



ORIGINAL ARTICLE

Vaccination counselling: The meeting point is possible ☆,☆☆



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Abstract

Introduction: There are recommendations for decision-making as regards parents who do not vaccinate their children, but there are few publications analysing this problem. In November 2014, a pioneer medical clinic opened in Spain, for counselling on immunisation practices. The aim of this study is to determine the success of the recommendations of the American and Spanish Paediatrics Associations according to the number of parents who finally accept vaccination.

Patients and methods: A descriptive, cross-sectional, prospective and single-centre study was conducted from November 2014 to March 2016. Children under the age of 16 not properly vaccinated, according to the immunisation schedule of the region where the study was conducted, were included after signing informed consent.

Results: A total of 20 families were counselled. The median age of the children was 2 years, and 80% of them received no vaccine. Absolute non-acceptance of vaccination was practiced by 45% of parents. The main reasons for not vaccinating were: 100% thimerosal-containing, 90% risk of autism, 85% aluminium-containing, 70% presence of other stabilisers and preservatives, and 65% risk of anaphylaxis. The immunisation advice was said to be helpful by 90% of parents. Vaccination was accepted by 90% of parents (45% completely).

Conclusions: Anti-vaccination ideologies are strong and hard to change. Paediatricians not denying medical care to parents who endanger the lives of their own children are also hard to find. The meeting point is possible, and society needs it. Active listening, empathy, and good quality information were the keys to our results.

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PALABRAS CLAVE

Vacunas;
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 Niños

Consulta de asesoramiento en vacunas: el encuentro es posible**Resumen**

Introducción: Existen recomendaciones para la toma de decisiones ante padres que no vacunan a sus hijos, pero son escasas las publicaciones que analizan este problema. En noviembre de 2014, se inaugura una consulta pionera en España, sobre asesoramiento en vacunas. El objetivo principal es dedicar tiempo y exclusividad a los padres, aplicar las recomendaciones de la AAP y la AEP, y analizar el éxito de las mismas, según el número de padres que aceptan la vacunación. **Pacientes y métodos:** Estudio descriptivo, transversal, prospectivo y unicéntrico llevado a cabo en el periodo de noviembre de 2014 a marzo de 2016. Se incluyen menores de 16 años no correctamente vacunados según el calendario de la comunidad autónoma donde se realiza el estudio, tras la firma del consentimiento informado.

Resultados: Veinte familias acudieron a la consulta. La edad mediana de los niños fue de 2 años. El 80% no tenía ninguna vacuna administrada. El 45% de los padres mostró rechazo absoluto a la vacunación. Los principales motivos para no vacunar fueron: 100% presencia de mercurio, 90% riesgo de desarrollar autismo, 85% presencia de aluminio, 70% presencia de estabilizantes y conservantes, y 65% riesgo de desarrollar anafilaxia. Al 90% de los padres les pareció útil la consulta. Un 90% aceptaron la vacunación (45% completa).

Conclusiones: El convencimiento de la filosofía antivacunas es firme y difícil de cambiar. También es complicado que los pediatras no rechacen a los padres que ponen en riesgo la vida de sus hijos. El encuentro es posible y la sociedad lo necesita. Tiempo para escuchar, empatía y transmisión de buena información han constituido las claves de nuestros resultados.

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Introduction

Childhood immunisation is the most effective health prevention measure of all times. In the XXI century, this strategy could die of its own success. Some vaccine-preventable diseases are nearly eradicated, and this leads the population to believe that they no longer exist or to underestimate their risks.¹

The key milestone in the emergence of "anti-vaccine" movements dates from 1998, when the journal *The Lancet* published an article by Wakefield et al.² that associated the measles vaccine with the development of autism, among other diseases. Ten years later, once the General Medical Council of the United Kingdom had condemned Wakefield's research as unethical, barred him and revoked his license to practise medicine, *The Lancet*³ retracted the article. But the damage had been done.

In 2011, Grossman et al.⁴ published the results of a survey completed by 393 primary care paediatricians in 24 European countries. Of all respondents, 93% estimated that the total vaccine refusal rate was of less than 1%, and the partial refusal rate between 1% and 5%. In the United States, the estimated total refusal rate for the same year ranged between 6% and 8%.

In 2013, the American Academy of Paediatrics (AAP) stated its position⁵ regarding the approach that should be taken by paediatricians in response to parents that refuse vaccination for their children. It reaffirmed the position stated in a document published previously in 2005,⁶ changing the wording in order to promote a more active approach by paediatricians facing this challenge.

