The popularity of the 5- and 6-component combination vaccines among infants' parents in a selected Primary Health Care Clinic

Popularityść pięcio- i szcześcioskładnikowych wysokoskojarzonych szczepionek wśród rodziców niemowląt w wybranej placówce Podstawowej Opieki Zdrowotnej

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Abstract

Introduction. Vaccination, one of the highest achievements of medicine, has contributed to a significant reduction of infectious diseases. According to the current vaccination calendar in Poland, parents have the possibility to choose a free cost classic (DTP, polio, HBV) or non-refundable 5- or 6-component combination vaccine.

Objective. The aim of the study was to assess the popularity of the 5- and 6-component combination vaccines in years 2010–2019 among infants' parents starting a mandatory series of vaccination in a selected Primary Health Care Clinic.

Materials and method. The study was conducted at the Med-All Medical Centre in Kraków which provided a Protective Vaccination Programme including 1,108 immunization cards of children born between 2010–2019, most of whom (98.5%) lived in Kraków. Analysis of medical records was used in the retrospective ecological study; data analysis by MS Excel (Microsoft) and PQStat Soft. Significance level was set at p<0.05.

Results. From 2010–2016, the 5-component combination vaccine was the most popular choice by parents for their infants. During the study period, use of the 5-component combination vaccine decreased (p=0.017). From 2017, the 6-component vaccine was the most popular, and its usage increased with time, with a strong statistically significance (p=0.005). However, in 2019, there occurred the biggest percentage of unvaccinated infants.

Conclusions. Despite the costs, in 2010–2016, the most popular vaccine for infants was the 5-component high-combination vaccine. Since 2017, the 6-component vaccine has gained the greatest popularity.

Key words

infant, vaccination calendar, 5-component combination vaccine, 6-component combination vaccine

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Streszczenie

Wprowadzenie i cel pracy. Zdobycz medycyny, jaką są szczepienia ochronne, przyczyniła się do ograniczenia występowania chorób zakaźnych. Aktualny kalendarz szczepień przewiduje możliwość zdecydowania przez rodziców o programie szczepień dla ich dziecka. Wybór może zostać dokonany między refundowanymi szczepionkami klasycznymi (DTP, polio, HBV), a pełnopłatną 5- lub 6-składnikową szczepionkę wysokoskojarzoną. Celem badań było zbadanie popularności 5- i 6-walentnej wysokoskojarzonej szczepionki na przestrzeni lat 2010–2019 wśród rodziców niemowląt rozpoczęwających cykl obowiązkowych szczepień ochronnych na przykładzie wybranej placówki Podstawowej Opieki Zdrowotnej.

Materiał i metody. Badanie przeprowadzono w centrum medycznym All-med w Krakowie, realizującym Pogram Szczepeń Ochronnych. Przeanalizowano 1108 kart uodpornienia dzieci urodzonych w latach 2010–2019. Do zrealizowania retrospektywnego badania ekologicznego użyto metody analizy dokumentacji medycznej. Analizę statystyczną przeprowadzono z wykorzystaniem programów MS Excel (Microsoft) oraz PQStat Soft. Przyjęto poziom istotności statystycznej p<0.05.

 Wyniki. Od 2010 do 2016 roku szczepionką najczęściej wybieraną dla niemowląt była 5-składnikowa szczepionka wysokoskojarzona. W badanym okresie stosowanie 5-składnikowej szczepionki zmniejszyło się wraz z upływem lat (p=0,017). Od 2017 roku najpopularniejszą szczepionką była 6-składnikowa szczepionka wysokoskojarzona, a jej użycie wzrosło z biegiem lat, przy czym odnotowano silną zależność statystyczną (p=0,005). W 2019 roku odsetek nieszczyplionych niemowląt był najwyższy.

Wnioski. Na przestrzeni lat 2010–2016, pomimo konieczności poniesienia kosztów przez rodziców niemowląt, szczepionkę dla niemowląt najczęściej wybieraną przez rodziców była 5-składnikowa szczepionka wysokoskojarzona. Od 2017 roku większą popularność zyskiwała szczepionka 6-składnikowa.

Słowa kluczowe

niemowlę, kalendarz szczepień, 5-walentna szczepionka wysokoskojarzona, 6-walentna szczepionka wysokoskojarzona
INTRODUCTION

Vaccination is one of the greatest achievements of medicine and has undeniably contributed to a significant reduction in deaths caused by infectious diseases. Most countries introduced compulsory preventive vaccination programmes against diseases which for years had been decimating the population. Vaccinations show a dual protective effect – for the individual and the health of the population [1, 2]. Individual protection refers to preventing morbidity and reducing complications. The effect on the whole population is related to the stopping of potential transmission of the disease to other members of the population who are more susceptible to this kind of pathogen. An optimal population resistance is reached when about 90.0% of the population is vaccinated against certain diseases [1, 2].

