ISSN: 1676-4285

OBJN Online Brazilian Journal of Nursing
ENGLISH
Federal Fluminense University
AURORA DE AFONSO COSTA NURSING SCHOOL
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Original Articles

Effects of educative intervention on adverse events from the pentavalent vaccine: a quasi-experimental study

Francisca Agda Alexandre Porto[1], Allan Raniere Santos Silva[1], Lívia Maia Pascoal[1], Ismália Cassandra Costa Maia Dias[1], Leonardo Hunaldo dos Santos[1], Ana Cristina Pereira de Jesus Costa[1]

1 Maranhão Federal University

ABSTRACT

Aim: To evaluate the knowledge of mothers regarding adverse consequences from the pentavalent vaccination before and after they participated in an educative intervention. **Method:** This is a quasi-experimental study, with a before-and-after analysis, of a single group of 100 mothers of breastfeeding babies, from September to October 2014, in an outpatient clinic of a public maternity hospital in the municipality of Imperatriz, Brazil. **Results:** Following the intervention, a significant increase in understanding was observed among the study participants in all questions ($p<0.05$) regarding adverse events after the pentavalent vaccine. After the intervention, there was a significant increase of right answers to the questions: who to seek advice from after an adverse event due to the vaccine ($p=0.004$) and which adverse events from the pentavalent vaccine are known to mothers ($p=0.04$). **Conclusion:** The results indicate a positive change in the level of understanding of mothers regarding the adverse events after the pentavalent vaccination. The study provides a basis for the adoption of long-term intervention strategies for nurses.

Descriptors: Education in Health; Knowledge; Vaccines.

Porto FAA, Silva ARS, Pascoal LM, Dias ICCM, Santos LH, Costa ACPJ. Effects of educative intervention on adverse events from the pentavalent vaccine: a quasi-experimental study. Online braz j nurs [internet] 2016 Jun [cited year month day]; 15 (2):114-123. Available from: http://www.objnursing.uff.br/index.php/nursing/article/view/5296

INTRODUCTION

The use of educative interventions to bring awareness regarding post-vaccine adverse events (PVAE) in child care is little discussed and barely found in literature in the past years. According to the Brazilian Ministry of Health, a PVAE is any undesired clinical occurrence in an individual who has received any immunobiological agent[1].

Over the past decades, the PVAE and deaths related to the same nature were attributed to the immunological agents used, considering that no vaccine is completely free from provoking such results. However, the risks for serious implications caused by PVAE are low when compared to the risks of the illnesses that are immunopredictable[2].

The pentavalent vaccine is of a combined type, or, in other words, elaborated with the aim to reduce the number of injections, consolidating in one single vaccine the prevention against diphtheria, tetanus, whooping cough, meningitis by *Haemophilus influenza* type b and hepatitis B. Thus, it has a higher number of antigens capable of stimulating the immunological response against more than one infectious agent and it is therefore able to generate many PVAE at the same time[3-4].

Among the countless roles attributed to nurses, the handling and administration of immunobiological agents are two of the main ones; therefore, the information that is provided by the professionals represents an important link in the prevention and control of PVAE, in particular with regard to the pentavalent vaccine. Nurses have the role of educators, promoting health education in the most adequate environment for such a task. As family educators as well, nurses must collaborate and participate actively in the process of teaching and learning, to make it as effective as possible[4].

By the time the nurse understands the importance of this dialectical relationship between him/herself and the mothers of breastfeeding children, the necessity to implement health educative interventions becomes an everyday practice, contributing to the process of communication, dialogue and empowerment[5].

Publications regarding the implementation of educative interventions by nurses that discuss mothers' awareness of PVAE of pentavalent vaccines are rare in literature[3,5]. Therefore, the inclusion of these tasks in the everyday routines of nurses must assist mothers to become co-participants in the process of health construction of their children; moreover, it also needs to become a new habit for the professional aiming to promote children's health.

Whenever possible, interventions enable the sharing of knowledge that can avoid and/or minimize the events of PVAE in children's organisms[6]. The lack of awareness regarding these events can contribute to parents wrongly blaming the nursing professionals for episodes of PVAE. Hence, the lack of knowledge can lead to parents not taking their children to vaccination campaigns, directly compromising the support of child health[3].

With the intention to amplify the coverage of information regarding PVAE of the mentioned vaccine over the primary care network, the objective of this study is to analyze the understanding of mothers regarding adverse events after the application of the pentavalent vaccine before and after an educative intervention. In this context, the authors believe this research will identify some gaps related to the promotion of the knowledge of PVAE in the pentavalent vaccine and that it will generate other interventions for all those involved in child care.

