പതിമൂന്നാം കേരള നിയമസഭ
നാലാം സമ്മേളനം

നക്ഷത്രചിഹ്നമിടാത്ത ചോദ്യം നം. **639** — 08.03.2012-ൽ മറുപടിക്ക്

പെന്റാവാലന്റ് വാക്സിൻ

ചോദ്യം

ശ്രീ. എസ്.ശർമ്മ :
ശ്രീ.കെ.വി.അബ്ദുൾ ഖാദർ :
ശ്രീ.കെ.കെ.നാരായണൻ :
ശ്രീ.ബി.ഡി.ദേവസ്സി :

ഉത്തരം

ശ്രീ.അടൂർ പ്രകാശ്
(ആരോഗ്യവും കയറും വകുപ്പുമന്ത്രി)

(എ) പെന്റാവാലന്റ് വാക്സിൻ ശ്രീലങ്ക, ഭൂട്ടാൻ തുടങ്ങിയ രാജ്യങ്ങൾ വിപരീത ഫലത്തെ തുടർന്ന് നിരോധിച്ചിട്ടുള്ളതാണെന്ന വിവരം ശ്രദ്ധയിൽപ്പെട്ടിട്ടുണ്ടോ ;

(എ) പെന്റാവാലന്റ് വാക്സിൻ നിലവിൽ വന്നശേഷം ശ്രീലങ്ക,ബംഗ്ലാദേശ് എന്നീ രാജ്യങ്ങളിൽ ചില മരണങ്ങൾ റിപ്പോർട്ട ചെയ്തതിനെ തുടർന്ന് താൽക്കാലികമായി വാക്സിനേഷൻ പരിപാടി നിർത്തിവെച്ചിരുന്നതായി ശ്രദ്ധയിൽപ്പെട്ടിട്ടുണ്ട്. എന്നാൽ വിദഗ്ധവും വിശദവുമായ പരിശോധനകൾക്കു ശേഷം ഈ മരണങ്ങൾക്ക് പെന്റാവാലന്റ് വാക്സിനുമായി ബന്ധമില്ല എന്നു കണ്ടെത്തിയതിനെ തുടർന്ന് ഇതു പുനരാരംഭിക്കുകയും നിലവിൽ ഇപ്പോഴും നൽകിവരികയും ചെയ്യുന്നുണ്ട്. ഈ സ്ഥലങ്ങളിലൊന്നും തന്നെ വാക്സിൻ നിരോധിച്ചിട്ടില്ല.

(ബി) ഏതെങ്കിലും വികസിത രാജ്യങ്ങളിൽ പെന്റാവാലന്റ് വാക്സിൻ പ്രയോഗത്തിലിരിക്കുന്നതായി അറിയുമോ ;

(ബി) അമേരിക്ക, ഫ്രാൻസ്, യൂറോപ്യൻ രാജ്യങ്ങൾ എന്നീ വികസിത രാജ്യങ്ങൾ ഉൾപ്പെടെ 132 രാജ്യങ്ങളിൽ പെന്റാവാലന്റ് വാക്സിൻ നൽകിവരുന്നു. ഇവിടെ നിന്നും മരണങ്ങളോ മറ്റ് അപകടകരമായ പാർശ്വഫലങ്ങളോ ഇതുവരെ റിപ്പോർട്ട ചെയ്യപ്പെട്ടിട്ടില്ല.

(സി) പെന്റാവാലന്റ് വാക്സിനെക്കുറിച്ച് ആശങ്കകൾ ഉയർന്ന സാഹചര്യത്തിൽ കേരളത്തിൽ ഇതിന്റെ ഉപയോഗവുമായി ബന്ധപ്പെട്ട് അഭിപ്രായരൂപീകരണം നടത്തിയതിനുശേഷം മാത്രമേ ഇക്കാര്യത്തിൽ തീരുമാനം എടുക്കുകയുള്ളൂ എന്ന് ഒരു ഉറപ്പ് നൽകിയിരുന്നോ ; എങ്കിൽ അതിന് വിരുദ്ധമായി തിടുക്കത്തിൽ ഉപയോഗം ആരംഭിക്കുവാൻ ഇടയായ സാഹചര്യം വ്യക്തമാക്കുമോ ;