The possibility for parents to choose different types of vaccines depends on the moment of licensing the vaccine, which is related to making it available for sale. For 5-component vaccines, an example of a marketing approval year is 2001 for Infanrix IPV + Hib and 2003 for Pentaxim. Marketing approval for 6-in-1 vaccines was started in 2012 for Hexaxim [3], 2013 for Hexacima [4] and Hexyon [5], and in 2016, marketing approval was granted for Vaxelis [6]. In the first years after the start of distribution, during the study period there arose problems with the availability of multi-component vaccines. Producers delivered them first to countries where they had concluded government agreements, and in consequence, combined vaccines did not reach Poland until the second round.

According to the current vaccination calendar, which sets the rules for immunizing children in Poland, vaccinations against the following diseases are mandatory: tuberculosis, hepatitis B, diphtheria, tetanus, pertussis, acute common paralysis (poliomyelitis), haemophilus influenzae, pneumococcus, measles, mumps and rubella. The first vaccination has to be given in the hospital during the first days of life of the infant. After the 6th week of life, the parents have to decide about their choice of vaccination programme for their child in Primary Health Care Clinic. The choice can be made between the standard vaccines (DTP, polio, HBV) and a 5- or 6-component combination vaccine. Multi-component vaccines contain antigens of: diphtheria, tetanus, pertussis, polio, haemophilus influenzae, and additionally recombinant HBV antigens in a 6-component vaccine [7, 8]. The combination vaccine programme is presented in the vaccination calendar as an alternative scheme (Tab. 1).

The most important advantages of using the 5- or 6-component products are:
– a smaller number of injections, in the case of using a 5-component vaccine the number of injections decreases by 7, and for a 6-component vaccine by 9 [9];
– lower risk of infection due to the significantly smaller number of injections needed;
– smaller quantities of preservatives in smaller volume [8];
– elimination of the thiomersal, an organomercury compound, which is controversial due to its potential damage to health [10];
– lower risk of adverse post-vaccination reactions associated with the pertussis component.

High combination vaccines contain between 1–5 pertussis antigens instead of whole killed bacteria, as in the DTP vaccine [8, 11]. Despite the advantages, the greatest deterrent to using combination vaccines seems to be their price. In Poland, the cost is not refundable by the State [10]. For this reason, parents have to choose between a free of charge programme, standard vaccines or the expensive 5- or 6-component vaccines requiring an extra payment.

The whole-cell pertussis antigen vaccine is not recommended for children in a high risk group, e.g. children born before 37 weeks or with a birth weight below 2,000g. In such exceptional cases, a cost-free 5-component vaccine is provided [7, 8].

### Table 1. Vaccine calendar with alternative multicomponent scheme

| VACCINE | 24 hour | 6th week | 2nd month | 3rd month | 4th month | 5th month | 6th month | 7th month | 13-15 month | 16-18th month | 6th year | 12-13rd year | 14th year |
|---------|---------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-------------|-------------|----------|-------------|----------|
| TUBERCULOSIS | BCG | | | | | | | | | | | | |
| HEPATITIS B | HBV | HBV | HBV | | | | | | | | | | |
| ROTAVIRUSES | RV | | | | | | | | | | | | |
| DIPHTHERIA, TETANUS, PERTUSSIS | DTP | DTP | DTP | DTP | DTP | DTP | Tdap | | | | | | |
| POLIOMYELITIS | IPV | IPV | IPV | IPV | IPV | IPV | | | | | | | |
| HAEMOPHILUS INFLUENZAE | Hib | Hib | Hib | Hib | Hib | Hib | | | | | | | |
| PNEUMOCOCCUS | PCV | PCV | PCV | PCV | PCV | PCV | | | | | | | |
| MEASLES, MUMPS, RUBELLA | | | | | | | | | | | | | |

### ALTERNATIVE MULTICOMPONENT VACCINE SCHEME

- **DTaP IPV Hib**: WZW “B”
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OBJECTIVE
The aim of this study was to investigate the popularity of the 5- or 6-component combination vaccines among parents of infants starting a mandatory vaccination series in a selected Primary Health Care clinic.

MATERIALS AND METHOD
The study was conducted at the Med-All Medical Centre in Kraków which provides a Primary Health Care service and undertakes a Protective Vaccination Programme. Analysis was performed of 1,108 immunization cards of children born between 2010 and the end of October 2019. The cards included information about the type of programme chosen by the parents. Infants born in November and December 2019, and did not start the vaccination programme in 2020 were not included. When an immunization card showed that a child had started a vaccination course with one classic vaccine, but subsequently received 3 doses of a 5-component vaccine, this choice was credited to the 5-component programme. The other types of vaccine were accredited similarly. The obtained data was subjected to statistical analysis in MS Excel (Microsoft) and PQStat Soft. Nominal data were examined with the chi-square test and significance level set at p<0.05.

