

Comments in response to the Government's expert statements

Impact of the vaccination on lowering of mortality

The Government states that since the introduction of compulsory vaccination, occurrence of deaths caused by the diseases has radically decreased. However, as it is apparent from the graphs of mortality rates regarding particular diseases¹, which cover decades before the vaccination has been introduced, vaccination itself could have only minimal impact on lowering the mortality caused by the communicable diseases. The only exception might be polio vaccination, which could have significant impact on morbidity rates.

Argumentation of the Government in this regard contradicts the known statistical data. It shall be borne in mind that correlation is not causality, in other words, time sequence does not mean casual relation (and we believe the Government is well aware of this fact given that they use the same argument when talking about health issues that occurred after the vaccination). This rule also applies to the introduction of vaccination and subsequent decrease of mortality rates – these two things in fact does not necessarily need to be related, although the decrease of mortality rates followed introduction of the vaccination. Judging by the development (significant decrease) of mortality which occurred prior to the introduction of vaccination, it is very possible that these two things are not related at all.

Susceptibility of infants to infections

Some of the infections truly more often affect infants and are more dangerous for them. The same, however, is also true for vaccination - in early age the vaccination is much more unsafe, as evidenced by the fact that the toxicity is being indicated in unit numbers per kilogram per day, which means that the same vaccine (containing e.g. neurotoxic aluminum compound, formaldehyde and trace amounts of mercury) is considerably more dangerous to a 5kg weighing infant than to a 15kg weighing toddler.

The problem is that damage of certain brain centers which are responsible for managing of higher brain functions, become apparent only at the later age of life of a child (in three or more years of age), when the nervous system of the child is more developed. Therefore (almost) nobody connects vaccination in the first year of life of a child with these brain damages, even though vaccination could have caused them. If the children were vaccinated only after two or three years of age, the link would be more obvious, which is probably the reason for the misconception that younger children handle vaccinations better than older ones.

Use of hexa-vaccine

While the use of combination vaccine minimizes the stress of the child of an injection, it also increases the onetime burden placed on the immune system, ie. acute toxicity. It is logical that if the vaccine against several different diseases is administrated in one dose (acute toxicity), the immune system of a child is much more burdened than it would be if the vaccines were administrated in more but smaller doses (chronic toxicity). For an explanation and better imagination, administration of the vaccine can be compared to drinking an alcohol. Although one shot of the hard alcohol once a week for one year

¹ See <https://childhealthsafety.wordpress.com/graphs/> or TUHÁRSKY, P.: Štatistiky: infekčné ochorenia a očkovanie. 2015. (a review article covering relevant data and citations of originál sources, available only in Slovak)

(50ml) will in sum be equal to amount of more than one liter, one liter of alcohol drunk at once will definitely cause more harm than that one shot per week.

Referring to the opinion Czech Vaccinology Society (CVS), the Government also argues that the immune system of infants is not fully developed especially as regards protection of the body against some of the bacteria causing invasive diseases (e.g. *Haemophilus influenza b*). According to the CVS the hexa vaccine in use contains such components that enable the children to overcome the immaturity of the immune system to provide protection against haemophilus infections. This argument, however, may be valid only in case of children who are not being breastfed. Children who are breastfed by their mothers are passively protected by the antibodies produced by bodies of their mother, given that virtually every mother (even if not vaccinated against haemophilia) has come into contact with these bacteria, since they are widespread (over 17% of the population may be asymptomatic carriers of the haemophilia).²

Nationwide vaccination against haemophilia in this regard makes no sense given that it has no practical benefit for the breastfed children.

As regards vaccination against Hepatitis B virus, although it is fact that this virus has the worst impact on small children, at the same time it is fact that these children are least likely to become infected provided that they do not belong to risk group (meaning mainly children of HBsAg-positive mothers). Expert opinion, drawn up by Czech specialists before the introduction of this vaccination had not recommended mass vaccination.³ Ministry of Health of the Czech Republic, however, failed to take this opinion into account, what's more, without any justification.