METHOD

This study has a quasi-experimental approach, with a single group type and before-and--after analysis. It is self-controlled, in that each participant is the control element of him/herself. In this research, a control group is not necessary, as the application of instruments was used in a short period of time, reducing to zero any possibility of learning regarding the analyzed topic without the intervention.

The research was performed between September and October 2014, in the outpatient clinic of a public maternity hospital in the municipality of Imperatriz, Brazil. The hospital is a reference model in mother-child care and provides support to the population of the municipality and the other 42 cities that belong to the macro-region of Imperatriz, plus some additional cities that belong to the neighboring states of Pará and Tocantins. The immunization service of the maternity hospital is performed daily by three nursing technicians, under the supervision of a nurse, providing assistance to pregnant mothers and children, from newborns to 10 years old.

The studied population was composed of breastfeeding mothers who arrived in the outpatient clinic to vaccinate their children with the pentavalent immunization shot. The sample was chosen according to convenience, comprising 100 mothers who were searching for the mentioned service during the period of data collection and who matched the following criteria for inclusion: breastfeeding mother who searched for the outpatient clinic of the public maternity hospital to immunize her children without previous pentavalent vaccines; and participating in all stages of investigation of this research. One mother was excluded from the study because she was illiterate and a second was excluded due to mental limitations. None of the mothers objected to participating in the study.

The main objective of the intervention was to promote understanding regarding PVAE of the pentavalent vaccine. During the entire period of intervention, information regarding the topic was shared using a flip chart.

The flip chart, called "Knowledge regarding adverse events from pentavalent vaccine", was designed by the nurses responsible for educative interventions, based on the information present on the technical notes of the pentavalent vaccine. This information was provided by the Brazilian Ministry of Health[2]. The intervention took place only once for all present mothers of each group investigated. Its subject matter was composed of seven illustrated script cards, with a total of 17 pages:

1) What the pentavalent vaccine is for;
2) Illnesses that the vaccine protects against;
3) The potential adverse events post-vaccination;
4) Caring practices to avoid or reduce the adverse events from the pentavalent vaccine;
5) Guidelines regarding the use or the avoidance of antipyretic drugs after the vaccination;
6) Who should be informed in the case that the child presents an adverse event post--vaccination;
7) Importance of the complete vaccine scheme to immunize the child.

The research was performed by two research nurses in three stages: first, the application of a pre-test questionnaire, which analyzed social and demographical variables and other knowledge related to PVAE of the pentavalent vaccine before mothers participated in the intervention; second, the educative intervention using a flip chart, performed by two research nurses in a room where the immunization screening took place. The intervention occurred once a week, in a total of five sessions of 20 minutes each, for eight weeks. Sessions were conducted in groups of

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10 to 12 participants, placed randomly in those groups. The third and last stage was the use of a post-test questionnaire, composed of the same questions as the pre-test questionnaire, related to the variables of understanding of PVAE of the pentavalent vaccine. After the data were collected, the mothers were taken to vaccinate their children.

The data were organized in a Microsoft Office Excel spreadsheet and then analyzed using SAS® software. It was considered a complete causal experiment to evaluate the knowledge observed in pre- and post-test samples produced by the mothers, regarding their understanding of PVAE of the pentavalent vaccine on those two occasions. As there were discrete quantitative variables, the criteria was used based on the mentioned variables using a non-parametric test of Wilcoxon Pareado, with a level of significance of 5%. The general understanding of mothers was also analyzed (before and after the intervention) using the McNemar Chi-Square Test, comparing the results before and after. In addition, the odds ratio was calculated, based on a confidence interval of 95%.

The study was approved by the Committee of Ethics of Maranhão Federal University, under protocol #1.073.645, authorized by the participants by their signature of the Free and Clear Consent Agreement and by the place of research, according to the Brazilian Ministry of Health/ Brazilian National Health Council #466/12.

RESULTS

This study evaluates the effect of an educative intervention focused on the understanding of adverse events from the pentavalent vaccine. In order to evaluate this enquiry, 100 mothers were interviewed. They were between 19 and 24 years old, married (74%) and with 12 years of schooling (High School diploma; 69%). With regard to the number of children, 63% reported that they only have one child.

Table 1 presents the distribution of questions related to the interviewees' correct answers before and after the intervention. The average percentages of correct answers before and after the educative intervention were, respectively, 66% ± 15.97 and 87.1% ± 16.05. After the intervention, the participants' awareness regarding PVAE of the pentavalent vaccine at the place where the intervention occurred improved significantly ($p<0.001$).

