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REVIEW

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Evaluation of the Immunization Program in the Federation of Bosnia and Herzegovina - Possible Modalities for Improvement

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ABSTRACT

Introduction: Immunization is a lifelong preventive activity that helps prevent/reduce disease, prevent/ reduce mortality and prevent disability from specific infectious diseases. **Material and Methods:** Authors of this paper researched the WHO extended program of mandatory immunization of children from birth to the age of 18 years and analyzed how it has been implemented in the Federation of Bosnia and Herzegovina (FB&H), because the guidelines of the specialist physician societies on immunization of adults, elderly people and risk groups of the population are missing. **Results:** The paper presents the basic characteristics of the immunization program in the FB&H and the world, points to the most frequent problems that the doctor practitioner has in carrying out immunization, and also presents possible modalities of improving immunization. It is pointed out the need to develop the national guidelines and individual immunization booklets, introduction of electronic registration of immunization, and continuous education of health professionals of all profiles, population, educators, teachers and harmonious partnership relations of health workers, population, social entities and the media with the aim of achieving an appropriate lifelong vaccination.

Keywords: immunization, prevention, morbidity, mortality, vaccine-preventable diseases

1. INTRODUCTION

Despite the proven efficacy, safety and economic justification of the use of vaccines in prevention and control of infectious diseases, 19.5 million children worldwide still have not been fully immunized with DTP vaccine, and in case of a complete global vaccine status, the death of an additional 1.5 million children could be

avoided (1).

In all countries of the world immunization should be priority in the context of prevention and control of vaccine-preventable diseases. The main objectives of the WHO Global Action Vaccine Plan 2011-2020 (GAVP) and the European Vaccine Plan 2015-2020 (EVAP) are: the global strengthening of the immunization program; overcoming of differences in implementation of immunization program at the local, regional and national levels; complete eradication of poliomyelitis in the world and elimination of measles, maternal and neonatal tetanus as well as rubella congenital syndrome; introduction of new and improved vaccines into the national immunization programs and encouraging the research and development of new generations of vaccines and technologies (2, 3).

The aim of the paper is to present certain aspects of immunization programs, i.e. national calendars of immunization of children, young people and adults, specificity of the vaccine coverage, most common problems in the realization of the immunization program with which the doctor practitioner meets in everyday work, as well as possible modalities for improving immunization.

2. IMMUNIZATION OF CHILDREN AND YOUTH

Development of recommendations for immunization and national immunization calendars are dependent on: epidemiology of vaccine-preventable diseases, age-specific morbidity and mortality, life expectancy, immunogenicity of vaccines, risk of possible post-vaccination reactions, vaccine price and health care organization (4).

In order to evaluate implementation of national immunization programs, a project called Vaccine European New Integrated Collaboration Effort (VENICE) was designed in 2010, which included 29

Country	BCG	HepB	D	TT	aP	Polio	Hib	MMR	PCV	MenB, MenC	RV	HPV	INF
Austria	A	R	R	R	R	R	R	R	R	R	R	R	R
Bulgaria	MA	MA	MA	MA	MA	MA	MA	MA	MA	A	N	R	N
Croatia	R	MA	MA	MA	MA	MA	MA	MA	A	A	A	R	RR
Czech Republic	RR	MA	MA	MA	MA	MA	MA	MA	R	RR	R	A	A
Denmark	A	RR	R	R	R	R	R	R	R	A	A	R	A
FBiH	MA	MA	MA	MA	MA	MA	MA	MA	A	A	A	A	RR
France	RR	RR	MA	MA	RR	MA	RA	R	R	R	N	R	A
Germany	A	R	R	R	R	R	R	R	R	R	R	R	A
Hungary	R	MA	MA	MA	MA	MA	MA	MA	MA	N	N	R	R
Italy	N	MA	MA	MA	MA	MA	MA	MA	R	R	R	R	A
Latvia	MA	MA	MA	MA	MA	MA	MA	MA	MA	N	MA	MA	R
Romania	R	R	R	R	R	R	R	R	R	A	A	RR	R
Slovenia	RR	MA	MA	MA	MA	MA	MA	MA	R	A	A	R	R
United Kingdom	RR	R	R	R	R	R	R	R	R	R	R	R	R
United States	RR	R	R	R	R	R	R	R	R	R	R	R	R