The AAP recommends^{6,7}:

- To listen to the concerns of parents carefully and respectfully.
- To keep in mind that vaccines are neither risk-free nor 100% effective.
- To clearly share the known benefits and risks of vaccines, as well as the risks of remaining unimmunised.
- To provide reliable sources of information.

There are instances in which refusal is based on issues that can be resolved. Each case must be addressed individually, and a solution sought.^{6,7} If in spite of adequate efforts the parents continue to refuse vaccination, the AAP advises that providers should respect the decision unless it places the child at substantial risk.

The position on this issue of the Ethics Committee of the Asociación Española de Pediatría (Spanish Paediatrics Association [AEP]) is the following⁸:

1. In the diverse society of today, it is only to be expected that parents will at times disagree with providers, and not only on the subject of vaccination, due to different views of what may be beneficial to children.
2. Respecting the autonomy of parents does not preclude attempts to discuss and persuade (whenever there is scientific evidence of the benefits of our recommendation, as is the case with vaccines) to foster attitudes and decisions that promote the health of children.

- It is essential that providers remain respectful and empathic and avoid confrontation to attempt to reach an agreement, promoting shared decision-making.

Despite the above recommendations, few nationwide studies have been published demonstrating the success of these recommendations.⁹ The beliefs underlying the "anti-vaccine" movement are deeply ingrained and difficult to change.⁹ It is almost as challenging as asking paediatricians not to refuse care to parents that put their children's lives at risk.

In November 2014, a tertiary care hospital developed a specialised vaccine counselling service, a pioneer initiative in Spain, to devote time and exclusive attention to parents that refuse to vaccinate their children and adhering to the current recommendations of the AAP and the AEP. This hospital-based service was designed to reinforce the excellent guidance work already conducted in primary care settings.

The main objective of the study was to analyse the success of the recommendations of the AAP and AEP based on the number of parents that accepted vaccination for their children following one or more counselling visits. The secondary objectives were to identify the different reasons for which parents choose not to vaccinate and to assess the sociological characteristics of these parents.

Patients and methods

We conducted a single-centre prospective cross-sectional descriptive study. The population under study were children aged less than 16 years with incomplete vaccination whose parents voluntarily requested an appointment with the counselling service. Patients were recruited from primary care centres, hospital paediatric emergency departments and through advertising posters distributed through the main cities and towns in the catchment area of our hospital.

Inclusion criteria:

- Children aged less than 16 years.
- Residents of the autonomous community where the study was conducted.
- Not vaccinated or with incomplete vaccination based on the immunisation schedule of the autonomous community where the study was conducted.
- Voluntary consent of parents to schedule an appointment to receive counselling regarding vaccines, during which vaccines themselves would not be administered, and which would provide no benefits to the paediatrician, child or family, save from any that might derive from the subsequent administration of vaccines, if it were to happen.

Exclusion criteria:

- Parents who sought counselling to supplement the well-child followup offered at their primary care centres.
- Parents who sought counselling to obtain vaccines that were not funded by the public health system for free.

Source of data in the study: data collection by questionnaire administered during the counselling session (Appendix 1), designed using Google Drive[®]. We decided to perform an initial cross section for the study at one year and four months from the opening of the counselling service.

The survey was conducted between November 1, 2014 and March 1, 2016, collecting data for the following variables:

- For children: sex, age and history of vaccine-preventable diseases.
- For parents: age, educational attainment, vaccination status, past negative personal experience with vaccination, main reasons for refusing vaccination for their children, sources of information and other sociological aspects that may be related to the refusal to vaccinate. At the end of the questionnaire, parents were asked whether they had found the counselling session helpful and whether they would accept or consider vaccination for their children. When they answered in the affirmative, they were advised to adhere to the accelerated catch-up schedule¹⁰ proposed by the Advisory Committee on Vaccines of the AEP.

Families were counselled regarding the advisability of administering the vaccines included in the official immunisation schedule of the autonomous community where the study was conducted. They were also advised to administer the vaccines that are not included in this schedule, with the suggestion that they follow the vaccination schedules recommended by the Advisory Committee on Vaccines of the AEP.¹¹

The descriptive analysis of the variables involved the calculation of relative frequencies using SPSS version 21.0. The principal investigator was the only person that had access to the data of the survey, which was conducted solely for the purpose of statistical analysis.

Results

In the first 16 months that counselling was provided, 20 families used the service. The median age of the parents was 31 years, and the median age of their children was 2 years.

