

Minutes # 4
of the meeting of Scientific and Technical Expert Group on
Immunoprophylaxis dated 21.11.2012

Agenda:

1. Issues concerning the introduction of pneumococcal vaccine into the Kyrgyz Republic
2. Issues concerning the introduction of rotavirus vaccine into the Kyrgyz Republic.

In attendance were:

1. N. Zh. Babadzhanov, Chief of the Pathologic Perinatal Life Department of the National Center for Maternal and Child Welfare, Candidate of Medical Science
2. Zh. S. Kalilov – Head of the Republican Center for Immunoprophylaxis
3. Batmunkh Nyambat - Research Scientist International Vaccine Institute Seoul, South Korea SIVAC
4. B. M. Barktobasova – Specialist of the Centre for Health Care Development and Information Technology
5. Z. Sh. Nurmatov, Head of the Sanitary Epidemiological Supervision Department, Candidate of Medical Science, SSES
6. K.T. Kasymbekova, Head of the Centre of microbiological molecular and genetic tests of the State Sanitary Epidemiological Supervision Department, Doctor of Medical Science
7. O.V. Safonova – Deputy Head of the Republican Center for Immunoprophylaxis
8. D.K. Chynyeva – Associate Professor of Pediatric Infection Chair of the Kyrgyz State Medical Academy, Candidate of Medical Science
9. V.S. Toigonbaeva – Head of the Chair of microbiology, virology, immunology, epidemiology of the Kyrgyz-Russian Slavic University, Candidate of Medical Science
10. M.E. Ashiraliev – Doctor of Medical Science, Chief of the Allergology Department of the National Center for Maternal and Child Welfare
11. K.A. Jumashaeva – Chief of the Clinic Diagnostic Department of the National Center for Maternal and Child Welfare
12. G.A. Miristenova – Chief Doctor of the National Center for Maternal and Child Welfare
13. R.K. Usmanov – Chief of the Centre for Virological Tests of the PM NGO, Doctor of Medical Science, Professor
14. A.A. Bure – Chief Doctor of the Family Practice Center # 11, Bishkek city
15. S.T. Mukeeva – Head of the Family Group Practice Association (FGPA)
16. A.K. Imakeev – MCHIP Project
17. N.M. Mamasadykov – Chief Doctor of the State Sanitary Epidemiological Supervision Center, Bishkek city
18. B.Sh. Asykbekova – Doctor of Immunology, State Sanitary Epidemiological Supervision Center, Bishkek city
19. T.R. Buteshov – Epidemiologist of the Republican Center for Immunoprophylaxis
20. G.Zh. Zhumagulova – Pediatrician- Immunologist of the Republican Center for Immunoprophylaxis
21. O.D. Plotnikova – Pediatrician- Immunologist of the Republican Center for Immunoprophylaxis

The meeting was opened by Mr. N.Zh. Babadzhanov, the Chairman of the Scientific and Technical Expert Group on Immunoprophylaxis (STEGI)

- When the “Immunoprophylaxis” National Program 2012-2016 was adopted, it included the section “introduction of new vaccines,” whereby 2 vaccines such as pneumococcal and rotavirus should be introduced into the Republic in 2013 and 2014. But the approach in those times was wrong, as we had to introduce 2 vaccines for 2 years. If to cite the neighboring Republic of Kazakhstan as an example, they have been implementing in phases one pneumococcal vaccine within the period of 3 years. Wherefore, as of today we must review our strategy of introduction of the vaccines, which are included in a list of the Global Alliance for Vaccination and Immunization (GAVI) and lend support to low-income countries. The meeting of the Technology Advisory Group on Immunoprophylaxis was held in Copenhagen from 3 to 4 October, 2012. The composition of this Committee has been completely renewed, and having heard the presented material, the role of this Committee looked great. And the subsequent strategy of the National Program will depend on us currently. For instance, which decisions or recommendations will be given by us to the Ministry of Health.

The European Committee considered global issues, and for the moment they raised a question concerning introduction of the strategy for adult population vaccination.

Calendars of Prophylactic Immunization are revised as the vaccines are combined and the inoculating terms are changed etc.

Now the anti-vaccination campaigns are conducted in our country and not only in Kyrgyzstan, therefore we need the global plan of actions concerning data. According to the plan 2 meetings had to be held per annum, but because of previous adverse factors in immunization sphere, we have to meet more frequently.