The results of the Wilcoxon test demonstrated a significant difference in the scores before and after the intervention for the questions: *"who to seek help from after an adverse event"* ($p=0.004$) and "*known adverse events"* ($p=0.04$).

After the educative intervention, the largest differences about the knowledge of PVAE from the pentavalent vaccine were *"what is an adverse event post-vaccination"* (from 19.0% to 78.0%) and *"objective and goal of the pentavalent vaccine"* (from 45% to 88%).

It is important to mention that, before the educative intervention, none of the participating mothers mentioned that they used additional care practices after the pentavalent vaccine. On the other hand, after the educative intervention, 20% of the mothers referred to the application of cold water showers and pads in the place where the vaccine was applied, as well as the increased ingestion of water and breastmilk, as additional care that must be implemented after the pentavalent vaccine.

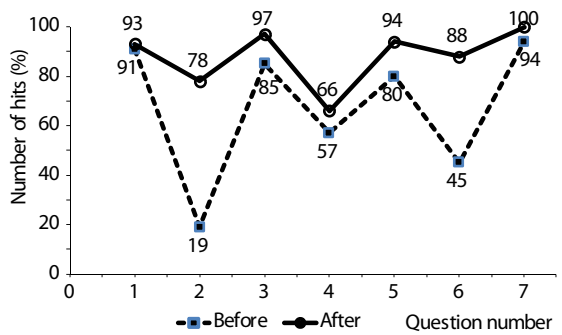
When evaluating the knowledge shown by the mothers before and after the educative intervention, it is possible to observe an increase, in percentage levels, in the knowledge regarding the topic, when compared to the stage before the intervention (Image 1).

Tabla 1 - Distribución de las cuestiones por cierto, relacionadas al conocimiento de las entrevistadas antes y despues después de la intervención educativa (n=100). Imperatriz, 2014.

		n (%)	Valor de p1		Odds Ratio (IC 95%)
Q1.Efecto de las vacunas	Antes	91 (91%)	0,72	Ref	1
	Después	93 (93%)		1,67	(0,324 – 10,73)
Q2.Que es evento adverso después de la vacuna	Antes	19(19%)	<0,001	*	*
	Después	78(78%)		*	*
Q3.Medicamentos antes de la vacuna	Antes	85(85%)	0,003	Ref	1
	Después	97(97%)		13	(1,95 – 552,47)
Q4.Cuidados después vacunar	Antes	57(57%)	0,12	Ref	1
	Después	66(66%)		2	(0,85 – 5,05)
Q5.A quién dirigirse después del evento adverso	Antes	80/(80%)	0,004	Ref	1
	Después	94/(94%)		5,67	(1,64 - 30,18)
Q6.Finalidad de la vacuna pentavalente	Antes	45(45%)	<0,001	Ref	1
	Después	88(88%)		44	(7,50 – 1.776,90)
Q7.Eventos adversos conocidos	Antes	94(94%)	0,04	*	*
	Después	100(100%)		*	*
General	Antes	471 (66%)	Ref	1,00	
	después	616 (87,4%)	(5,77- 16,76)		

*Fuente: Primaria. Notas:1Valores de p≤0,05, o número de aciertos antes y después difieren significativamente. *EL odds proporcional y su intervalo de confianza no pudieron ser calculados, pues uno o más valores fueron iguales a cero.*

Image 1 - Percentage distribution of correct answers regarding the knowledge of adverse events from pentavalent vaccine, before and after educative intervention. Imperatriz, Brazil, 2014.



DISCUSSION

The main results of this study lead to the hypothesis that the intervention used is a productive strategy to increase the awareness of mothers regarding PVAE of the pentavalent vaccine. The increased knowledge was consistent during the post-test stage, with a significant difference, which indicates that the change produced through intervention is clearly relevant.

The analysis performed before the educative intervention revealed that many adequate aspects of the knowledge were present. The participants already knew the importance and advantages of vaccination for children's health, but they lacked enough background information regarding the adverse events and the post pentavalent vaccine care procedures.

One study[7] suggests that the increased knowledge shown in the results of interventions is related to the use of learning tools. In this context, the use of a flip chart for short-term educative purposes can contribute to the debate on the topic being studied.

Considering the results found after the educative intervention, the use of the flip chart, with information related to the pentavalent vaccine, can be considered as a facilitating and collaborative mechanism to increase the understanding measured in the post-test stage in all questions

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raised. Similar to this present study, an investigation performed in the Brazilian state of Ceará used a flip chart to increase the self-efficacy of mothers during breastfeeding. The results showed that, after the educative intervention, there was a significant increase in the average scores (p=0.002) of the knowledge regarding breastfeeding[8]. Another research demonstrated an increase in knowledge from 47.1% to 98% in the level of understanding, attitude and practice of consumption of regional foods by relatives of pre-school children after the use of a flip chart in an educative intervention[9].

