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Federal Medical Chamber of Federation of Bosnia and Herzegovina
prim. dr. med. Goran Pavic, an epidemiologist
The chair of the Commission for International collaboration

prim. doc. dr. sci. med. Jelena Ravlija
Public health institute of Federation of Bosnia and Herzegovina
Problems in immunization in Federation of Bosnia and Herzegovina

Immunization-The discovery that has saved millions of human lives and it is still saving of human lives

Vaccination-The process of active immunization using vaccines

*Vacca, ae, f, (Lat.)-Cow*

No one presentation about immunization could be without mention of the name of this great man

Edward Jenner 1749-1823
"The father of immunology"
1. 1796 Edward Jenner tested the hypothesis that infection with cowpox could protect a person from smallpox infection

2. 1885 Louise Pasteur successfully prevented rabies in nine-year-old Joseph Meister by post-exposure vaccination

3. 1904 Albert Calmette and Jean-Marie Camille Guérin made attenuation of Mycobacterium tuberculosis (BCG)

4. 1921 First human tests of BCG

5. 1945 Influenza vaccine was approved
Timeline milestones of immunization

6. 1948 Pertussis vaccine combined with those for tetanus and diphtheria
7. 1957 Hilary Koprowski's first OPV tests
8. 1958 First measles vaccine was tested
9. 1960 Sabin's polio vaccine was licensed
10. 1961 Rabies-Human testing of new live virus vaccine
Timeline milestones of immunization

11.1963 Measles vaccine was licensed
12.1965 Hepatitis B-The Australia antigen was discovered
13.1968 Attenuvax-New measles vaccine
14.1969 Rubella vaccine licensed
15.1971-Measles, mumps, rubella vaccine was licensed
Timeline milestones of immunization

16. 1971 Rabies-New inactivated vaccine
17. 1974 WHO-EPI programme of immunization
18. 1975 Last wild case of variola major
19. 1976 Swine flu vaccine was produced
20. 1977 Pneumococcal-Multi-serotype vaccine was licensed
20. 1979-Rubella-An improved vaccine was licensed
Timeline milestones of immunization

20.1979 Rubella-An improved vaccine was licensed
21.1980 Smallpox declared eradicated
22.1981 Hepatitis B-First subunit viral vaccine in the U.S.A.
23.1981 Varicella-Attenuated strain was licensed in the U.S.A.
24.1987 Conjugated HiB vaccine was licensed
25.1989 Oral typhoid vaccine was licensed in the U.S.A.
Timeline milestones of immunization

26. 1994 Polio declared eliminated from the Americas
27. 1995 Hepatitis A vaccine was licensed
28. 2000 Pneumococcal conjugated vaccine for children
29. 2000 Endemic measles eliminated from the U.S.A.
30. 2002 Polio eradicated in Europe
Basic terminology

1. Immunization
2. Active natural immunization (recovery from disease)
3. Active artificial immunization (vaccination)
4. Passive natural immunization (from mother to child)
5. Passive artificial immunization (immunoglobulins, immunosera)
6. Vaccines
7. Immunoglobulins
8. Immunosera
9. Elimination (it means no more endemic cases)
10. Eradication (it means no more any cases)
Immunological products

1. Lyophilized vaccines
2. Liquid vaccines
3. Immunoglobulins (antitoxins) (human origin)
4. Immunoser (antitoxins) (animal origin)
5. Adjuvants in immunological products
6. Single dose vaccine vials usually do not need preservatives
7. Multi dose vaccine vials usually need thiomersal (organic mercury compound) as preservative
8. Single component vaccine
9. Combined vaccines
10. Live attenuated, inactivated, toxoid, DNA recombinant vaccines
Immunological products storage and transportation

1. Immunological products are very sensitive to temperature
2. The most of immunological products must be stored and transported on temperature between +2°C to +8°C ("cold chain")
3. Some of vaccines could be stored and transported on temperature on -20°C (OPV, MMR)
4. Freezing of other vaccines will destroy their potency
5. Heating of vaccines will destroy their potency
6. Immunological products should be kept in special refrigerators.

7. Every refrigerator for immunological product storing should be equipped with internal thermometer (Fridge-Tag, classic).

8. Every refrigerator for immunological product storing should be equipped with paper temperature list.

9. There are special refrigerating rooms.

10. Immunological products should be transported only by special vehicles which are have refrigerating department with temperature monitoring, storing, transporting, and using of immunological products should be carefully registered continuously.