Eighty percent of the children had not received any vaccines, 15% had received at least one vaccine, and one family only sought information about the human papillomavirus and the measles-mumps-rubella vaccines in relation to a daughter that was otherwise fully vaccinated. Two of the unvaccinated children had suffered a vaccine-preventable disease, which was pertussis in both. One of them required admission to the PICU for two weeks, in spite of which parents chose to continue refusing vaccination.

When it came to the parents, 100% reported having received all their vaccines as children. We chose to trust their reports without requesting their vaccination records for confirmation. Forty-five percent reported a total refusal to vaccines, 25% reported a refusal of most vaccines and another 25% refusing only a few vaccines, while a single family reported not refusing vaccines and only seeking to obtain information. Sixty-five percent of parents had a higher education degree (35% associate's degree, 25%

bachelor's degree, 5% doctorate degree), compared to 30% of those with a high school diploma and 5% that had completed primary education. None of the parents reported having no education.

Thirty percent of the parents reported having had a previous negative experience with vaccination that directly involved a family member. None of these experiences involved serious illness; they mostly consisted of episodes of transient hypotonia following the administration of vaccines and typical febrile seizures. When asked about negative experiences involving other acquaintances, the percentage rose to 70%. When it came to acquaintances, the parents did report four cases of autism, two of anaphylaxis, two of multiple sclerosis and one of chronic fatigue. The parents did not provide any medical documentation regarding these cases.

The sources from which parents that objected to vaccination reported obtaining information were the following: websites (75%), social networks (70%), friends (60%), associations (40%) and doctors (15%). The association mentioned most frequently was the Liga para la Libertad de la Vacunación (League for Freedom in Vaccination), followed by the Asociación de Afectadas por la Vacuna del Papiloma (Association of Patients Injured by the Papillomavirus Vaccine) and the Asociación Afectados por Vacunas (Association of Vaccine Injured Patients).

Table 1 presents the reasons reported for not vaccinating children. Table 2 summarises aspects related to the sociological profile of parents that are against vaccination.

Ninety percent of the parents found the counselling session of interest. The median time devoted to each family was of 30 min per visit, including the time spent completing the questionnaire. Forty percent made a single visit, another

Table 1 Reasons given by parents for refusing vaccination for their children.

- Presence of mercury in vaccines (100%)
- Fear that child may develop autism (90%)
- Presence of aluminium in vaccines (85%)
- Vaccines provide no benefits; the reduction in the incidence of certain infectious diseases is due exclusively to improvements in hygiene and sanitation measures (80%)
- Vaccines tamper with the immune systems of children, who need to suffer from certain diseases to gain a better natural protection (75%)
- Presence of preservatives and stabilisers in vaccines (70%)
- Fear of anaphylaxis (65%)
- Fear of the development of other neurologic diseases, such as multiple sclerosis, epilepsy, Guillain-Barré syndrome, encephalopathy, psychomotor delay, sleep disorders, language disorders or tics (65%)
- Generally speaking, vaccines are a business (60%)
- Objection to the mandatory measures enforced by governments, which does not apply to Spain, where vaccination is not compulsory (45%)
- Vaccines are a source of profit for paediatricians (25%)
- Fear of mild adverse events, such as fever or pain at the site of injection (10%)
- Religious reasons (0%)

Table 2 Sociological characteristics of parents that are against vaccination.

- Generally in favour of breastfeeding (100%)
- In favour of the use of homoeopathy in children (95%)
- In favour of prolonged breastfeeding, beyond age 24 months, for as long as the mother and child desire (90%)
- Subscribe to naturopathy (80%)
- In favour of using other types of nontraditional medicine in their children (75%)
- Follow nontraditional diets with the voluntary exclusion of specific foods from their children's diet (65%)
- Against the use of antibiotics (50%)

40% made two visits, 15% made three visits and one family more than three visits.

The final choices of parents were: 45% accepted all vaccinations, 40% accepted partial vaccination (of who 56% accepted all vaccines except the measles-mumps-rubella) and 10% decided to continue refusing vaccinations for their children—the same group of parents that did not find the session to be of interest.

Discussion

Parents that refuse vaccination are not acting frivolously or recklessly. Like any other parents, they just want what is best for their children, even if in this case, based on current scientific evidence, they are mistaken. The decision is not taken on a whim; these parents are highly informed individuals that took a long time deciding that not vaccinating was the best option for their children. The problem is that the information comes from sources of questionable scientific basis, and parents usually obtain it through the 2.0 world (Internet and social networks), where anti-vaccine activists move with extraordinary ease, whereas most health care professionals do not. This would be clear, simply by asking any collective of physicians what percentage of its members has an active Twitter profile.