MMR vaccine in the Czech Republic (vaccination against measles, mumps and rubella)

Argumentation by the mortality from measles in developing countries (see page no. 5) is irrelevant, since, unlike in the Czech Republic, malnutrition, which is a secondary immunodeficiency (decreased immunity) is common in those countries which indicates that a similar occurrence of such diseases in the conditions of the Czech Republic would most probably lead to much lower (possibly zero) mortality. England and Wales recorded 96.525 measles diseases between 1993 and 2013, but there was only one death from acute measles and two deaths that occurred in people with severely disrupted immune system. Some deaths occurred as "late effects of the disease from the '80s."⁴

When the Government refers to the fact that the number of child deaths caused by measles reached 770.000 worldwide in 2000, it needs to be added that 85% of these deaths is attributable to poor countries in Asia and Africa.⁵ Fact is that, as mentioned above, the mortality from measles has decreased in developed countries before the nationwide vaccination was introduced.

² See http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0041-87812004000500003

³ http://www.rozalio.cz/images/PDF/hepb_zaverecna_%20zprava_helcl_1995.pdf (available only in Czech) or Helcl, J., DrSc., SZÚ, Částková, CSc., Švandová, CSc., Beneš, MUDr.: Podklady pro strategii očkování proti virové hepatitidě typu B v ČR. Závěrečná zpráva o řešení grantu interní grantové agentury MZ ČR. SZÚ. Reg.č.: E/2478-1

⁴ Public Health England: Measles notifications and deaths in England and Wales, 1940 – 2013.

⁵ See Mishra A, Mishra S, Lahariya C, Jain P, Bhadoriya RS, Shrivastav D, Marathe N. Practical observations from an epidemiological investigation of a measles outbreak in a district of India. Indian J Community Med. 2009 Apr;34(2):117-21. PMID: 19966957. PMCID: PMC2781117. DOI:10.4103/0970-0218.51234; or MMWR: Morb Mortal Wkly Rep. 2009 Dec 4;58(47):1321-6. PMID:19959985.

Subacute sclerotizing panefencalitis (SSPE) can be also caused by the vaccination and given the current ration of number of vaccinated persons against those who naturally fell ill by measles; it is far more likely that the SSPE would be caused by vaccination rather than by wild virus.

Also the argumentation by world numbers in 1963 is irrelevant. Since that time, many other (besides vaccination) anti-epidemic measures have been introduced (e.g. clean drinking water, better nutrition, better hygiene, sanitation, food safety control etc.). Therefore today a similar rate of morbidity would result in significantly lower mortality.

With regard vaccination against mumps (see page no. 6), this vaccination is completely counterproductive because in practice, it leads to shifting of the disease incidence from the less risky age (3-12 years of age) to the age when the risk of infection is much higher (from puberty to adulthood). Furthermore, the serological report of 2013 clearly shows that people who have been vaccinated as children have minimum of antibodies. Vaccination against mumps thus actually destroys the original collective immunity.⁶

As to the dangerousness of the rubella to pregnant women and unborn child (page no. 6), argumentation of necessity of vaccination is only applicable to adult women (or teenage girls) but definitely not to toddlers. Also other viruses, such as flu or varicella are teratogenic (fetus damaging) and yet, there is no nationwide compulsory vaccination against these viruses. As regards the claim that mumps infection of pregnant women may result in abortion more likely than in case of rubella, the Government does not provide reference to any scientific source, which would confirm this. According to the study from 2005, there was no increased risk of miscarriage in connection with the mumps.⁷

Moreover, MMR vaccine itself may cause diseases or spread the vaccine viruses, and thus cause precisely what it was supposed to prevent.⁸

The Government claims that the most effective and also the most important preventive tool in the protection against these diseases remains MMR, which protects the individual from infection and in case of high vaccination coverage, which achieves collective immunity prevents circulation of infectious agents in the population (see page no. 7). This conclusion, however, have not been scientifically proven yet. It has been proven that vaccinated people are being commonly infected during the epidemic, but the disease has only mild course or it is subclinical. It is also known that these people can spread the virus in their surroundings. It is not known to what extent they are infectious.⁹ It has also been shown