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Immunological products storage and transportation

Classical thermometer vs. electronically thermometer

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## Immunological products storage and transportation

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Explanation</th>
<th>Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>😃</td>
<td>The inner square is lighter than the outer circle. If the expiry date has not passed, <strong>USE</strong> the vaccine.</td>
<td>I</td>
</tr>
<tr>
<td>😃</td>
<td>As time passes the inner square is still lighter than the outer circle. If the expiry date has not passed, <strong>USE</strong> the vaccine.</td>
<td>II</td>
</tr>
<tr>
<td>🚫</td>
<td><strong>Discard point:</strong> the color of the inner square matches that of the outer circle. <strong>DO NOT</strong> USE the vaccine.</td>
<td>III</td>
</tr>
<tr>
<td>🚫</td>
<td>Beyond the discard point: inner square is darker than the outer circle. <strong>DO NOT</strong> USE the vaccine.</td>
<td>IV</td>
</tr>
</tbody>
</table>

From WHO ([www.who.int](http://www.who.int)).

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### Vaccine Vial Monitor

- **Stage 1 = good:** Utilize
- **Stage 2 = good:** Utilize
- **Stage 3 = bad:** Don’t Utilize
- **Stage 4 = bad:** Don’t Utilize

- The central square is lighter than the surrounding circle.
- The central square is equal to, or darker than the surrounding circle.
The most important immunological products

1. Vaccine against tuberculosis (BCG)
2. Vaccine against diphtheria, tetanus, pertussis (DTPa)
3. Vaccine against hepatitis B (HBV)
4. Vaccine against HiB infections (HiB)
5. Vaccine against mumps, measles, and rubella (MMR)
6. Oral polio vaccine (OPV) Inactivated polio vaccine (IPV)
7. Vaccine against diphtheria and tetanus (DT)
8. Vaccine against tetanus (TT)
9. Vaccine against influenza
10. Vaccine against pneumococcal disease

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The most important immunological products

11. Vaccine against varicella
12. Vaccine against yellow fever
13. Vaccine against typhoid fever
14. Vaccine against cholera
15. Vaccine against rotaviruses
16. Vaccine against rabies
17. Vaccine against meningococcal disease
18. Vaccine against hepatitis A
19. Immuglobulin against tetanus
20. Immunoglobulin against rabies
21. Immunoserum against vipers bite

22. Immunoserum against "black widow" spider bite

23. Immunoglobulin against hepatitis B

24. Vaccine against human papillomavirus (HPV)

25. Vaccine against zoster
Administrative organization of Bosnia and Herzegovina

Federation of Bosnia and Herzegovina

Republic of Srpska

Brcko District
Timeline milestones of immunization in Bosnia and Herzegovina

1. 1946-Introduction of TT vaccine
2. 1948-Introduction of BCG, Diphtheria vaccine
3. 1961-Introduction of pertussis, polio vaccine
4. 1971-Introduction of measles vaccine
5. 1974-The last case of poliomyelitis
6. 1980-Introduction of mumps, rubella vaccine
7. 1980-The last case of diphtheria
8. 1999-Introduction of HVB vaccine in the 7th year of life
9. 2000-Introduction of neonatal HVB vaccine
10. 2002-Introduction of HiB vaccine (2006 end of GAVI program for HiB, HiB is now financed by FMOH)

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Health care facts

BOSNIA AND HERZEGOVINA

Republic of Srpska  District Brcko  Federation of B&H

Ministry of Health  Ministry of Health  Federal Ministry of Health

10 Cantonal Ministries of Health

3 different NIP  =  3 different tenders in B&H

There is no quality criteria on tenders in B&H
Decisive criteria is only price
Protection of people in Federation of Bosnia and Herzegovina from infectious diseases has been regulated by the Law of protection of people from infectious diseases (Official journal of Federation of Bosnia and Herzegovina No. 29/05) and by related rulebooks and by related directions and decisions.