RESULTS
The study included the immunization cards of 1,108 children, the majority of whom (98.5%) lived in Kraków. Among these children, there were 26 (2.35%) who did not start a preventive vaccination course. The reasons for this were not analysed. The study showed that from 2010–2016, the 5-component combination vaccine was the most popular choice by parents for their infants. Although 2010 was the year with the greatest popularity (72.32%), vaccination in the classic programme was at the lowest level (9.82%). In 2011, the highest frequency occurred of using the classic vaccine (31.33%); from 2016, popularity of 5-component vaccine gradually decreased, and from 2017, the 6-component vaccine the one most preferred. The peak of popularity occurred in 2018, when up to 57.15% parents chose this type of vaccine for their child (Fig. 1).

During the study period, the 5-component vaccine became less and less popular and the usage decreased with years (r= -0.6; p=0.017). In 2015, the 6-component vaccine was released on a larger scale, which was also associated with the beginning of an increase in its selectivity. The usage of 6-component vaccine increased with years, with a strong statistical significance (r= 0.689; p=0.005). However, the percentage of parents choosing the classic vaccination programme did not correlate with years (p=0.601) (Tab. 2), and the average number of children vaccinated was stable during the 10-year period at 16% (SD=5%). During the 10-year analysis, the number of children who did not start any protective vaccinations did not increase (p=0.601) and was between 1% – 3%. The exception was the year 2019, when there occurred the highest percentage of unvaccinated children (5.45%) (Tab. 2).

DISCUSSION
Multi-component vaccines are a way to reduce the child’s suffering associated with the number of injections. This is the most important reason for parents deciding to buy the 5- or 6-component vaccines. A study of Szymoniak et al. shows that 52% of Polish parents chose non-reimbursed vaccines instead of those free of charge [12]. Although most European countries finance their compulsory vaccination programmes, Poland is one of the few countries where the 5- or 6-component vaccines are not free [13, 14]. The current study shows that the popularity of multi-component vaccines, on average, was 81%. In the study of Pieszka et al. the percentage of parents choosing high-associated vaccines was 64%, of which 78% of parents chose a 5-component vaccine and 22% a 6-component vaccine [15]. Additionally, in the Nitsch Osuch et al. study, 17.6% of parents chose the 5-component vaccine and 10.8% the 6-component vaccine [16]. However, a different trend was noted in a study by Pomian-Osiąk et al. in which the most popular was a 6-component vaccine (53%), and only 23% of parents chose a 5-component product [17]. All the studies, however, showed a high popularity for choosing multi-component vaccines. Pieszka’s study, which confirms the claims in the current study, paid attention to the reduction in the number of injections, lower stress experience, and high level of vaccine safety. The necessity of paying for the multi-component vaccine, however, was indicated as a disadvantage [15]. This study corresponds with that by Kędzierska et al., which claims that, despite the additional costs, parents extended the compulsory vaccination calendar with optional vaccination [18]. Hubicki observed that the major factor behind opting for the classical vaccination programme was socioeconomic [19]. These studies showed a strong positive correlation between the parents’ economic situation and the use of recommended vaccinations.

The stable use of classic vaccines, as well as a significant increase in the amount of parents who did not vaccinate...
their children in 2019, could have been caused by fear of the multi-component vaccine content. Some parents did not want to choose vaccine with higher number of antigens administered simultaneously. It is correlated with Pieszka’s study in which 15.9% of the parents surveyed believed that a high combination vaccine could be harmful to a child’s health [15]. In the scheme with the use of classic vaccines, subsequent vaccines can be administered individually, which is associated with fewer antigens administered to the child during one vaccination visit. Gańczak et al. believes that the most important role with making decisions about the type of vaccine is knowledge provided by medical personnel whom parents meet at the medical centre [20]. Furthermore, in the Pieszka study, 94% of parents received satisfactory information about the vaccines during their first visit [15]. High combination vaccines are not only popular among parents who want to avoid suffering in their child. Compared to the classical vaccination, the multi-component version have proved to be safer, while ensuring proper immunity for the child, which could be the reason for more countries deciding to fund them from State budgets [21].

CONCLUSIONS

Multi-component vaccines were the most popular among infants’ parents, despite the necessity to pay and the lack of refunds. Between 2010–2016, during which time the 5-component vaccine was particularly popular, in 2017 it was been replaced by the 6-component vaccine. In the analyzed period, a similar percentage of parents chose the classic vaccine. The fact that the percentage of vaccinated children was the lowest in 2019 should be the subject of further, more detailed research to clarify the phenomenon.

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