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## **Pneumococcal Conjugate 7-valent Vaccine in Children. Regional Experience**

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According to the position of the World Health Organization, pneumococcal disease is the main reason for morbidity and mortality from infectious diseases in the world [1, 2]. Pneumococcus is the causative agent of otites, sinusites (28-56% of cases), severe invasive infections: meningites (24-43%), bacteremia/septicaemia (68-83%), bacterial pneumonia (38-75%). Children younger than 2 years of age are the primary high-risk group in the developed countries. Increase in pneumococcus congenital resistance to the antibacterial therapy present a serious problem all around the world [3, 4].

According to the Russian Federal State Statistics Service data, the leading positions in the primary morbidity structure among children of 0-14 years of age for many years are occupied by diseases of the respiratory system. Thus, in Yaroslavl region in 2009 the general disease incidence index of the 0-15 year old children exceeded the corresponding index for Russia by 24%. Pneumoniae are considered to be the severest among respiratory diseases. In 2009 the pneumonia morbidity index in Yaroslavl region exceeded the corresponding index for Russia by 28%, in the Central Federal District (CFF) – by 38%. In Yaroslavl region in the same period diseases of the ear and mastoid process were registered considerably more often than in Russia and CFF (by 57% and 44% respectively).

Infectious diseases take the 4<sup>th</sup> place in the children's mortality structure, among which the worst is pneumonia which has pneumococcal etiology in 38-75% of cases. Thus, pneumococcal disease seriously threatens the health and lives of children and considerably harms demographic and economic circumstances.

In such conditions vaccinal prevention as a preventive system of the pneumococcal disease appearance and spread becomes all the more important and is an economically sound measure. After the introduction of obligatory vaccination of all children against pneumococcus in the USA the frequency of invasive pneumococcal diseases (meningitis, pneumonia with bacteremia, bacteremia) among the children younger than 5 years of age reduced by 77%, and the frequency of complaints to the hospitals about pneumonia among the children younger than 2 years of age reduced by 39% [5]. One year after the vaccination against invasive pneumococcal disease introduction to the vaccination calendar of the Netherlands for the children from 2 months of age the morbidity rate among children of 0-11 months of age reduced by 70%. Pharmacoeconomic studies conducted in May 2010 in the research institute for clinical-economic examination at RSMU (Moscow) showed that vaccination against pneumococcal disease introduction to the National vaccination calendar of Russia for children of 0-5 years of age will save ca. 57 billion roubles in 5 years. Thus, vaccination is an effective and economically sound pneumococcal disease prevention technique. At present, polysaccharide and conjugate polysaccharide vaccines are used around the world to prevent diseases caused by pneumococcus. Pneumococcal conjugate septivalent vaccine Prevenar (PCV7) has been used in the European countries since 2001 and was registered in Russia in January 2009. The advantage of PCV7 is the possibility of its application to children from 2 months of age.

**The research objective** is the examination of safety, reactogenicity and acceptability of PCV7 by children with various deviations in medical condition, younger than 5 years of age.

An evaluation of the course of postvaccinal period of 196 children of 1-5 years of age in July-October 2011 was made. Children of 12-23 months of age were vaccinated according to the vaccination schedule 2 with an interval of eight weeks (out of 75 children of this age 36 had been vaccinated twice by the time of the study) children of 24-59 months of age were vaccinated once (tbl. 1). The numbers of boys and girls were comparable. Vaccination was done at parents' will who were informed about the necessity, immunological efficacy and possible postvaccinal reactions beforehand together with planned immunization of the children who did not have acute, or exacerbation of, chronic diseases. Vaccinated children's condition control was exercised in 3-4 days after the immunization.

**Table 1.** Vaccinated children's age structure.

Age at the time of vaccination	Number of children		Notes
	Abs.	%	
1-2 years of age	75	38.3	including those vaccinated twice – 36 children
2-5 years of age	121	61.7	-
Total	196	100	-

18 children (out of 196) of 1-2 years of age received the associated immunization: concurrent introduction of PCV7 and: OPV vaccine – 5 children, Hiberix – 8, Bubo-coc vaccine – 2, B hepatitis vaccine – 2, vaccine against measles and parotitis – 1. Clinical state of the vaccinated children is given on the Fig 1, 2.