Today the issue on pneumococcal and rotavirus vaccine appears on the agenda.

Therefore, today I would like to hear experts and accord the right to speak first to Olga Dmitrievna Plotnikova.

Speech of O. D. Plotnikova

- This information is prepared by the working group jointly with G.S. Kitarova.

The information was submitted concerning pneumococcal infection serotype, vaccination purposes, risk of development of severe pneumococcal infection in the children from “risk group”, forms of serotypes and specific mortality from pneumococcal infection among children under five years of age in Asia, kinds of vaccines and their efficiency and safety, vaccination terms and PCV introduction into Kazakhstan.

Speech of D.K. Chynyeva

She submitted the material on pneumococcal meningitis morbidity in the Kyrgyz Republic and showed the ethiology, pathogenesis and clinical picture in children at pneumococcal infection, strains prevalence rate all over the world, morbidity and mortality from meningitis in 2004-2005, comparative analysis of age composition of the sick, classification of pneumococcal diseases as well as the graphical data of medical research conducted in Bishkek with regard to meningitis morbidity.

N. Zh. Babadzhanov – Why laboratory tests were not conducted in Kazakhstan when introducing pneumococcal vaccine?

Answer of O. D. Plotnikova – Such data are not available, but as already mentioned in presentation, the introduction was based on the WHO experience and the country didn’t conduct any tests.

N. Zh. Babadzhanov – Whether the specialists of Kazakhstan know which serotype of pneumococcal infection prevails?

- The presentation concerned that immunization reactions are not registered in Kazakhstan. Whether severe reactions are rather not available? The reactions after vaccine will be in any case, and thus we misinform people saying that vaccine is non-hazardous. And when the child has temperature after vaccine, the mother is struck with panic, therefore it is necessary to say that the reactions will take place but insignificant.

Answer of O. D. Plotnikova – According to SDS, any local reactions are possible, but there are no severe complications, toxic and other bacterinia.

N. Zh. Babadzhanov – It is necessary to define more precisely financial and economic data, as the vaccine cost for the European countries is 200 US dollars. And which cost will be for Kyrgyzstan? How much vaccine per year will be required?

Answer of O. D. Plotnikova – If today we decide to introduce this vaccine, then we will discuss with the GAVI, upon which terms the deliveries will be made?

O.V. Safonova – If under the auspices of GAVI the pneumococcal vaccine cost for Kyrgyzstan is 0,20 US dollars, then upon completion of support from GAVI we will pay for vaccine under general conditions, notably 30 US dollars per a dose. The annual demand for vaccine will be 500 000 doses.

N. Zh. Babadzhanov – Therefore the groups were to have estimate every nicety, such as what is the price under the auspices of GAVI and what is the price without support and what amount will be required from the Republican budget?

O.V. Safonova – The additional amount of 16 million soms will be required from budgetary funds to procure this vaccine. Currently under the auspices of GAVI the immunoprophylaxis budget is 30 million soms.

M. Ashiraliev – How many per cents are spent by pneumococcal infection? And why should we speak about prices, when our tests don't determine, and in fact there are not laboratory tests?

V.S. Toigombaev – So far, we should not speak about prices, as all data are stale, and we must plan the additional study of this question, i.e. laboratory diagnostics etc. And we must find a person who will study extensively this question, and it will take about 5-6 months in order to make epidemiological conclusion and to make further decision on whether the vaccine should be introduced or not.

K.T. Kasymbekova – The report stated that the pneumococcal vaccine is used for treatment purpose, the manner in which it is used and upon which conditions. For that laboratory confirmation is required, because the vaccine is specific, i.e. it is used for prophylactic purposes rather than for therapy.

Answer of O. D. Plotnikova – For therapy purposes it is exclusively used for patients with chronic diseases, chronic bronchitis, bronchial asthma etc. and only pneumo-23 is used.

M. Ashiraliev - The reports stated that there are many antibiotic-resistant strains in Spain. What is the reason for that? In fact, medicinal drugs are not dispensed without a prescription.

Answer of D.K. Chynyeva – More likely it is as in Kyrgyzstan, when you come to a drugstore, and they recommend amoxicillin or biseptol or other antimicrobials, which have not been helping long before in case of diseases.