Table 1. Vaccination calendar (most commonly used of vaccine) of children and adolescents in the world. Abbreviations: FBiH, Federation Bosnia and Herzegovina; BCG, Bacillus Calmette–Guérin vaccine; HepB, hepatitis B vaccine; D, diptheria toxoid vaccine; TT, tetanus toxoid vaccine; aP, acellular pertussis vaccine; Polio, poliomyelitis vaccine; Hib, haemophilus influenzae type b vaccine; MMR, measles-mumps –rubella vaccine; PCV, pneumococcal conjugate vaccine; Men B, meningococcal B vaccine; MenACWY, meningococcal conjugate vaccine; RV, rotavirus vaccine; HPV, human papilloma vaccine; INF, influenza vaccine. A, absence of recommendation; MA, mandatory for all; R, recommended; RR, recommended for children at risk. Source: European Centre for Disease Prevention and Control (ECDC) 2005-2017, US Centers for Disease Control and Prevention, The Public Institution Health Centre of Sarajevo Canton

European countries, referring to the vaccine implementation strategy in these countries (5). The investigated countries are practicing IPV, DTaP / dTap / dT, HepB, Hib, MMR and INF vaccine. PCV vaccine had 28 countries, BCG vaccine, HPV vaccine, VAR vaccine, MenACWY vaccine and HepA vaccine have been administered by 20 European countries, while 9/29 countries have introduced RV vaccine. A total of 15 countries have no compulsory vaccine in the immunization program; at least one compulsory vaccine had 14 European countries, polio vaccine was mandatory for children and adults in 12 countries, D/d and T vaccine in 11 countries, and 8/15 countries had combined strategy for the administration of vaccines—vaccines are recommended for the entire population, and mandatory vaccination relates to certain risk groups of the population (5).

Mostly in the former socialist countries of eastern and southeastern Europe is a mandatory method of implementing routine immunization; most countries in the world have a recommended immunization strategy; and there is a combined way of implementing an immunization program in a few countries (5, 6).

By analyzing the connection between methods of implementing the immunization program and frequency of vaccination are noticed various results. The mandatory method of immunization was designed to improve the coverage of immunization, but in some countries, despite this approach, the level of vaccination is below the recommended <90-95%, while in a large number of countries with the recommended immunization (5) vaccination is present in significant numbers. Probably the attributes “mandatory” and “recommended” are not a fundamental determinant in the assessment of local, regional and national vaccination, and consideration should also be made about historical and cultural characteristics, type of vaccine, price of vaccines, health care organization and education level (5).

There is a legally mandatory continuous immunization program in the FB&H, which is updated annually, and children from birth to 18 years of age are obliged to be immunized by BCG, HepB, bOPV / IPV, DTaP / dT, Hib and MMR vaccine in 2017 (7).

In most European countries, except for routine vaccines, it is recommended to use RV, PCV, HPV, MenACWY / MenB and INF vaccines. In Bulgaria, except mandatory BCG vaccine at birth, children are re-vaccinated in the 7th month of life if the Mantoux test has been previously negative, and booster doses are given in the 7th, 11th and 17th year to individuals with a negative Mantoux test; among other things MMR and VAR vaccines are mandatory in Italy, and PCV vaccine is mandatory in Bulgaria (6).

National immunization calendars of school children are different, dT is given in the final grade of the primary school in the FB&H (7), while dT booster vaccine, if not previously, is given in the final grade, in Croatia at the 14th year booster dose of dT + IPV, in Germany from the 9th to 17th year is given dTap + IPV and HPV vaccine at the age of 9-14 years (6). In most European countries, it is possible that children who do not have a regular vaccine status during the school period can catch up with missed doses of vaccine/revaccination (6).