Some other studies point out that all resources used to sensitize must be offered to encourage children to use health services in general, with child immunization fundamental to promoting health and suppressing immuno--preventable illnesses[10-11].

Immunization has significantly changed the way illnesses operate, as it has permitted an accentuated decrease in morbidity and mortality from avoidable infectious diseases[12].

Despite the fact that it is considered a low--cost strategy with high effectivity in guaranteeing the promotion and protection of health, there are still children who are not included in this strategy of promotion of health.

When verifying the results of studies regarding the immunization of children, the main reasons demonstrated for not vaccinating a child are a lack of awareness of the vaccination calendar by the parents, unease related to the components of the vaccine and fear of adverse events and countereffects from vaccines[13].

In agreement with these results, evidence shows that it is essential to share information about vaccines as, although they are considered safe and generate beneficial effects in controlling illnesses, they can also spark a series of adverse events that can vary from light to severe, from expected to unusual[3]. Adding to this inference, the result of a study about the prevalence of late vaccination of children demonstrated that 63.5% of the children who were not immunized had parents who were unaware of the possible adverse events from this practice[10].

Some factors contribute to the lack of knowledge regarding vaccines and their possible adverse events, associated with a low level of schooling and a lack of adequate information[14].

Considering that the pentavalent vaccine was recently added to the calendar of child immunization in Brazil, there is some resistance from parents to its use, due to the existing PVAE. Conclusive studies by the Brazilian Ministry of Health show that, despite the pentavalent vaccine being considered safe and carrying a high level of immunogenicity against the component antigens, it can lead to uncomfortable PVAE in children[2,15-16].

In particular during the breastfeeding stage (from newborn to two years old), the adverse events are potentially important, possibly due to the immunological immaturity of the child and the very large number of vaccines required by the Brazilian National Immunization Program (PNI, in Portuguese) during this stage[1].

Research has demonstrated that PVAE can occur systematically or locally and are classified according to their intensity as severe, moderate, or light[11,15]. The adverse events of the pentavalent vaccine can be systemic, generating irritability, fever, persistent crying, drowsiness, febrile seizures, hypotonic episodes, allergic reactions and reactions in the vaccine injection site, such as intense pain, redness, heat, swelling, induration and skin rash[2].

The effects of the pentavalent vaccine usually generate countless PVAE of low intensity during the first 48 hours after the injection of the immunological agent. In the initial stage most of the children have irritability and fever. This can last from some minutes to a day or more[11].

A study performed on 306 children in India found that the most common PVAE after the administration of the pentavalent vaccine were pain, redness, fever and constant crying[15].

Studies performed to evaluate the prevalence of PVAE found that a higher frequency of hyperesthesia or sensibility was demonstrated after a pentavalent vaccine; the most common adverse event found was skin rash[17,18]. Therefore, the information shared with the mothers of the present study regarding these PVAE is fundamental to demystify any doubt or cause that is related to the pentavalent vaccine.

Research produced by the Brazilian Ministry of Health indicates that low to moderate fever can be frequent in up to 58.8% of children who receive the pentavalent vaccine. It is observed that, most commonly on the first dose, high fever is present in up to 1.75% of children[1].

The fact is that, when recognizing the main post pentavalent vaccine PVAE, the mother will be able to act accordingly regarding the care and the attention to be given to the child whenever necessary. Consistent with the previous data, some further clinical studies have demonstrated some of the post pentavalent vaccine PVAE: local reactions, fever > 39.5ºC (around 103ºF), febrile seizures, hypotonic-hyporesponsive syndrome, thrombocytopenic purpura, headache, difficulty in walking, hypersensitivity reaction for up to two hours, generalized rash and urticaria[15,17,19], requiring both palliative care and specialized support from health professionals.

It is important to highlight as a potentially serious PVAE after the pentavalent vaccine the events of convulsion, hypotonic-hyporesponsive episode, acute encephalopathy and anaphylactic shock history after previous administration of the vaccine[1]. A hypotonic--hyporesponsive episode is usually related to diet allergies to components of the vaccine formula. It is necessary to mention that all PVAE of the pentavalent vaccine with a high level of severity must be communicated within the first 24 hours, from the local to the national authority, according to the flux of information described in the PNI[2].