B.M. Barktabasova – Brief comments on 2 presentations

1. When selecting between vaccines PCV7 and PCV 13, it is necessary to rest upon PCV 13 definitely, as it has already confirmed its efficiency, safety and more wide coverage of serotypes.

2. As to firm names, one must view the subject differently. Select the vaccine which conforms to the international requirements and has the quality certificate, as well as on a tender basis, when according to the rules the conditions will be announced and the product suitable for your country in terms of safety will be selected.

3. Vaccine procurement – Our country can not be compared with Kazakhstan, as it is not able to afford free oncological and vaccination agents for the population. This variant must be excluded, as our Republic won't conform to such conditions. It is possible only under donor support. It should be appreciated that there is a concept "Medical equipment assessment," i.e. one must size up the situation in our Republic concerning our economic problems before introducing vaccine into the Republic.

At present the World Health Organization accepts the terms and conditions of integration, regions are united, i.e. nobody prohibits us to unite with Kazakhstan and Uzbekistan. It is a political issue, when the total volume is purchased, the part of which would be intended for our state. Thus we can preserve those 0, 20 US dollars as against 30 US dollars, namely the vaccine cost can be decreased by several times and be accessible.

4. It was questionable why the phased introduction of pneumococcal vaccine was in Kazakhstan. This is due to in Kazakhstan there is one region bordering the territory of Kyrgyzstan and due to the population rate. Our country has a great pull when introducing the vaccine, as it is compact. The system of experience of vaccines introduction is available, and it can come into action again. Regard must be paid to organization, and the policy of the Ministry of Health and the strategy and documentation should be available.

5. As to research, presentations stated that according to the evidentiary medicine principle, the epidemiological research should be conducted in a mandatory manner. Sure, it is actually right that each country should know its profile, but we can again face the challenge such as financial barrier. There are no finances for research.

As to laboratories, it was stated that no adequate laboratory is available. Therefore, the laboratories of the State Sanitary Epidemiological Supervision Department, State Sanitary Epidemiological Supervision Center and all our National laboratories will not find pneumococcus, as strains, chemical reagents and standard procedures are out of date. The international experts appraised our laboratories at the rate of 80%, and accordingly our results are not always correct and we will hit the jackpot. Namely, the absence of research should not be counter-indication for vaccination. The specialists from the RF said us that they conducted research and compared their results with the results of other CIS countries, and to a greater extent strains overlap each other, and that PCV 13 can be used in Kyrgyzstan.

7. In addition it was stated that 1 person should conduct research. It extremely contradicts the arrangement of adequate research design. The reproductive epidemiological research of country significance should be conducted. 1 person will not manage it, and we have not such scientific potential so that it should make it. But we can rely on the international practices.

8. As regards postvaccinal complications, the immunization reactions will be always, and we should not deceive the child parents, and on the contrary any doctors should warn that any reactions are possible and what they must undertake.

V.S. Toigombaeva – Certainly, 1 person will not be able to conduct all of those researches. On this account a coordinator is required.

N. Zh. Babadzhanov – In order to conduct research prior to introducing the pneumococcal vaccine into a particular country, many projects were submitted to the WHO, but the WHO said that such researches had been already conducted, and there is no sense to finance again a similar project.

N. Zh. Babadzhanov – Damira Kamchibekovna, what is the situation on meningitis morbidity? Did it become less frequently or is it still becoming more pronounced?

Answer of D.K. Chynyeva – Now meningococcal and pneumococcal meningitis is beginning to decline, but Hib meningitis takes place. According to frequency the meningococcal meningitis takes the first place, pneumococcal meningitis takes the second place and Hib meningitis – third place, few as they are.

Z.Sh. Nurmatov – One must be governed by statistical data and from there it is necessary to view an etiological structure. Unfortunately, our evaluation of statistical and laboratory data is not coordinated, and the laboratory doesn't carry out the work, which shall be executed on infection morbidity by the State Sanitary Epidemiological Supervision Department. Moreover, the methods of pneumococcus isolation are very complicated.

B.M. Barktabasova – Additional comments

- There are confirmations that the pneumococcal vaccine is cost-efficient. It has been proved, that the value of disease burden is higher many times for society and each patient separately and for the health care system as a whole. But whether we have funds to reach that moment, when we will be able to vaccinate all people and will receive this cost effectiveness? Economic expenditures and cost-effectiveness are estimated in many counties and show the same result. Perhaps it is not sensibly in the developed countries, but it will be sensibly in the developing countries expressly. We connected with the RF Scientific Center of Children's Health, and they advised to include this vaccine in the Calendar of Prophylactic Immunization.