The Rulebook of methods of enforcement of obligatory immunization, immunoprophylaxis, and chemoprophylaxis against infectious disease (Official journal of Federation of Bosnia and Herzegovina, No. 22/07, 19/08, 6/10, 8/11, 12/12) is basic law document for mentioned Federal ministry of health every year publish in Official journal of Federation of Bosnia and Herzegovina the Order of obligatory immunization against infectious diseases. (The Order for 2014 is published in Official journal of Federation of Bosnia and Herzegovina No. 11/14)
# Obligatory immunization schedule 2014

<table>
<thead>
<tr>
<th>Type of vaccine</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>After birth</td>
<td>HVB 1 + BCG</td>
</tr>
<tr>
<td>1st month</td>
<td>HVB 2</td>
</tr>
<tr>
<td>2nd month</td>
<td>DTPa 1 + IPV 1 + HiB 1</td>
</tr>
<tr>
<td>4th month</td>
<td>DTPa 2 + IPV 2 + HiB 2</td>
</tr>
<tr>
<td>6th month</td>
<td>DTPa 3 + IPV 3 + HVB 3</td>
</tr>
<tr>
<td>12th month</td>
<td>MMR 1</td>
</tr>
<tr>
<td>18th month</td>
<td>HiB 3 + OPV 1</td>
</tr>
<tr>
<td>5th year</td>
<td>DTPa 4 + IPV 4</td>
</tr>
<tr>
<td>6th year</td>
<td>MMR 2</td>
</tr>
<tr>
<td>14th year</td>
<td>DT adult + OPV 2</td>
</tr>
<tr>
<td>18th year</td>
<td>TT</td>
</tr>
</tbody>
</table>
Calculations in immunization

1. Calculations in immunization is very important factor in the process of immunization

2. Percentage of immunized (%) = Number of immunized persons / number of immunization planned persons * 100

3. Vaccine usage/wastage is calculated by these formulas:

   Vaccine usage rate (%) = Number of doses administered / Number of doses issued * 100

   Vaccine wastage rate (%) = 100 - Vaccine usage rate

   Vaccine wastage rate (%) = Number of doses wasted / Number of doses supplied

   Vaccine wastage factor = 100 / 100 - Vaccine wastage rate

4. Allowed vaccine wastage factors are: single dose vials up to 1,05, multiple dose vials up to 1,25, BCG up to 12
1. Reporting in immunization is very important factor in the process of immunization

2. We introduced pyramidal (vertical) system of reporting

3. Medical professionals from primary healthcare levels (municipality levels) monthly send reports to cantonal public health institutes

4. Cantonal public health institutes monthly send reports to Federal public health institute

5. Types of reporting are: temperature lists, reports of immunized peoples, reports of spending and wasting vaccines
Opened vaccine vials politics

1. Lyophilized vaccines (MMR, HiB, BCG) must be used within of 6 hours after dissolving

2. Liquid vaccines (OPV, DTPa, DT, Ana-Te, HBV (multi dose)) can be used within 14 days

3. Opened vaccine vials must comply with WHO Opened vaccine vials politics (WHO/V&B/00.09) (that means)

4. Vaccine has not reached expire date

5. Vaccine should been stored under cold chain conditions

6. All asepsis elements have been assured during aspiration

7. Vaccine vial monitor (if it is exist) has not reach point of withdrawal

8. Vaccine vial rubber has not been emerged into water
Results in immunization in Federation of Bosnia and Herzegovina

Coverage rates and their comments

1. 95% of immunization coverage "ensures" immunological barriers

2. In some cantons yearly coverage rate for some vaccines is below 95% and there is risk of occurrence of some epidemics

3. Possible reasons for lower coverage rate are problems with procurement of vaccines, lack of vaccines, delay in supply of vaccines, anti vaccination organizations and their activities, media rumors about vaccine safety, migration of people in cantons near border to Croatia, problems with cold chain, etc.

4. In some cases medical doctors are "threatened" and make false contraindications for vaccination

5. Some people (especially from specific ethnic groups, and social poor people do not bring their children to vaccination
Results in immunization in Federation of Bosnia and Herzegovina

Coverage rates and their comments

6. Campaigns for vaccination of children from specific ethnic groups (i.e. Roma people) in their places of residence is very difficult and it is not safe.

7. Despite of all mentioned epidemiological situation is relative stable but with fluctuation of occurrence of some epidemics.

8. Vaccination against vaccine preventable diseases can really reduce occurrence of epidemics and it is a tool for their control.

9. Vaccines are not 100% safe, and they can cause adverse reactions also vaccines cannot produce 100% protection.

10. Continuously monitoring of the whole process of immunization is "Conditio sine quanon" (The condition cannot be omitted).
Results in immunization in Federation of Bosnia and Herzegovina

Poliomyelitis incidence rate, B&H/F B&H

Stopa oboljevanja od difterije, BiH/FBiH1946.-2008.

