only brings as a consequence the loss of confidence in the institutions responsible of Public Health; the respect and proper communication with those individuals and communities that refuse immunization due to religious, philosophical or ideological reasons warning them of the responsibilities they are taking; and the measures they could adopt in case of a probable and serious risk to public health.

In conclusion, through our report, more than giving solutions, which essentially corresponds to public authorities, our purpose is to give arguments for an indispensable debate to continue working on an effective protection of public health in Spain.

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