The United States immunization calendar pays considerable attention to the immunization of school children and students (8, 9) and recommends annual INF vaccine, dTap / dT vaccine every 10 years, HPV vaccine—if they have not previously been immunized up to 26 years for girls and 21 years for youngsters, MMR and VAR vaccine- if not previously immunized (9). If the school children and students have incomplete / unknown immunization status or risk factors, they can receive PCV, HepA, HepB, MenACWY and Hib vaccine (8, 9) according to the guidelines of the American Center for Disease Control and Prevention (CDC).

There are no written official recommendations from rel-

Country	BCG 2016	BCG 2011	HepB3 2016	HepB3 2011	Pol3 2016	Pol3 2011	DTP3 2016	DTP3 2011	Hib3 2016	Hib3 2011	MCV1 2016	MCV1 2011	MCV2 2016	MCV2 2011
Austria	-	-	87	-	87	-	87	-	87	-	95	-	89	-
Bulgaria	86	98	91	96	92	95	92	95	92	95	92	94	88	94
BiH	97	94	78	88	79	89	78	88	69	88	68	89	78	88
FBiH	96,4	-	72,9	-	71,7	-	72,9	-	60,9	-	63,5	-	74,4	-
Canton of Sarajevo	100	-	62,7	-	58,3	-	59,8	-	26,7	-	47,4	-	68,4	-
Croatia	99	99	93	97	93	96	93	96	93	96	90	96	96	98
Equatorial Guinea	46	53	33	-	30	53	33	54	33	-	29	59	-	-
Germany	-	-	88	87	95	94	-	96	93	93	97	96	93	92
Greece	-	-	96	99	96	99	96	99	96	96	99	98	93	98
Hungary	100	100	-	-	100	100	100	100	100	100	100	100	-	100
Israel	-	95	98	94	94	94	94	94	94	94	97	97	97	97
Kenya	86	92	78	88	76	88	78	88	78	88	75	87	32	-
Montenegro	76	97	89	95	96	99	95	89	89	90	47	91	86	97
Romania	97	98	91	90	91	96	89	93	89	78	88	91	95	97
Slovenia	-	-	88	96	94	96	94	96	94	96	92	96	93	96
Turkey	96	96	98	96	98	97	98	97	98	97	98	98	85	86
Ukraine	75	90	26	21	56	54	19	50	47	26	42	67	31	56
United Arab Emirates	99	-	100	-	100	-	100	-	100	-	100	-	100	-
USA	-	-	93	91	94	94	95	96	93	94	92	92	-	-

Table 2. Vaccination coverage rates (%) for children on local, regional, national and international level. Abbreviations: BiH, Bosnia and Herzegovina; FBiH, Federation Bosnia and Herzegovina; HepB3, hepatitis b vaccine 3th dose; Pol3, polio vaccine 3th dose; Hib3, haemophilus influenzae type b vaccine 3th dose, DTP3, diphtheria toxoid, tetanus toxoid and pertussis vaccine 3th dose; MCV1, measles-containing vaccine 1st dose; MCV2, measles-containing vaccine 2nd dose. Source: WHO vaccine –preventable diseases: monitoring system. 2017 global summary, Institute for Public Health FBiH.

evant specialist societies on the use of vaccines that are not included in the program of extended immunization of children and youth in the FB&H, and on the basis of relevant international expert recommendations the physicians’ practitioners indicate the administration of specific vaccines.

3. IMMUNIZATION OF ADULTS

Vaccination of a preventable disease can also occur in adulthood, in which these diseases can have a more severe course and complications due to the age, weaker defense potential of the immune system, presence of chronic disease and incomplete immunization status. Diphtheria and tetanus can be serious diseases in older people, individual immunity is important in these diseases, and it is important that adults have an appropriate vaccination/revaccination status (10). Pertussis often occur in adolescents and adults, and frequently it is not adequately detected and diagnosed in adolescents and adults (11). Elderly people are the most common source of infections for pertussis for underage children, and for the timely protection of infants the WHO recommends vaccination of pregnant women, adolescents and adults by dTap vaccine (12, 13).

In 29 European surveyed countries, immunization scheme for all recommended vaccines for adults is present in six countries; i.e. the IIV and HepB vaccine is generally recommended for all adults, giving a boost dose of d i T vaccine exists in 21 and 22 country respectively, 9 countries recommended ap vaccine, one country has a recommendation for HZV vaccine (14).