⁶ See graph on the page no. 38 here <http://www.zuusti.cz/wp-content/uploads/2015/04/SP-2013-vnit%C5%99ek-do-TISKU.pdf> (note that the vaccination begun in 1987 and there is a noticeable difference between a group of 25-29 years old people (the first to be vaccinated) and a group of 30-40 years old people (the last not vaccinated)).

⁷ Enders M, Rist B, Enders G. [Frequency of spontaneous abortion and premature birth after acute mumps infection in pregnancy]. *Gynakol Geburtshilfliche Rundsch.* 2005 Jan;45(1):39-43. PMID:15644639

⁸ See <http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19652>

⁹ Hickman, C. J. et al: Laboratory characterization of measles virus infection in previously vaccinated and unvaccinated individuals. *J Infect Dis.* 2011 Jul;204 Suppl 1:S549-58. PMID: 21666212

Sheppard, V. et al: Vaccine failures and vaccine effectiveness in children during measles outbreaks in New South Wales, March-May 2006. *Commun Dis Intell.* 2009 Mar;33(1):21-6. PMID: 19618764

Mossong, J. et al: Modeling the impact of subclinical measles transmission in vaccinated populations with waning immunity. *Am J Epidemiol.* 1999 Dec 1;150(11):1238-49. PMID:10588085

Pedersen, I. R. et al: Subclinical measles infection in vaccinated seropositive individuals in arctic Greenland. *Vaccine.* 1989 Aug;7(4):345-8. PMID:2815970.

that the vaccination protect only against 10 out of 20 strains of virus.¹⁰

In reality, when an epidemic occurs, overwhelming majority of people who get infected are those who have been vaccinated against the disease (see e.g. epidemic of pertussis in California in 2010 when 92% of the sick have been vaccinated¹¹; or epidemic of mumps in New York with 97% of the sick being vaccinated¹²; or even epidemic of measles where all of the sick have been vaccinated occurred¹³).

Negative impact of non-vaccination

Claim that children who do not undergo vaccination in accordance with the vaccination schedule are more at risk (page no. 8) is also misleading. Even if a child is vaccinated according to the vaccination schedule, they do not necessarily will be protected against the concerned disease (CVS itself admits this fact on page no. 7). Also according to documents from post-marketing surveillance as well as from the outcomes of clinical studies, mere temporal division of the vaccination by hexa vaccine and pneumococcal vaccine would probably may reduce the incidence of neurological complications of vaccination up to four times.¹⁴

At a later age, side effects of vaccination have acute and “external” character (higher fever, swelling at the injection site, etc.). On the other hand, long term (chronic) side effects (such as immune disorders or neurological disorders) are less common if the vaccination takes place at later age.

As regards the collective immunity argument, Government’s claim that “unvaccinated population poses a risk to anyone, allowing the spread of the disease in the society” must also be refuted. As already mentioned, the tetanus vaccine has absolutely no effect on the spread of the disease and as regards diphtheria and polio, such ability is also very questionable. Live polio vaccine, which had this ability for a short time, paradoxically has also an ability to spread the virus in the population (this, however, is irrelevant, since it is no more in use in western countries or in the Czech Republic).

“Efficiency” of the vaccine against mumps can be monitored in the epidemic outbreaks in the Czech Republic and Slovakia in recent years, where the epidemics takes places almost exclusively among young, fully vaccinated people. This is a serious evidence of the ineffectiveness of the vaccines in the

Lisse, I. et al: Acute and long-term changes in T-lymphocyte subsets in response to clinical and subclinical measles. A community study from rural Senegal. *Scand J Infect Dis.* 1998;30(1):17-21. PMID:9670353.