A key aspect in this service is that the main principle of empathy is respect. If paediatricians respond to anti-vaccine families with anger, the parents will continue to refuse vaccination for their children. The goal is not to persuade or argue, but to vaccinate, and what must be pursued is protecting the health of the child. In fact, we should try to eliminate the "anti-vaccine" label, as most families find it derogatory and stigmatising. These families express that they have concerns about vaccination and have decided not to vaccinate their children, but may change their minds in the future.

There is sufficient scientific evidence and information to refute the arguments in support of not vaccinating¹²⁻¹⁶:

- More than 50 vaccines are currently marketed in Spain.^{17,18} The only one that contains thiomersal among its excipients (0.05 mg) is the LETI tetanus toxoid,¹⁹ whose marketing has been suspended.¹⁷ Therefore, the fact is that none of the vaccines currently available

and marketed in Spain contains mercury or any mercury derivatives.

- Some vaccines contain aluminium. It is used as an adjuvant in insignificant amounts, and it is necessary for the vaccine to be effective.^{12,14,16} Even breast milk in mothers that follow a normal diet and many other foods, such as fish, naturally contain larger amounts of aluminium.^{12,16}
- Improvements in hygiene and sanitation have indeed succeeded in reducing the incidence of some diseases. However, eradication is achieved by the systematic vaccination of an entire population.¹²
- No study has found evidence of a direct causal relationship between vaccination overall and the development of autism, sudden infant death, multiple sclerosis, leukaemia or any other severe diseases, especially neurologic ones. There will always be a temporal association with vaccines, but it is causality that needs to be established, and so far it has not.¹²⁻¹⁶
- The immunity generated by infection is stronger than passive immunity (vaccination) and more enduring. This is the case as long as the disease is overcome and does not result in sequelae. The greater protection conferred by immunisation by infection does not justify taking the risks associated with having a severe infectious disease.^{12,16}
- Vaccines require preservatives and stabilisers, as do many other medical and food products. Without them, products expire and become contaminated.^{12,16}
- The overall risk of anaphylaxis is of one case per one million administered doses.^{12,16,20} Furthermore, any other drugs, foods, cosmetic products etc. carry a risk of anaphylaxis.
- Anything in life can be made into a business, including vaccines, the anti-vaccine movement and homoeopathy.

There are significant contradictions in the attitudes of parents that object to vaccination. On the one hand, they refuse vaccines, drugs that have undergone numerous and rigorous randomised controlled clinical trials and have been subject to long periods of postmarketing surveillance without evidence of severe adverse effects after the administration of millions of doses. Yet, on the other, they approve of the use of homoeopathy in the paediatric population and administer these remedies to their children. These products, which are regulated by Law 29/2006 and Royal Decree 1345/2007 in Spain, can be obtained over the counter in any pharmacy, are not supported by any form of evidence as to their efficacy, have not been subjected to appropriate clinical trials and are not free of significant adverse effects.²¹

We need to devote time to these families, as most of them did not make the decision to refuse vaccination in a rash and irrational manner. Parents are not going to change their mind in a quick five-to-ten-minute visit. Just as we do with immigrant or adopted children, we must approach unvaccinated children as an opportunity for vaccination. One of the principles of the counselling service is "one vaccine is better than none," and "customised immunisation" must be offered. There should be no administrative or bureaucratic barriers to families that choose to vaccinate their children, even if they do not accept all of the vaccines.

We also need to explain that the anti-vaccine movement is an exclusively first-world trend. There are more than 18 million unvaccinated children, and only 0.1 million reside in developed countries.²² In regions of the world where an advanced health care system is not available, the choice to refuse vaccination is inconceivable.

We must inform parents of the risks that not vaccinating poses to the child as well as the population. The risks should be explained without alarming parents. Providers need to be assertive, and educate but not punish. If after counselling parents continue to not vaccinate their children, they have to accept the associated risks, and a possible option from the medical-legal perspective is to have them sign a vaccination refusal form.²³ For the time being, we have chosen not to use such a form in our service, as we feel that it may somehow detract from the rapport developed with the parents and we would not want to discourage them from returning for further counselling. Documenting the voluntary decision to refuse vaccination in the medical record is a sufficient measure for medical liability purposes.