**Figure 1**

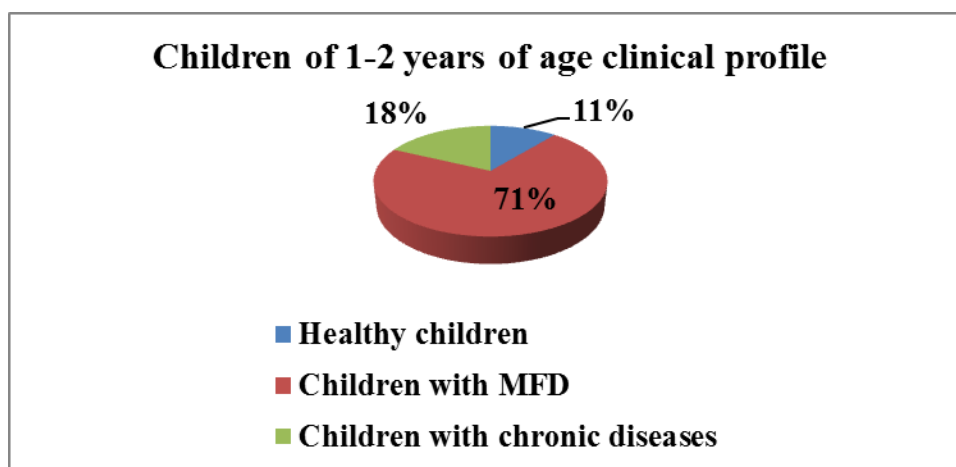
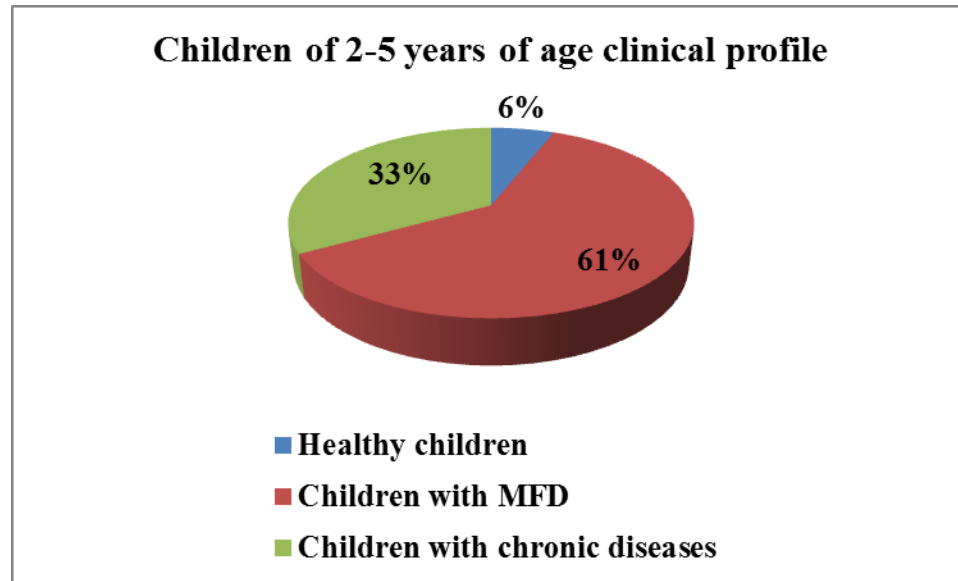
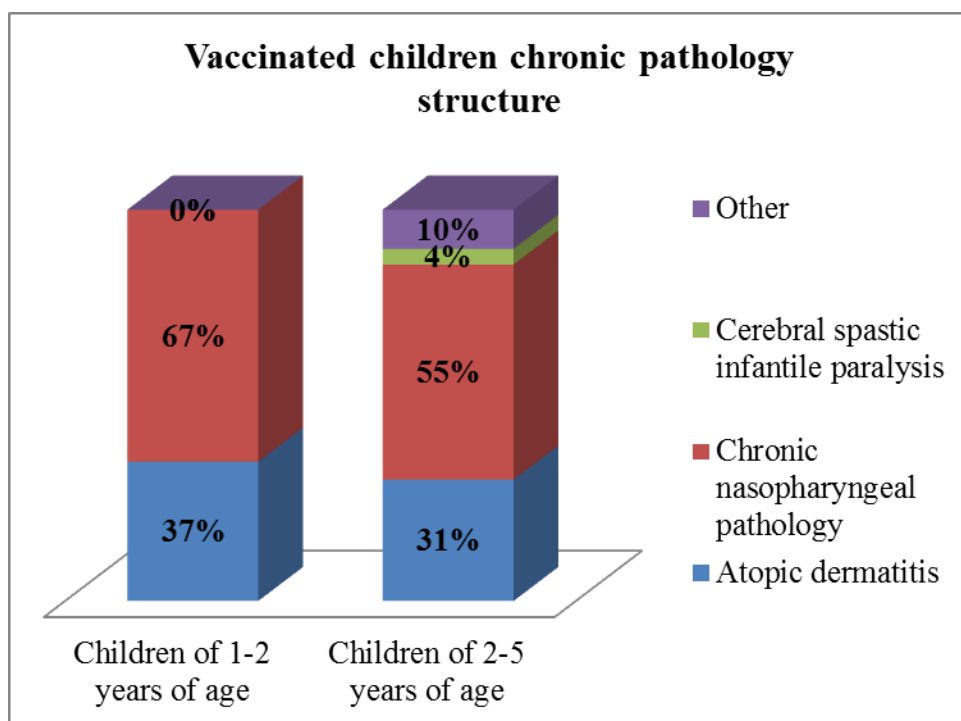


Figure 2.