Damien, B. et al: Estimated susceptibility to asymptomatic secondary immune response against measles in late convalescent and vaccinated persons. *J Med Virol.* 1998 Sep;56(1):85-90. PMID:9700638

Wu, T. – Wang, S. L. – Xiang, Y. Z.: [Study on the subclinical infection of the recipients of measles vaccine]. *Zhonghua Liu Xing Bing Xue Za Zhi.* 1996 Apr;17(2):70-2. PMID:8758397

Fathy, M. M. – el-Khashaab, T. H. – Darwish, M. A.: Antibody level after measles vaccination. *J Egypt Public Health Assoc.* 1992;67(3-4):369-78. PMID:1296968

Lee, M. S. et al: Protective titres of measles neutralising antibody. *J Med Virol.* 2000 Dec;62(4):511-7. PMID:11074481

¹⁰ Klingele, M. et al: Resistance of recent measles virus wild-type isolates to antibody-mediated neutralization by vaccinees with antibody. *J Med Virol.* 2000 Sep;62(1):91-8. PMID:10935994

¹¹ <http://cid.oxfordjournals.org/content/54/12/1730.full>

¹² <http://www.nejm.org/doi/full/10.1056/NEJMoa1202865>

¹³ <http://www.ncbi.nlm.nih.gov/pubmed/8483623>

¹⁴ Prevenar – Scientific Discussion. WC500041560. EMA/EPAR 2005

Prevenar 13. Pneumococcal saccharide conjugated vaccine, 13 valent adsorbed. PSUR 04 - Response to RSI Neurological Events

a half generation until the majority of those who had overcome the disease naturally die off.¹⁷

In any case, collective immunity argument lacks validation in cases of:

- Tetanus (this disease cannot be transmitted from human to human)
- Diphtheria (vaccine does not produce any antibodies against the causative agent of the disease – bacteria – but only against its products – toxins)
- Polio (inactive vaccine used in the Czech Republic is capable of protecting the vaccinated but after being infected by a wild virus, the vaccine does not reduce multiplication and excretion of the virus)
- Pertussis (acellular vaccine used in the Czech Republic in fact prolongs the infectivity period of the infected but vaccinated individual as compared to non-vaccinated one¹⁸)
- Furthermore, there is no real vaccine-induced collective immunity as regards:
- Hemophilia (majority of the population has not been vaccinated and large part of population are asymptomatic carriers of this disease)
- Pneumococci (once again, majority of the population has not been vaccinated and large part of population are asymptomatic carriers of this disease)
- Mumps (majority of the population has not been vaccinated and the vaccination only leads to shifting of the morbidity to higher age – see above)

To sum up, vaccine-induced collective immunity argument is not valid as regards the majority of the compulsory vaccinations in the Czech Republic.

Some additional information regarding selected diseases

POLIO¹⁹

Government claims that vaccination against polio is a part of a global program of the WHO for the eradication of this disease. This disease is already almost eradicated – there is only approximately 2000

¹⁷ For more details on collective immunity see http://rizikaockovania.sk/dok/Kolektivna_imunita-myty_a_fakty.pdf

¹⁸ See <http://www.pnas.org/content/111/2/787>

¹⁹ TUHÁRSKY, P.: Hovorme o vede 33) Poliomyelitída: Velká dilema. Dieta 2016:3. ISSN 1335-0919

Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Wolfe S, Hamborsky J, eds. 13Th ed. Washington DC: Public Health Foundation. 2015. Chapter 18. Poliomyelitis

SHAHZAD, A.: Time for a worldwide shift from oral polio vaccine to inactivated polio vaccine. Clin Infect Dis. 2009 Oct 15;49(8):1287-8. doi: 10.1086/605691. PMID:1978066

KEW, O. et al. Circulating vaccine-derived polioviruses: current state of knowledge. Bull World Health Organ 2004 Jan;82(1):16–23. PMID:15106296

JAFARI, H. et al: Polio eradication. Efficacy of inactivated poliovirus vaccine in India. Science. 2014 Aug 22;345(6199):922-5. doi: 10.1126/science.1255006. PMID:25146288