(സി) പെന്റാവാലന്റ് വാക്സിൻ കേരളത്തിൽ സെപ്തംബർ മാസത്തിലാണ് ആരംഭിക്കുവാൻ ഉദ്ദേശിച്ചിരുന്നത്. എന്നാൽ ചില കോണിൽ നിന്ന് എതിർപ്പുകൾ ഉയർന്ന സാഹചര്യത്തിൽ കേരളത്തിൽ ഇത് ഉപയോഗിക്കുവാൻ വേണ്ട സാഹചര്യത്തെക്കുറിച്ച് പഠിക്കുവാൻ തിരുവനന്തപുരം മെഡിക്കൽ കോളേജിലെ ശിശുരോഗ വിദഗ്ധനായ ഡോ.നോയൽ നാരായണന്റെ നേതൃത്വത്തിൽ ഒരു കമ്മിറ്റിയെ ചുമതലപ്പെടുത്തി. ഈ കമ്മിറ്റി സമർപ്പിച്ച റിപ്പോർട്ടിന്റെ അടിസ്ഥാനത്തിലാണ് ഈ വാക്സിൻ സാർവ്വത്രിക

പ്രതിരോധ കുത്തിവെയ്പ് പട്ടികയിൽ ഉൾപ്പെടുത്താൻ തീരുമാനമെടുത്തത്. ഈ വാക്സിൻ ആരംഭിക്കുന്നതിനു മുൻപായി എല്ലാ തലങ്ങളിലും ശിൽപശാലകളും ബോധവൽക്കരണ പ്രവർത്തനങ്ങളും നടത്തുകയുണ്ടായി. അതുകൊണ്ടുതന്നെ ഈ വാക്സിൻ ആരംഭിക്കുന്നതിന് തിടുക്കം ഉണ്ടായില്ല എന്നു മാത്രമല്ല, പഠനങ്ങൾക്കും അഭിപ്രായ സമന്വയങ്ങൾക്കും ബോധവൽക്കരണ പ്രവർത്തനങ്ങൾക്കും ശേഷം ഏകദേശം രണ്ടു മാസം കഴിഞ്ഞ് ഡിസംബർ 14-നാണ് ഇത് ഉദ്ഘാടനം ചെയ്തത്.

(ഡി) ഇക്കാര്യത്തിൽ നാഷണൽ ടെക്നിക്കൽ അഡ്വൈസറി ഗ്രൂപ്പ് ഓൺ വാക്സിൻസ് ആന്റ് ഇമ്മ്യൂണൈസേഷന്റെ വിദഗ്ധോപദേശം എന്തായിരുന്നു ; പകർപ്പ് മേശപ്പുറത്ത് വയ്ക്കാമോ ?

(ഡി) നാഷണൽ ടെക്നിക്കൽ അഡ്വൈസറി ഗ്രൂപ്പ് ഓൺ വാക്സിനേഷൻ ആന്റ് ഇമ്മ്യൂണൈസേഷൻ (NTAGI) യുടെ അംഗീകാരം ഉണ്ടെങ്കിൽ മാത്രമേ നമ്മുടെ രാജ്യത്ത് ഏതെങ്കിലും വാക്സിനേഷൻ നിയമപരമായി നൽകുവാൻ സാധിക്കുകയുള്ളൂ. ഇന്ത്യയിൽ പെന്റാവാലന്റ് വാക്സിൻ ആരംഭിക്കുന്നതിനും ഇത് കേരളത്തിലും തമിഴ്നാട്ടിലും പൈലറ്റ് പ്രോഗ്രാമായി തുടങ്ങുവാനും അംഗീകാരം നൽകിയത് നാഷണൽ ടെക്നിക്കൽ അഡ്വൈസറി ഗ്രൂപ്പ് ഓൺ വാക്സിനേഷൻ ആന്റ് ഇമ്മ്യൂണൈസേഷൻ ആണ്. റിപ്പോർട്ടിന്റെ പൂർണരൂപം അനുബന്ധമായി ചേർക്കുന്നു.

സെക്ഷൻ ഓഫീസർ

Meeting of National Technical Advisory Group on Immunization
26th August 2010, R. No. 155A, Nirman Bhawan

Minutes of Meeting

The meeting of National Technical Advisory Group on Immunization was held on 26th August 2010 chaired by Secretary (H&FW) and co-chaired by Secretary (DHR) & DG (ICMR). The list of participants is annexed.

The meeting started with a welcome note by Secretary (H&FW) who highlighted the fact that NTAGI has been reconstituted with representation from the specialist from Paediatrics, Public Health, Researchers, program division etc to encourage healthy technical discussions in an open and transparent manner.