N. Zh. Babadzhanov – As regards safety I'd like to say that we always speak of adverse health effect of vaccines, but nobody wonder when any doctors prescribe cefazolin for sick child having bronchitis or pneumonia, but it is crime and nobody speaks of that cefazolin is prohibited for children. So what is more harmless? The question of immunization reactions had been discussed with Kazakhstan specialists, but they said that no reactions and complications are available. And in my opinion, today we should include this vaccine in the Calendar of Prophylactic Immunization.

M.E. Ashiraliev – I also think that the pneumococcal vaccine must be included in the Calendar, as I am engaged in treatment of bronchitis, bronchial asthma, and pneumonia in children. As mentioned above, the laboratories don't operate. The Bonetskiy laboratory began to conduct tests 20 years ago, nevertheless they analysis are not correct. I say that I am agreed, but only with one nuance, we have not and will not have any adequate laboratory diagnostics of pneumococcal infections.

K.T. Kasymbekova – The laboratory service moves forward. Certainly, at present we have not diagnostics, but have delivery of PCR laboratory all over the country, and currently 5 regions of the country are provided. As to the private laboratories, it is other sphere, private interests and commerce, and they will not be interested in studying our problems. As regards the state laboratories, these issues must be raised somewhere. It is necessary to purchase test-systems, and these laboratories will conduct research and solve our tasks. There is expensive equipment in some laboratories and they must be use in full.

N. Zh. Babadzhanov – Possibly we will use the variant of Zurdin Sharipovich. While introducing the pneumococcal vaccine we can conduct the research test, and when results are on hand we will compare the situation.

O.V. Safonova – Addition to the foregoing. Before making decision we should remember the fact, that the GAVI approved the support to us only till 2015. Namely, if we don't introduce till 2012, then we will not be able to do it, therefore they don't give us the grant for vaccine introduction. So we have such a question – either we will introduce till 2015 under the support of GAVI, or we will introduce after 2015 out of proceeds of the Republican budget.

N. Zh. Babadzhanov – We will discuss a matter of time in other meetings, and now we must decide whether we will introduce the vaccine or not.

The Chairman took a vote among members on the question of pneumococcal vaccine introduction, and it has been unanimously decided to introduce this vaccine into the Republic.

Z.Sh. Nurmatov spoke to the second issue

He submitted the material on the epidemiological supervision over rotavirus infection in the Kyrgyz Republic and on the economic burden and efficiency of rotavirus vaccine in the Kyrgyz Republic. Also he showed the dynamics of acute enteric infection morbidity by ages, multiannual morbidity structure, conducted sentinel surveillance, joint research by the National Institute of Health and the State Sanitary Epidemiological Supervision Department – research methods. Also he stated the laboratory analyses of children with acute gastroenteritis, strains characteristics, specific methods of cost estimate, and economic damage from rotavirus infection.

Speech of V.S. Toigombaeva

Vera Sadybakasovna submitted material on the rotavirus infection epidemiology, having pointed its actuality due to high registration of this infection in the world. She showed the situation of rotavirus infection morbidity in the Kyrgyz Republic and submitted in detail etiology, clinical picture, pathogenesis, epidemiological features. Also she told about kinds of vaccines, contra indications, and possible adverse events of the field of rotavirus vaccine inoculation.

Speech of G.Zh. Zhumagulova

She submitted the revised material on rotavirus vaccines and presented the experience of this vaccine introduction in other states. Also she told about all kinds of vaccines from the moment of development until today and about those vaccines, which are in the development stage. She laid main emphasis on 2 kinds of vaccines such as rotaryx and rotatek, which are currently used in the European countries and America. She provided information on successful vaccine introduction into the European countries by the example of Moldavia.

N. Zh. Babadzhanov – Question for G.Zh. Zhumagulova – WHO promised to review all recommendations on the terms of vaccines introduction. Are these recommendations reviewed?

Answer of G.Zh. Zhumagulova – Currently, new recommendations on the terms of introduction are not available

K.T. Kasymbekova – The question on Calendar of Prophylactic Immunization. Children vaccination is saturated, 8 vaccines simultaneously is a heavy load on a child. What do you think, whether our Republic will adhere to the similar calendar, or another calendar will

be developed? The second question on vaccines – it was mentioned that ROTARYX is more efficient. How to explain that, because of vaccines are almost identical?