Parents must also be made aware that when an unvaccinated child seeks care from a paediatrician, he or she may need to undergo additional tests or receive more aggressive treatments that would not be necessary if the child had been correctly vaccinated.

The main limitation of the study can be found in the recruitment phase, as the only parents that made counselling appointments were those that were willing to discuss vaccines or had concerns about them. This is a source of bias, as it is easier to counsel parents that have doubts than parents who are determined not to vaccinate. However, there was no way to eliminate this bias, as we cannot impose counselling any more than we can impose vaccination.

In fact, countries in which vaccination is compulsory have lower vaccination rates than countries like Spain^{8,11,16} in which vaccination is a free choice (except when outbreaks occur). A possible model to follow is that of Australia, where parents that choose not to vaccinate get smaller tax deductions per child,²⁴ and where vaccination rates are optimal. On the other hand, it would make sense to consider some type of disciplinary measures against doctors that openly oppose vaccination. This would seem like a logical consideration if any doctor were to recommend smoking to patients, as it would go against all scientific evidence and the ethical code. Any doctor that opposes vaccination is attacking the health of children and, more importantly, of the entire population. The medical licensing board of Barcelona recently suggested this approach,²⁵ although the proposal was subsequently rejected by the Organización Médica Colegial (Spanish Association of Medical Licensing Boards).²⁶

Families that choose not to vaccinate their children pose a challenge to paediatricians that must be met with strong determination. We have sufficient information to know how to approach this situation. As health care professionals we must keep a positive attitude, refraining from the unconstructive criticism in which we get caught up at times.¹ The pioneering counselling service presented in this article is a good example of this approach that has given satisfactory and promising results. This service can be replicated easily in other health care facilities. The beliefs of parents that choose not to vaccinate their children are firm and difficult to change. Taking the time to listen, respect, empathy,

patience and providing reliable information were the key factors that contributed to our results.

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Conflict of interest

The authors have no conflict of interest to declare.

Appendix 1. Survey conducted during vaccination counselling appointments

- Children:
 - Decimal age: blank field.
 - Sex: male/female.
 - Has your child been given any vaccines? None/only a few/all. If only a few, specify which.
 - Has your child suffered from any vaccine-preventable diseases? Yes/No. If applicable, specify.
- Parents: individual answers of the father/mother.
 - Profession: blank field.
 - Did you receive the childhood/adolescence vaccines? (Up to age 16 years): none/only a few/all. If only a few, specify which.
 - Educational attainment: no education/primary education/secondary education/associate's degree/bachelor's degree/doctorate.
 - To which degree do you refuse vaccination? Totally/nearly all vaccines/only some vaccines/I do not refuse vaccination. If applicable, specify which vaccines are refused.
 - ¿ Have you had any previous negative experiences with vaccines that involved a relative? Yes/no. If yes, specify.
 - Have you had any previous negative experiences with vaccines that involved an acquaintance other than a relative? Yes/no. If yes, specify.
 - Which types of sources do you usually obtain information on vaccines from? Choose as many as apply: websites/social networks/friends/associations/doctors. If applicable, specify which websites, associations and social networks you tend to consult.
 - Select which of the following reasons have led to your decision to not vaccinate your child:
 - Presence of mercury in vaccines.
 - Presence of aluminium in vaccines.
 - Presence of preservatives and stabilisers in vaccines.
 - Risk of developing autism.
 - Risk of developing other neurologic diseases (such as multiple sclerosis, epilepsy, Guillain-Barré syndrome, encephalopathies psychomotor delay, sleep disorders, language disorders or tics, among others).
 - Risk of severe allergic reaction (anaphylaxis).
 - Risk of mild adverse events, such as fever or pain at the site of injection.
 - Vaccines offer no benefits, the decrease in the incidence of certain infectious diseases is due exclusively

to the improvement of hygiene and sanitation measures.

- Vaccines tamper with the immune systems of children, who need to suffer from certain diseases to gain a better natural protection.
- Generally speaking, vaccines are a business.
- Vaccines are a source of profit for paediatricians.
- Objection to the mandatory measures enforced by some governments.
- Religious reasons.
- Other reasons (specify).
 - Note whether you approve of or object to the following treatments or types of diet:
 - Use of antibiotics for the treatment of infectious diseases.
 - Breastfeeding.
 - Prolonged breastfeeding (beyond age 2 years for as long as the mother and child desire, without limit).
 - Homoeopathy.
 - Naturopathy.
 - Other nontraditional medicine (specify).
 - Nontraditional diets (specify).

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