On suggestion for audio-recording of the proceedings, the house felt that NTAGI should be a forum where the technical experts can provide inputs in an open and free manner; and such recording might preclude such open discussions. Further it was agreed to circulate the detailed minutes of the proceedings at the earliest.

Secretary (H&FW) also expressed concern at the recent incident of Adverse Event Following Immunization (AEFIs) in UP and its significance in view of the introduction of newer vaccines and therefore urged the NTAGI to consider such issues while recommending new vaccines under the National Program.

The key recommendations of last NTAGI meeting held on 3rd Aug'09 and action taken note was presented. Thereafter the meeting deliberated on the agenda items.

Agenda Item1- Introduction of Pentavalent vaccine

The house was informed that Hib vaccine has been introduced in 137 countries of the world and out of these the vaccine is part of the programme as Pentavalent vaccine in 56 countries and remaining countries use Hib vaccine in different combination. There are multiple studies providing data in support of Hib vaccination. The studies like Million Death Study by Dr Prabhat K Jha et al and on status of Millennium Development Goal (MDG) by Prof V. K. Paul et al have raised the concern on continued burden of lower respiratory illness as one of the major cause of child mortality and morbidity, thereby precluding achievement of the MDG goals. Dr. Ganguly mentioned that there have been various studies from Lambok (Indonesia), Bangladesh, Sri Lanka, Myanmar

and Pakistan on efficacy of Hib vaccine. Further Cochrane review also strengthens the fact that vaccine is efficacious in reducing morbidity and mortality burden due to Hib pneumonia and meningitis. Dr. Jacob Puliyel pointed out that this contradicts what has been published in BMJ & IJMR which showed that there was no statistical difference between those vaccinated and the non- vaccinated.

The house also deliberated upon as to why some of the developed countries are not using Hib combination vaccine as Pentavalent vaccine while it is being used in developing countries. In response, various experts cited that the different situation in immunization delivery system in developed and developing countries as one of the reasons for adopting Pentavalent vaccine. As introduction of newer vaccine in developing countries is always a challenge to cold chain with weaker immunization delivery systems therefore Pentavalent vaccine is preferred which provides operational advantages - one vaccine conferring protection against five diseases, with no change in immunization schedule thus no needs for beneficiary to approach health facility at different time interval , saves cold-chain space and logistics. While in developed countries, the vaccine schedule is different based on local epidemiology, market dynamics and also influenced by Advisory Committees on Immunization. Also these developed countries are using DTaP, (having acellular Pertussis vaccine which is costlier as compared to DTP containing whole cell pertussis vaccine), where combination vaccine has reduced seroconversion. In addition these developed countries are using Hib and Hep-B vaccine. The pentavalent vaccine used in the developing countries are combination of Hepatitis B, Hib and DPT (having whole cell Pertussis vaccine).

In the ensuing discussion, concern was raised regarding the safety and efficacy of the Pentavalent vaccine in view of the AEFIs reported following usage of this vaccine in Sri Lanka, Bhutan and Pakistan. The vaccination in Sri Lanka and Bhutan was stopped following these incidents of AEFI, however, after investigation; Srilanka has resumed vaccination in 2010 and Bhutan have decided to resume the Pentavalent vaccination. The available reports published by WHO have concluded that these events are unlikely due to Pentavalent vaccine, some of the members felt that the complete report of these incidents should be accessed for analysis. Keeping in view the number of children vaccinated in these countries, the background rate of these AEFI may not be significant and the benefit gain may not have raised alarm to stop vaccination. As the vaccine has

vaccine should be initially used in the states with better AEFI management and surveillance systems to monitor the vaccine safety. The house was of unanimous opinion on the use of Hib vaccine, but few members had reservations about using the formulation combination vaccine of Pentavalent vaccine. The house considered that lives saved by the Pentavalent vaccine far outnumber the few AEFI deaths reported in the neighbouring countries and therefore has favourable risk-benefit ratio. However Dr. Puliyel said that if Hib vaccine was to be introduced to look for utility, it may be introduced as a standalone vaccine.

The house also deliberated upon the immunogenicity of combination vaccines and it was felt that the available evidence based on Cochrane review reveals that although there is reduced immunogenicity of some of the components of vaccine when compared to given separately, this reduction in sero-conversion is not significant enough to affect protective levels of antibodies.