According to the Brazilian Ministry of Health, when learning about PVAE of the pentavalent vaccine, it is possible that some precautions can be taken in order to prevent and/or minimize the PVAE[1].

Local events, such as red skin, heat, induration, edemas followed by/not followed by pain, which can be few, intense and restricted to the place of the vaccine application, can be common after the pentavalent vaccine; therefore, it is recommended to use symptomatic treatment with analgesics whenever necessary and cold pads during the first 24 hours, up to 48 hours[18].

Based on the observed events, it is fundamental to make adequate information available to the parents regarding such events, in particular because it is the nurse's responsibility to administer the vaccine and to notify PVAE of all vaccines. The information provided at the time of vaccination, such as the reason for vaccination, possible adverse events and post-vaccine care, are one of the main elements in the continuation of the process of child immunization. This inference is consistent with scientific literature, in that it signals that the promotion of health considers education as a fundamental instrument for intervention[17,19]. As a consequence, it is essential for the nurse to assume the role of educator in his/her nursing care and then to understand the importance of the communicative process in all tasks he/she is involved with[4,20].

Many studies demonstrate the importance of the use of educative interventions to promote knowledge regarding health care in childhood in topics such as health nutrition[7], personal hygiene and prevention of

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helminthiasis[13] and empowerment over one's health[5], among others. It then becomes imperative to include in the core of the nursing practices the interventions that will increase the understanding of child caregivers about PVAE.

The dialogue about health between the professionals and the caregivers during educative interventions is an important instrument for the education in health programs, in particular when using scientific evidence and appropriate tools and strategies to reach the targeted audience[4,20]. As a consequence, the educative process must be built into all childcare practices and, specifically, it must involve the entire family in its context.

Promoting child health must include care roles by professionals and by the family, in a mutual learning process[9]. The educative interventions are an essential part of care, unifying scientific knowledge with the everyday experience of the individuals, allowing them to be more critical, more participative, more autonomous and empowering them with their own health care practices on an everyday basis[11].

This study presents limitations, in terms of its reduced number of results produced and that are related to the strategies to increase the understanding of the topic of PVAE. The small amount of research on the topic presents information regarding the epidemiological survey and the vaccine components. Therefore, it is recommended that further studies take place, including in their scope the effects of intervention with different educative tools, as well as subsequent follow-up to the intervention and the sharing of information, a higher number of participants and a long-term evaluation of the changes in preventive care. Furthermore, it is suggested that other subjects are included, such as fathers, nannies, grandparents and other child caregivers, with intervention techniques that involve a larger number of caregivers.

CONCLUSION

There was an increase in the level of understanding of mothers regarding the adverse events from the pentavalent vaccine after the educative intervention used in this study.

It is believed that the educative tool used in the intervention helped to facilitate the discussion regarding the topic among the participants. It was also suggested that a subsequent validation of the content and the results found should be carried out, for use in future investigations, as well as an evaluation after various time frames, to identify if the knowledge acquired is kept through time.

Furthermore, it is fundamental to train the various health professionals, including nurses, to work and share information regarding this topic, in particular with child caregivers, and to evaluate the effects not only regarding their knowledge, but also in their change of behavior related to child care.

The results of this study reaffirm the necessity to perform educative interventions that increase the awareness of mothers of adverse events from the pentavalent vaccine, as, when they are well planned and implemented, there is a large beneficial effect upon the subject who acquires that knowledge, influencing the conduct and behavior of his/her health and that of his/her family members.

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All authors participated in the phases of this publication in one or more of the following steps, in According to the recommendations of the International Committee of Medical Journal Editors (ICMJE, 2013): (a) substantial involvement in the planning or preparation of the manuscript or in the collection, analysis or interpretation of data; (b) preparation of the manuscript or conducting critical revision of intellectual content; (c) approval of the versión submitted of this manuscript. All authors declare for the appropriate purposes that the responsibilities related to all aspects of the manuscript submitted to OBJN are yours. They ensure that issues related to the accuracy or integrity of any part of the article were properly investigated and resolved. Therefore, they exempt the OBJN of any participation whatsoever in any imbroglios concerning the content under consideration. All authors declare that they have no conflict of interest of financial or personal nature concerning this manuscript which may influence the writing and/or interpretation of the findings. This statement has been digitally signed by all authors as recommended by the ICMJE, whose model is available in http://www.objnursing.uff.br/normas/DUDE_eng_13-06-2013.pdf

Financial support: Fund for the Support to Scientific Research and Development of Maranhão (FAPEMA)

Received: 08/20/2015
Revised: 04/28/2016
Approved: 04/28/2016