FRANCIS, T. Jr. et al.: An evaluation of the 1954 poliomyelitis vaccine trials. Am J Public Health Nations Health. 1955 May;45(5 Pt 2):1-63. PMID:14361811. PMCID: PMC1622939

HENRY, J. L. et al: A study of poliovaccination in infancy: excretion following challenge with live virus by children given killed or living poliovaccine. J Hyg (Lond). 1966 Mar;64(1):105-20. PMID: 5219018.PMCID: PMC2134687

cases per year and these cases are mostly in 5 specific developing countries.

While it is true that vaccination against polio is part of the program, but not in the form in which it is used in the European developed countries.

This (inactivated) vaccine, which is a part of the hexa vaccine, has no ability to eradicate the disease, which is also known by the WHO. No significant anti-infective effect of this vaccine has been proven. Clinical studies have not shown a reduction in the number of mild infections, they have shown only reduction of the risk of serious complications caused by the disease by about 72% in overall frequency of occurrence of the strains of poliovirus. Vaccination works by reducing the risks and intensity of viraemia and thus reducing the risk of penetration of the virus into the brain. Although facts are favorable for vaccinated individuals, they do not present any protection for the society as a whole.

Also the duration of the effect of the vaccination has yet been proven to last only for 10 years. Longer effect is only assumed. Majority of the population may thus fall outside the protective effect of the vaccination even in a hypothetical case when 100% of the children would be vaccinated.

These facts are also known to the scientific community (CDC and WHO) and they cause difficulties in determining the final eradication vaccination strategy. If this was not the case, there would not be any dilemma whether to vaccinate by live or inactivated vaccine, or what combinations to use. Based on these reasons, all of the current plans on eradication of the disease in various combinations calculate with live oral vaccine, which have not been in use in western countries (neither in the Czech Republic) for a long time.

DIPHTHERIA, TETANUS

According to the Government vaccination against diphtheria and tetanus represent another established vaccinations based on the effectiveness of the vaccination leading to a reduction of the risk of contagion.

These vaccines have virtually no effect on the risk of contagion of humans, because they are just toxoid vaccines. No component of these vaccines prevents contagion – an infection caused by pathogenic bacteria. Effect of the vaccine may be manifested only if the bacteria begin to produce a specific toxin during the infection, since the vaccine is solely designed against this toxin. When the vaccine prevents the activity of the toxin, also development of serious complications caused by the toxin can be prevented by the vaccine. This is a short description of the mechanism of how this vaccine works. It means that the vaccine does not contain any component that would fight against the bacteria itself.

The fact that these vaccines have no effect on the risk of infection is particularly evident for tetanus, wherein the transmission takes place via contaminated wounds. Put simply, the vaccine cannot prevent a child stepping on a rusty nail.

As regards the diphtheria, the ability of the vaccine to directly reduce the transmission of the disease by reducing the severity of the disease is currently being considered; however, so far it is just a hypothesis with a wide range of uncertainties and minimal evidence which is based only on a narrow interpretation of epidemiological data.

Just as well, one can imagine the opposite effect – mild symptoms of the disease by vaccinated individual will not lead to an isolation of this individual, will not be diagnosed a consequently will help spreading

of the illness. On the other hand infection of the unvaccinated individual will lead to typical symptoms which will be diagnosed and the individual concerned will be isolated and anti-epidemic measures will be taken, thus the disease will not spread amongst the population.

According to the legitimate expert opinions, even those of official authorities (Public Health Office of the Slovakia), diphtheria bacteria spread within the population regardless of the vaccination. Vaccination shall prevent the disease to break in its full seriousness in a particular individual. Thus the protection provided by the vaccine is purely personal and not collective.²⁰

It is important to say that in years 2009-2018 there was no case of diphtheria in the Czech Republic.²¹ Why this vaccination stays mandatory for admission to kindergarten and other child's groups stays unclear and unsupported by evidence.