The Core Committee recommendations on Pentavelant Vaccines were discussed and based on the recommendations the committee members felt that vaccine should be introduced in selected few well performing states and further roll-out should be based on an impact assessment of vaccination including safety aspects. The house also discussed the selection of states for studying the impact of Pentavalent vaccine introduction. Though some of the northern states are having high burden of Hib disease, the introduction in these states with poor coverage would not be able to demonstrate significant impact and also these states have poor monitoring of AEFI. Further, the introduction of newer vaccine requires good delivery systems and some of the states with high vaccination coverage like Tamil Nadu and Kerala may be selected. The house also considered the options of limited introduction of the vaccine in the hospitals (rather than in outreach sessions) or in selected districts; however it was felt that this would not provide the sufficient sample size to study the impact of the vaccine.

It was stressed that clinical trials for impact assessment is difficult in view of the large sample size that would be required and high cost that would be incurred for such study. It was pointed out that data from Hib probe study by ICMR is available for some of the areas in Tamil Nadu which can be taken as baseline data and will facilitate the study of post-vaccination impact. In the ensuing discussion the house was informed that vaccine is already available in private sector in many parts of the country and has brought about

decline in cases of Hib disease over a period as observed in PGI Chandigarh, though the private vaccination does not contribute much in the National scenario.

Recommendations:

- ***Pentavalent vaccine to be introduced in Immunization programme in the states of Tamil Nadu and Kerala.***
- ***Thereafter, data may be reviewed after 1 year of introduction before expanding the vaccine into other states.***
- ***A protocol will be prepared by the ICMR for surveillance of Hib meningitis in selected hospitals to understand the trend over time. This will be circulated to NCDC and NTAGI members through email; once the protocol is finalized, the surveillance will be carried out by ICMR.***
- ***Since AEFI is a concern hence same will be monitored and also system will be strengthened so as to ensure immediate management of AEFIs; NCDC to lead this activity.***

Agenda Item 2- Introduction of Hepatitis B vaccination

The house discussed expansion of Hepatitis B vaccine in the entire country under immunization programme. It was pointed out that even though safe, efficacious and cheap Hepatitis B vaccine is available and in spite of carrier rate of around 4% in India the vaccine is still not part of Universal Immunization programme although all the countries have been using this vaccine under the national programme. This vaccine is manufactured in the country and exported to many countries. There have been enough data showing impact of Hepatitis B vaccination on disease burden due to hepatitis B infection like acute hepatitis, as well as its long term sequel like chronic hepatitis, cirrhosis and liver cancer. Therefore it is high time that this vaccine is introduced all over the country at the earliest. Over the period the cost of the Hepatitis B vaccine has dropped and is one of the cheaper vaccine available in the market.

As the vaccinated cohort is only protected, any change in morbidity and mortality would take 10-15 years to be detected. However, the impact assessment on carrier rate may be carried out and the house was informed that ICMR has already initiated a study for the same. It was also brought to notice that there may be possibility of escape mutation of hepatitis B virus and this may also be monitored.

The experts also stressed that it is critical to give the vaccine at birth to cut down the vertical transmission and to impact the carrier rate. The house was informed that under the immunization programme of Hepatitis B in the selected States/Districts/Cities the Hepatitis B vaccine is given at birth (in institutional deliveries) and thereafter at 6th, 10th and 14th week of age of the child. The Janani Suraksha Yojana (JSY) has been launched to improve institutional delivery and this may further boost the coverage of Hepatitis B vaccination at birth.

Recommendation

- ***In view of the disease burden and availability of safe and efficacious vaccine, the expansion of Hepatitis B vaccine should be carried out all over the country as part of Universal Immunization Programme. Before rolling out in newer areas there should be a plan for trainings, microplanning etc.***
- ***Simultaneously, multi-centric impact study on carrier rate of hepatitis B will be conducted by ICMR.***

Agenda Item 3- Introduction of Rubella vaccination

The house deliberated upon the risks and benefits of introduction of rubella vaccine in the immunization programme. If the vaccine is introduced in form of MR and targeting to vaccinate children at 16-24 months of age, then it is critical to ensure coverage above 80% failing which the rubella will shift to older age group of susceptible cohort and this may lead to paradoxical increase in congenital rubella syndrome (CRS). The manufacturing capacity and availability of MR and rubella vaccines are need to be considered before introducing the Rubella vaccination in the National programme.

In view of the above, the house felt that Rubella vaccine may be introduced in adolescent girls of 10-15 year old so that those who have not acquired the natural immunity due to infection are also protected. This would reduce the risk of getting this infection during the pregnancy and thereby reduce CRS cases.