CDC and relevant US specialist societies recommend that all healthy individuals aged 19 to ≥65 years, depending on their previous immunization status, should receive: INF vaccine, dTap/dT at the beginning and every 10 years after that

booster dT vaccine, VAR vaccine; HPV vaccine in men under 21 years old and women under 21 if they have not previously been immunized and HZV vaccine after ≥60 years. Incompletely vaccinated/non-vaccinated and born in 1957 or later, if they do not have a serological confirmation of immunity, they need to receive 1 or 2 doses of MMR vaccine at the age of 19-60 years, and PCV vaccine is recommended at the age of ≥65 years (9,15).

US recommendations (15) include immunization of pregnant women (inactivated INF and dTap vaccines in the 27-36th week of gestation during each pregnancy) and, among others, a sick person suffering from chronic lung, heart, kidney, liver disease and diabetes mellitus should be immunized with an INF vaccine, with dT vaccine every 10 years, as well as MMR, VAR, HZV, PCV and HepB vaccine, considering possible contra indications and previous immunization status. The significance of immunization of health workers is also indicated, and it is recommended for them to be appropriately immunized–INF, Td/Tdap, MMR,VAR, HZV, HPV, PCV and HepB vaccine (15).

There are no clear written recommendations of specialized societies for immunization of adults in the FB&H, there is a different approach to immunization of adults. In practice doctors generally recommend immunization against influenza, tetanus, HepB, pneumococcus, rabies, typhus, cholera and meningococcus depending on risk factors, current immunization status and travel to risk areas.

4. IMMUNIZATION COVERAGE

A complete immunization status means complete immunization against vaccine-preventable Diseases– BCG, HepB3, Pol3, DTP3, Hib 2 or 3, MMR1 and MMR2, PVC 2 or

3, RV 2 or 3 vaccines, depending on national immunization calendars (16).

There are two ways of assessing the vulnerability - the administrative method and the research method. The most widely used, much cheaper, is administrative method for assessing the vulnerability, which is part of the routine reporting of the health institution that carried out implementation of the immunization program. Certain elements of subjectivity and imprecision (inaccurate counting of given vaccines, calculation of non-applied thrown bottles and imprecisely determined total number of target population) limit the significance of the administrative method in monitoring of vaccination (17).

A questionnaire assessment of vaccination allows for a more accurate determination of the vaccinal status of selected population and is carried out within the framework of population research (16). It is based on application of immunization documentation—paper form (immunization card or immunization booklet) or electronic form (electronic immunization register or electronic immunization card). In addition to assessing the immunization status of the target population, the survey includes an assessment of the variables that affect vaccination. This method is significantly more objective vs. an administrative method and can evaluate its precision in assessing the vaccination of the target group. WHO and UNICEF analyze the national vaccination data and make a country-by-country assessment of vaccination (18). According to the WHO data from 2016, the global vaccination is not at the recommended level for specific vaccines and is stable over the last few years, i.e. 86% for DTP3, for HepB3-84%, Pol3-85%, Hib3-70%, measles-containing vaccine (MCV1)–85%, MCV2-64%, PCV- 42% and for the RV vaccine was 42% (19). By analyzing the vaccination for routine vaccines at the international level for 2016, it can be established that for some countries, among other things, adequate vaccination has: for example Hungary, the UAE and the USA, while inadequate vaccination has Guinea, B&H and Austria (20).

By analyzing of vaccination in 2016 using the administrative method, in the FB&H, Sarajevo Canton and other cantons, it can be established that, in exception of the desirable vaccination for BCG vaccine for all administrative areas, the vaccination of other routine vaccines is at an inappropriate level (21).

Comparing the vaccination of routine immunization 2016 vs 2011, it was established a downward trend of vaccination in 2016 in all administrative areas of the FB&H (21).

In order to examine the immunization potential of the target population, it would be desirable to take into account the timeliness of the given vaccines against the chronological age in accordance with the national immunization calendar, and then could be more accurately evaluated the significance of the complete or incomplete immunization status of the target population (22).