MUMPS²²

It is a mild disease which is mostly connected to orchitis and sterility. Orchitis occurs approximately in one fifth of adolescent and adult patients. As regards younger children, it is far less common.

Weakening of the spermatogenesis affects approximately 13% of the cases of orchitis and in vast majority of cases only temporarily. Permanent damage of testicles caused by inflammation is very rare. Inflammation is usually one-sided. Permanent bilateral sterility is considered a medical curiosity.

RUBELLA

As regards rubella and the congenital rubella syndrome (CRS), it is necessary to point out the significant increase of CRS in USA after the introduction of vaccination and persisting for about two decades.²³

²⁰ For more detailed information see: TUHÁRSKY, P.: Hovorme o vede 26) Záškrť: Viac otázok ako odpovedí. Dieťa 2015:07. ISSN 1335-0919

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<http://www.szu.cz/publikace/data/2018/vyskyt-vybranych-infekci-v-ceske-republice-hlasenych-y?highlightWords=V%C3%BDskyt+vybran%C3%BDch+infekc%C3%AD>

²² For more details see following sources:

CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W et al. 10th ed. Chapter 14 - Mumps.

Yung CF et al. Mumps complications and effects of mumps vaccination, England and Wales, 2002-2006. Emerg Infect Dis. 2011 Apr;17(4):661-7. PMID:21470456

Barskey AE et al. Mumps outbreak in Orthodox Jewish communities in the United States. N Engl J Med. 2012 Nov;367(18):1704-13. PMID:23113481

Ternavasio-de la Vega HG et al. Mumps orchitis in the post-vaccine era (1967-2009). Medicine (Baltimore). 2010 Mar;89(2):96-116. PMID:20517181

Tae BS et al. Clinical features of mumps orchitis in vaccinated postpubertal males. Korean J Urol. 2012 Dec;53(12):865-9. PMID:23301132

Rubin SA et al. Recent mumps outbreaks in vaccinated populations: no evidence of immune escape. J Virol. 2012 Jan;86(1):615-20. PMID:22072778

²³ Watson JC, Hadler SC, Dykewicz CA, Reef S, Phillips L. Measles, mumps, and rubella--vaccine use and strategies for elimination of measles, rubella, and congenital rubella syndrome and control of mumps: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep. 1998 May 22;47(RR-8):1-57. PMID:9639369;

Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Wolfe S, Hamborsky J, eds. 12th ed., second printing. Washington DC: Public Health Foundation. Chapter 19. Rubella

Rubella issue is much more complex than presented. Vaccination does not reach the level of protection as needed to overcome the disease. Vaccinated women are at higher risk of reinfection and higher risk of fetal harm (CRS) than women with natural immunity²⁴.

Before the vaccination has been introduced, 85% of girls got permanent and reliable immunity by going through the mild disease in childhood. The first vaccination schedule required rubella vaccination only for girls over 12 years of age, who have not been immune yet. This approach was far more legitimate than the present one, where all the children, including boys, are forced to be vaccinated twice.

It would be legitimate solution to leave the decision to adult women, who have not yet acquired immunity to get vaccinated before starting a family. The number of rubella vaccination could thus drop 30 – 100 times. It is not ethically correct to enforce medical intervention on young children, given that this intervention has no practical importance and basically serves only to hypothetical protection of fetus of those women who, due to their own irresponsible approach to parenting became pregnant and there is a high probability that they will not be willing to bear the full term.

²⁴ Dontigny L et al. Rubella in Pregnancy. SOGC Clinical Practice Guidelines No. 203, February 2008; Horstmann DM et al. NEJM. 1970 Oct 8;283(15):771-8. PMID:5456233; Baba K et al. Biken J. 1978 Mar;21(1):25-31. PMID:666723; MMWR. 1991 Feb 15;40(6):93-9. PMID:1899464; Cradock-Watson JE et al. J Hyg (Lond). 1981 Oct;87(2):147-54. PMID:7288170