1946-1950
1951-1955
1956-1960
1961-1965
1966-1970
1971-1975


1948
1949-1950
1951-1955
1956-1960
1961-1965
1966-1970
1971-1975
1976-1980
1981-1985
1986-1990
1991-1995
1996-2000
2001-2005
2006-2010
2011-2015
2016-2020

Stopa oboljevanja od parotitis ep. BiH/FBiH

1977-1980
1981-1985
1986-1990
1991-1995
1996-2000
2001-2005
2006-2010
2011-2015
2016-2020

MMR 1980

Diphtheria vaccine 1960

Morbilli 1 doza 1970
Coverage by MMR vaccine

- Primoimunizacija
- Revakcinacija
Registered cases of mumps from 12/2010 to 09/2012 (n=7895)

- [Graph showing number of cases by month from XI/10 to IX/12]
- [Bar chart showing number of cases by age group from <1 to 30+]

- [Pie chart showing distribution of vaccinated, incompletely vaccinated, and unvaccinated individuals: vaccinated (15%), incompletely vaccinated (15%), unvaccinated (39%), unknown (31%)]
SWOT analysis

Strengths

1. Immunization is obligatory
2. Regular annual changing of immunization schedule
3. Centralized procurement of immunological products
4. Obligatory immunological products quality testing
5. Organized cold chain system
SWOT analysis

Strengths

6. System of commissions for immunization adverse reactions (federal, cantonal)

7. Counseling board for immunization at Federal ministry of health

8. System of EPI coordinators (federal, cantonal, local)

9. Regular meetings of federal and cantonal EPI coordinators

10. Regular immunization reporting
SWOT analysis

Weaknesses

1. Multi dose vaccine vials with higher wastage
2. OPV vaccine is still in use
3. Possible lack of information about benefits of immunization
4. False contraindications
5. Different vaccine schedule in Federation of Bosnia and Herzegovina and in Republic of Srpska and in Brcko District

(These 3 entities belongs to Bosnia and Herzegovina)
(Infected disease do not know entity barriers)
SWOT analysis

Opportunities

1. Introduction of new vaccines
2. Campaign programs to reach some low accessible ethnic groups (i.e. Roma people) and social poor people
3. Campaign programs to increase knowledge level of vaccines' safety and benefits
4. Continuously medical education of medical professionals
5. Renew elements of "cold chain"
SWOT analysis

Threats

1. Anti vaccination campaigns (Citizens' organization "Report your pediatrician", media rumors, false vaccine accusation...etc.)
2. Low accessibility and low immunization coverage of some ethnic groups (i.e. Roma people) and social poor peoples
3. Procurement problems with immunization process delay
4. Possible technical problems with old refrigerators on local levels
5. Low immunization coverage is the weak point of immunological barriers to infectious diseases (95% of coverage should be considered as immunological barrier to infectious diseases

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SWOT analysis

S/T strategies to avoid threats

1. Giving quality information to media
2. Special access to specific ethnic groups
3. Procurement with contracts for longer period
4. Procurement of new devices for cold chain
5. Decrease number of false contraindications
SWOT analysis

S/O strategies for advancement

1. 5 (6)-in-one vaccines (pentavalent, hexavalent)
2. Involvement of people from specific ethnic groups
3. European week of immunization (every year manifestation)
4. Professional meetings about immunization
5. Increasing levels of awareness of cold chain
SWOT analysis

W/O strategies to overcome weaknesses

1. Improving vertical system of reporting
2. Emergent phone report in a case of crisis situation
3. Education about communication in a case of crisis situation
4. Creating common strategy for treating "gaps" of immunization
5. Performing "national" and "subnational" days of immunization in a case of need
SWOT analysis

W/T strategies to avoid and overcome threats

1. Creating leaflets about immunization benefits
2. Implementation of using single dose vaccine vials
3. Implementation of use IPV instead of OPV vaccine
4. Education of medical professionals about contraindications
5. Creating unique immunization schedule for B&H

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Thank you for your attention
Vielen Dank für Ihre Aufmerksamkeit
Greeting from Bosnia and Herzegovina
Hvala Vam na pozornosti
Ďakujem Vám za Vašu pozornosť

14 September 2015