5. PROBLEMS IN REALIZATION OF THE IMMUNIZATION PROGRAM

Long-lasting successful realization of immunization in B&H and FB&H, in accordance with the WHO guidelines, resulted in the eradication of smallpox, elimination of poliomyelitis, diphtheria, neonatal tetanus and disseminated

forms of tuberculosis in children, and significantly decreased the frequency of measles, mumps and rubella. Taking into account WHO recommendations, the most modern vaccines are introduced in the FB&H—vaccine with aP component resulting in a negligible number of side effects/or no adverse events vsWP; a combined DTaP-IPV-Hib vaccine which led to fewer medical visits and a significantly smaller number of injections since June 2016.

One way of improving immunization and indicating the importance of regular immunization of school children, students, adults and elderly people is the existence of national guidelines on immunization of all age groups, and certainly attention should be paid to immunization of risk populations and immunization of persons who are late with immunization. In everyday practical work there is no significant attention paid to immunization of pregnant women, and it would be necessary to have professional guidelines on the importance of immunization of pregnant women with the recommendation, among other things, that each pregnant woman has a neat MMR vaccine status before pregnancy.

Advances in science and improved technology of vaccine production have made the immunization significantly safer, and there are fewer formal and specific contraindications now for immunization according to the WHO guidelines. According to the relevant WHO guidelines, among others, physiological jaundice, prematurity, atopic dermatitis, penicillin allergy, recent antibiotic use, recent exposure to infection, and positive skin test for eggs are not a contraindication for immunization of the child (23, 24). It is very important to immunize children, as well as adults with chronic diseases, respecting the formal WHO guidelines for the contraindication of vaccine-preventable diseases.

It is important to determine whether there is a correlation between vaccine products, improper storage and handling of the vaccine, improper vaccination, and possible postvaccination reactions, in order to differentiate the cause of potential post-vaccination states. The obligation of doctors in the FB&H is to record the post-vaccination reactions in the Post-Vaccination Reaction Report, and according to data of the FB&H Institute of Public Health in 2016 (21) 28 transient post-vaccination reactions were recorded without consequences (mostly on DTwp-14 and MMR vaccine- 6). In order to control immunization in the FB&H, it would be advisable for doctors to record any possible post-vaccination side effects, and with the existence of electronic documentation as well as the Immunization Registry at the FB&H level, a more systematic and more objective approach to the evaluation of post-vaccination complications at all administration levels in the FB&H would be provided.

Globally in the world, and also in our environment, there is a trend of a significant reduction in the vaccine coverage below the recommended values, and vaccination is an indicator of the population health status potential, the success of immunization program of the target population and the development of the health service at all administrative levels (16, 17).

By analyzing vaccination in the FB&H, it can be concluded that in the period 2012-2016 there was a tendency for low vaccination of all routine vaccines, especially Tuzla, Sarajevo and Central-Bosnia Cantons, and according to the WHO and

the Regional Committee for Certification of Polyomyelitis, FB&H and B&H are considered the area of endemic transmission of measles, and it is the country of risk for import of polyomyelitis as a result of low local, regional and national vaccination for MMR and polio vaccine (21). By investigating the characteristics of an epidemic of measles in Italy in 2017, it was found that from 4328 patients 288 were health care workers, the mean age of patients was 27 years, 88% of patients were not vaccinated and 7% received only one dose of MMR vaccine (25). Hukić M. and associates by investigating the vaccination status of 3804 patients with measles in the FB&H during 2014-2015 found that 70% of patients were not vaccinated and status of MMR vaccine for 20% was unknown, which indicates the importance of checks and complete MMR vaccination status (26). Nathan C. Lo and Hotez (27) found that a reduction in coverage of MMR vaccination by 5% per year results in a 3 times more increase in measles and an additional \$ 2.1 million public sector allocations. It is possible to increase vaccination (28,29,30) by regularly checking the vaccine status, by reminding and re-invoking parents (phone call, SMS, mail or e-mail).