Answer of G.Zh. Zhumagulova – As regards the Calendar of Prophylactic Immunization, each country has the right to draw up its own Calendar considering all features. Therefore Moldavia made decision to introduce the precisely this Calendar, our country will draw up its own Calendar subject to its characteristics.

B.M. Barktabasova – questions to 3 reporters

1. Are there any universal indicators of WHO, which any country can be oriented to and prepare specific data, as three reports stated different numbers in absolute and percentage terms, which convey nothing.
2. References are required to the data stated in reports. Many researches were conducted and works were executed, but references to the works executed are required.
3. It is necessary to view the matter of vaccines selection very carefully and to take into account the budget of our republic and to consider the cost so that it should be safe in quality.
4. The clinical trials on evidentiary medicine show that the vaccine is cost effective, profitable, and advisable, moreover for the countries with limited resources. The manufactures profiles and the clinical dossier on each vaccine will be weighted separately anyway after the decision on introduction is made.
5. Information campaign. Generally, in any country the information campaign on vaccination and the appraisal of medical technology can have results. For example: It will appear that all efforts on children vaccination will cost more expensive than the information campaign on hand washing. Until we undertake all measures for our population, our efforts will be unavailing. Possibly before undertaking such technologies and high-priced steps, we must create some common vision in the health care system, particularly for pediatricians. The Republican Center for Immunoprophylaxis and the State Sanitary Epidemiological Supervision Department have high potential and all that should be seen in one sense, who will do, what will do and in which periods.

G.Zh. Zhumagulova – As regards references, all the data stated in my report were the data of research of large-scale nature and were presented on WHO website.

Z.Sh. Nurmatov – As to the question on universal indicators, all researches on rotavirus infection were conducted in the Kyrgyz Republic according to the WHO standard protocols, and currently the introduction of manual for rotavirus infection supervision is being prepared.

We didn't examine the entire Republic; therefore it is decided to conduct the sentinel epidemiological surveillance including 2-3 regions of the Republic.

As regards the percentage data, they give the picture of situation in the Republic and the guide for vaccine introduction into the Republic. And the cost estimates are the mathematical calculation of WHO and SDS, which involved the entire institute and made data calculation.

N. Zh. Babadzhanov – Damira Kamchibekovna, and what can you say about this situation, as you are an infection disease doctor and are closely connected with rotaviruses?

D.K. Chynyeva – This problem is sufficiently urgent, as the economic approach is available and everything is proved. Generally infants are sick and there are mortal cases, but nevertheless there are some doubts about vaccine efficiency, and I am not sure that the vaccine can help.

N. Zh. Babadzhanov – As regards load, if we introduce the Calendar of Prophylactic Immunization with tight schedule, we must invite children every month. It is unclear that they

will come, there will be failure in the immunization system and will result in low coverage. Here the practical aspect of performance must be estimated.

A.A. Bure – It would be a good thing to interconnect rotavirus infection with other infections, but not every mother will agree so that several vaccines should be inoculated to the child on the same day.

M.E. Ashiraliev – The final word should rest with the health care organizers, it is necessary to ensure a pilot district where main source is available and where specific and goal-oriented actions are required.

N. Zh. Babadzhanov – This vaccine has efficiency, which is confirmed and proved. Cost effectiveness is confirmed by the scientific paper and is well proved.

According to the above one may say that the rotavirus vaccine is required, but subject to all the terms, economic opportunities, co-financing, support, Calendar of Prophylactic Immunization and other factors.

The Chairman took a vote among members on the issue of rotavirus vaccine introduction. 9 people from 14 gave vote for rotavirus vaccine introduction, and 5 people abstained from voting.

N. Zh. Babadzhanov – There is proposal to found a working group on consideration of issue on vaccine against human papilloma virus (HPV).

The group consists of 4 people:

1. O.V. Safonova – Group coordinator
2. B.M. Barktabasova
3. D.S. Otorbaeva – Specialist of the Department of Disease Prevention and Expert Review
4. N. Zh. Babadzhanov

The period from 3 to 6 months is provided for considering this issue, which will be submitted in the follow-up meeting.

Closing of the meeting

Chairman

N. Zh. Babadzhanov

Secretary

T.R. Buteshov