Before the study various morphofunctional deviations were diagnosed in the majority of vaccinated children: disharmonious physical growth and development, rachitis, mild anemia etc. 14% of the sickly children belonged to the group observed by the specialized clinics, CNS perinatal pathology was diagnosed in the early anamnesis of the 12% of the children. 18% of the children younger than 2 years of age and every 3<sup>rd</sup> child of 2-5 years of age had chronic diseases (Figure 3).

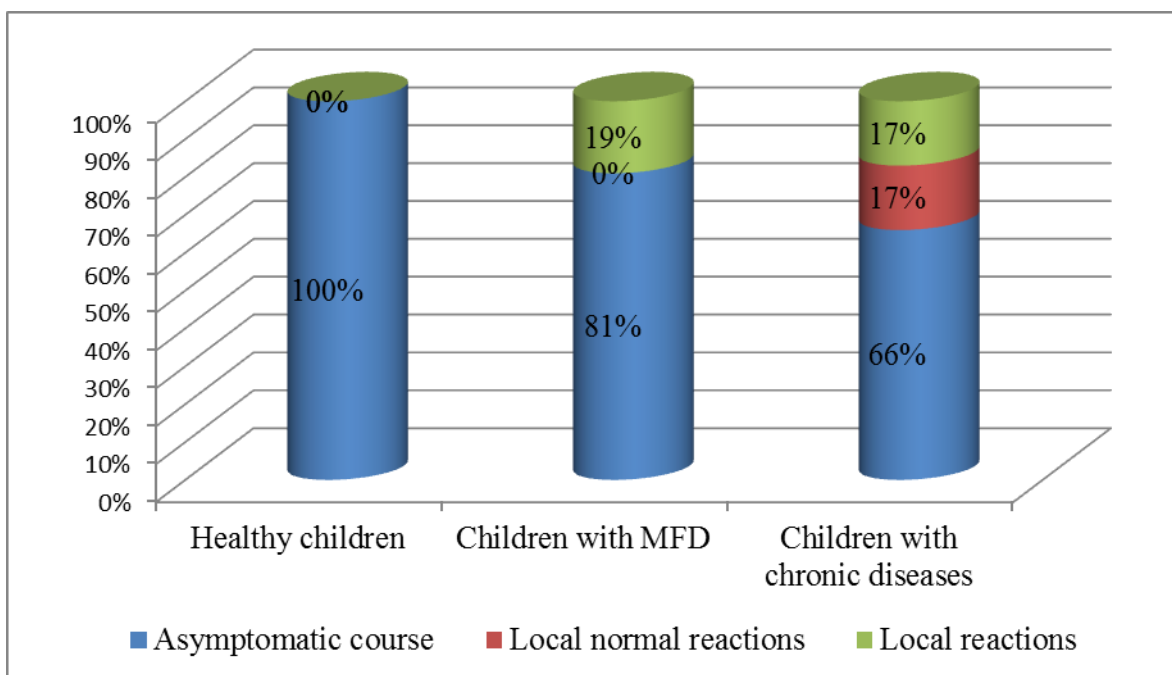
Figure 3.



The majority of the vaccinated children (81%) had an asymptomatic course of vaccinal period (Fig. 4).

Common mild and moderate postvaccinal reactions were observed only in the group of children with chronic diseases (III health group): temperature rise to 37.5-38.5°C – 10 children, with 8 out of them – only in the 1<sup>st</sup> postvaccinal day; mild irritability, somnolency and slight loss of appetite without any therapeutic actions needed – 5 children in the first 2 postvaccinal days. No severe vaccinal reactions or postvaccinal complications. Local normal (permissible) postvaccinal reactions – reddening in the place of injection up to 5cm (9.8% of children), swelling (8%), slight pain in the place of injection (3.3%) – cut off over 3 postvaccinal days with the absolute majority of the children.

**Figure 4. Postvaccinal reactions**



We have not revealed any difference in the frequency of vaccinal reactions between children with morphofunctional deviations, with chronic diseases and in the sickly group. Meanwhile, generalized, local or a combination of generalized and local (to Hiberix) reactions were noted among all children vaccinated with PCV7 together with vaccines Hiberix, Bubo-coc, DPT, measles+parotitis. No vaccinal reactions were noted at the concurrent introduction of PCV7 vaccine and a B hepatitis or an OPV vaccine.

Thus, the following conclusions may be drawn from the given observation:

- Pneumococcal conjugate septivalent vaccine is safe and does not cause severe postvaccinal adverse reactions.
- Normal mild and moderate postvaccinal reactions are typical among children with deviations in medical condition.
- Vaccine reactogenicity does not depend on the character of the child's pathology.
- PCV7 vaccine application together with other vaccines increases the number of normal postvaccinal reactions without any influence on its safety.