The beginning of the vaccination rejection phenomenon dates back to the middle of the 18th century when vaccine for smallpox was administered. The anti-vaccination attitude and campaign was intensified in 1998 when the British children's surgeon Wakefield published the work on association of MMR vaccine and autism, but additional numerous studies found that work was not based on scientific evidence, and the work was rejected in Lancet, but anti-vaccination phenomena is still present to a considerable extent. Studies have identified numerous reasons for the refusal or delay of immunization: personal or philosophical reasons (lack of knowledge about the frequency, severity and complications of vaccine-preventable diseases, the view that immunization against these diseases is not required and that it is better for children to get over the disease), distrust about the safety of vaccines and a certain group of individuals wants health professionals to inform them more about immunization (31, 32).

An appropriately implemented immunization program includes the immunization record, and in the FB&H it is mainly reported through paper documentation (the entry of all relevant data on the given vaccine/vaccines into the official vaccination card and the individual immunization booklet). Basically, there are no individual immunization booklets, and the immunization data is entered in the health booklet. Bearing in mind that we need to know the vaccination status of all ages, and that the health booklet can be damaged or lost, we consider that it is desirable to design individual immunization booklets in the FB&H, because in this way they would have the uniformity and systematic approach to evaluation of the vaccination status of population. This would provide a clear insight into the control of immunization during visits to health services at all levels, enrollment in kindergarten, primary and secondary schools, faculties, admission to children's and student dormitories, employment and travel abroad, and, according to the above assessment, to update the missed vaccine. Existence of electronic documentation (local and regional e-card of immunization, the FB&H Immunization Register) on immunization would facilitate a more precise evaluation of the vaccination, easier identification of

children who are not immunized or under-immunized, calling for continued immunization and more objective determination of post-vaccination reactions.

Periodic researches, involving municipalities and cantons in the FB&H, would objectify the distribution of vaccination and reasons for the refusal of immunization, thus creating specific strategic programs for improving immunization.

Health workers have the most important role in promoting and implementing the immunization, and activities should be intensified on the continuous medical education of all profiles of doctors and nurses, the development of immunization protocols, the national guidelines on immunization, the production of educational materials, the organization of expert meetings and expert lectures through the media and social networks, in order to have unique and up-to-date knowledge and attitudes on all aspects of immunization. Continuing education activities on immunization should be directed to parents, educators, teachers and creation of a coherent partnership relationship between health workers, parents, the media and social entities, and that will allow acquisition of the relevant knowledge for indicating the importance of immunization in preventing vaccine-preventable diseases.

6. CONCLUSION

Immunization is the most important, most effective and safest public health activity in prevention and control of Vaccine-Preventable Diseases. In addition to childhood, it is necessary to direct activities to improve the immunization of pregnant women, adults and elderly people. The updated vaccination status and compensation of missed vaccines, including developed system of reminders and calling for missed vaccines, is the best activity of appropriate immunity and that is preventing diseases at the local, regional, national or global level. Creation of the national guidelines and individual immunization booklets, introduction of electronic registration of immunization, periodical research projects, continuous education of health professionals of all profiles, educators, teachers and harmonious partnership relations of health workers, population, social entities and the media will enable us to acquire adequate knowledge, appropriate attitude and successful realization of the immunization program in the FB&H.

Abbreviations: *IPV-inactivated poliovirus vaccine; DTaP-diphtheria, tetanus and acellular pertussis vaccine, pediatric formulation; dTap-diphtheria, tetanus and acellular pertussis vaccine, adult/adolescent formulation; dT-diphtheria and tetanus vaccine, adult/adolescent formulation; HepB- hepatitis B vaccine; Hib-haemophilus influenzae type b; MMR-measles, mumps & rubella vaccine; INF-influenza; IIV- inactivated influenza vaccine; PCV-pneumococcal conjugate vaccine; BCG-tuberculosis vaccine; HPV-human papilloma virus, VAR-varicella vaccine, MenB-serogroup B meningococcal vaccine; MenACWY-meningococcal conjugate vaccine; HepA-hepatitis A vaccine; RV-rotavirus vaccine; Pol-poliomyelitis; aP-acellular pertussis vaccine, wP-whole-cell pertussis vaccine; bOPV- bivalent oral polio vaccine*

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critically reviewed of the manuscript for important intellectual content.
All authors read and approved the final manuscript.

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