Recommendation

- ***The NTAGI recommended the introduction of rubella vaccination for 10-15 year old adolescent girls under the Universal Immunization Programme in the entire country.***

Agenda Item 4- Draft Multi Year Strategic Plan 2010-17 for UIP

The house was unanimous that there is need for a Multi-year strategic Plan 2010-17 for UIP. The document does not comprehensively address Vaccine preventable disease surveillance; some of the points at page 58 in the document for setting up a new body with development partner to review, utilized information for deciding introduction of new and under-utilized vaccine were objected and house felt that this draft needs editorial corrections before any further discussion.

Recommendation:

- ***The draft MYP is to be revised for further discussion.***

Agenda Item 5- National Vaccine Policy

Secretary (H&FW) raised the need for a national vaccine policy and NTAGI unanimously agreed to the suggestion. There have been some attempts in drafting vaccine policy earlier, also a regional vaccine policy has been developed by WHO recently which may be used for developing this draft.

The need for a National Immunization Authority was also felt as the current technical structure of only 3 technical officers managing the immunization programme in the entire country like India is a daunting task. In this regard, the house was informed that IIM-Ahmedabad is conducting a study on the HR structure required for immunization programme in the country; it was felt that this study should be expedited.

Recommendation

- ***Dr. NK Ganguly, Ex-DG, ICMR agreed to draft a National Vaccine policy. Thereafter the policy document will be circulated to all members for their inputs before the final draft is discussed in the NTAGI meeting.***

Secretary (H&FW) also suggested members to suggest names of more experts to prepare broad contours of composition of NTAGI so that the terms of reference for NTAGI may be suitable amended including memberships. Dr. Jacob Puliyel suggested that appointment of members may be for two years and it must be specified that no person can serve more than three terms (except for Ex-officio appointments). For institutional memory, one third of the members must be replaced every two years. It

was also suggested that the committee should also have experts from the background of statistics, economist and public health nurse

The meeting was concluded with vote of thanks. The NTAGI is to meet again after 1 - 2 months.

Annexure

Meeting of National Technical Advisory Group on Immunization
26th August 2010, R. No. 155A, Nirman Bhawan

1. Chairperson : Ms. Sujatha Rao, Secretary, Health & Family Welfare, Govt. of India
2. Co-Chairperson : Dr. V.M Katoch, secretary, (Department of Health research), Govt. of India & director general, ICMR,

List of Participants

1. Prof. (Dr.) M. K. Bhan, Secretary (Department Bio-technology)
2. Dr. R. K. Srivastava, Director General Health Services
3. Mr. P. K. Pradhan, Additional Secretary & Mission Director, NRHM
4. Mr. Amit Mohan Prasad, Joint Secretary, RCH programme
5. Dr. N.K. Ganguly - Ex DG, ICMR
6. Prof. (Dr.) V. K. Paul, Prof.& Head, Dept. of Pediatrics, AIIMS, New Delhi
7. Dr. N. K. Arora, Paediatrician, & ED, INCLEN
8. Prof. (Dr.) A. P. Dubey, Head, Dept of Pediatrics, MAMC
9. Prof. (Dr.) Rajesh Kumar, Prof. & Head School of Public Health, PGIMER, Chandigarh
10. Dr. J. Pulliyel, Head, Deptt. of Pediatrics, St. Stephen's Hospital, Delhi
11. Dr. Shahid Jameel, Prof. of Virology, ICGEB, New Delhi
12. Dr. Sudhanshu Vrati, Dean, THSTI, Faridabad.
13. Dr. R. L. Icchpujani, Director, National Centre for Disease Control, Delhi
14. Dr V. G. Somani, Dy. Drugs Controller (India), CDSCO
15. Dr. A. C. Bannerjea, Staff Scientist, National Institute of Immunology
16. Dr Shyam Kukreja, Executive Director, Indian Academy of Paediatrics
17. Dr Henri van den Hombergh, Chief, Health, UNICEF, India office
18. Dr. Satish Gupta, Health Specialist (Immunization), UNICEF
19. Dr. Sangey Thinley, WHO Representative (Act), India office
20. Dr. Hamid Jafari, Project Manager, WHO-NPSP
21. Dr. Pradeep Haldar, Assistant Commissioner, (UIP)

22. Dr. N. K. Dhamija Assistant Commissioner,(I)

23. Dr. V. K. Mishra, SMO(Immunization)

24. Dr. Siddhartha Saha, Consultant, Immunization

25. Dr. Ajay Khera, Deputy Commissioner, member secretary