T.13013/01/2018-Imm
Government of India
Ministry of Health & Family Welfare
Immunization Division

Nirman Bhawan, New Delhi
Dated: 20th January, 2021

To,

All NTAGI members/Participants
(As per list enclosed)

Subject: Minutes of the meeting of National Technical Advisory Group on Immunization (NTAGI), held on 10th December, 2020 under the Chairpersonship of Secretary (Health & Family Welfare) at Nirman Bhawan, New Delhi.

Sir/Madam,

Please find enclosed herewith the minutes of the meeting of National Technical Advisory Group on Immunization (NTAGI), held on 10th December, 2020 at Nirman Bhawan, New Delhi, under the Chairpersonship of Secretary (Health & Family Welfare), for kind perusal.

Yours faithfully,

Enclosure: as above

20/01/21

(Dr MK Aggarwal)
Additional Commissioner (UIP)
011- 23062728

Copy to:

1. PPS to Secretary (H&FW), MoHFW
2. PPS to DGHS, MoHFW
3. PPS to Secretary (Department of Health Research), MoHFW
4. PPS to Secretary (Department of Bio-technology), MoS&T
5. PPS to AS&MD (NHM), MoHFW
6. PPS to JS (RCH), MoHFW
7. Office copy

15th National Technical Advisory Group on Immunization (NTAGI)
Meeting (Through Video Conferencing)
December 10, 2020, Thursday, 12:00 PM to 2:00 PM
1st Floor Nirman Bhawan, MoHFW, New Delhi

Minutes of the Meeting

Welcome & Introduction

The 15th NTAGI meeting was held on 10th December, 2020 at MoHFW, New Delhi under the Chairpersonship of Shri Rajesh Bhushan, Secretary Health and Family Welfare, and Co-chairpersonship of Dr Renu Swarup, Secretary, Department of Biotechnology. The Joint Secretary (RCH) welcomed Shri Rajesh Bhushan, Chairperson and Dr Renu Swarup, Co-chairperson, and informed the members that due to health issues Dr Balram Bhargava, Secretary Department of Health Research (DHR) and DG-ICMR and one of the Co-Chairperson could not attend the meeting. The list of attendees is Annexed as Annexure-1 and agenda as Annexure-2.

All participating NTAGI members and invited attendees had duly filled and signed the confidentiality agreement, and declared conflict of interests (if any), and shared these with the NTAGI Secretariat. No conflict of interest was noted.

Participants were welcomed by the Chairperson. Following a brief round of introduction, the meeting was called to order. The following items were discussed:

Agenda Item 1: Action Taken Report on previous NTAGI meeting held on December 17, 2018

The Joint Secretary (RCH) informed the Chairperson that the last meeting of NTAGI was held on December 17, 2018. In 2019, the meeting could not be convened due to unavoidable circumstances.

Agenda Item 1.1: Action taken report on the minutes of previous meeting of the NTAGI

The Joint Secretary (RCH) presented the action taken report (ATR) based on four recommendations made in previous NTAGI meeting (held on December 17, 2018), which is as follows: -

Japanese Encephalitis (JE) Vaccines: It was apprised that the matter on number of doses and recommended schedule for the Universal Immunization Program (UIP) was referred to Standing Technical Sub-Committee (STSC). In addition, STSC was requested to generate evidence on interchangeability of three JE vaccines (SA-14-14-2, Jeev and Jenvac). It was informed that the position on recommendations will be presented in the meeting.

Rotavirus Vaccines: It was apprised that the STSC was requested to examine the available evidence on program implementation review (PIR) reports of Rotavac & Rotasiil, and vaccine wastage study reports of both the vaccines. It was informed that the position on actionable points will be presented in the meeting.

Human Vaccines Interchangeability SOP: During the last NTAGI meeting, it was recommended that the Drugs Controller General of India (DCGI) should develop a document on standard operating procedures for all vaccine manufacturers which should include interchangeability studies to address the requirement of immunization program. It was shared that a report on the same will be presented by the DCGI.

Global Experience on Human Vaccines Interchangeability: The members were apprised that the country office of World Health Organization (WHO) was requested to provide evidence on international experiences on interchangeability of vaccines, especially JE, rotavirus, pneumococcal conjugate vaccine. In this regard, a

report was shared by the country office of WHO which is part of the dossier (Page#94). It was reported that at present there is no published data on interchangeability of both indigenous vaccines i.e., Rotavac & Rotasiil. There is no safety concern for mixed RotaTeq & Rotarix schedule, another two available Rotavirus vaccines. In case of Pneumococcal Conjugate Vaccines (PCV), product switching is not recommended, however in case of unavailability of same type of vaccine, available product can be used. Further, it was informed that there is no peer reviewed published information on JE vaccine interchangeability.
It was informed that the minutes of the NTAGI meeting held on December 17, 2018, were shared with the members and no comments were received.

The minutes were formally confirmed by the NTAGI.

Agenda Item 1.2: Summary of action taken by the STSC on the NTAGI recommendations (Rotavirus and JE vaccines)

In absence of Dr Balram Bhargava, DG ICMR and Co-chairperson NTAGI, Dr Samiran Panda, from ICMR made a presentation on summary of action taken by STSC on the recommendations of NTAGI, concerning the Rotavirus vaccines and JE vaccines. Members/invited attendees were informed about the existing 8 working groups [(i) Standing Working Group (SWG) on Immunization and Vaccine Research & Capacity Building (IVRCB), (ii) SWG on Vaccine Preventable Disease (VPD) Surveillance, (iii) Leprosy Working Group (WG), (iv) Cholera WG, (v) Influenza WG, (vi) JE WG, (vii) Vaccine Cost-Effectiveness WG, and (viii) COVID-19 WG)] and 2 sub-groups [(i) Vaccine Confidence sub-group and (ii) Maternal immunization sub-group)] under the STSC.
Rotavirus Vaccines: STSC examined the Program Implementation Reports (PIRs) and vaccine wastage studies of Rotavac and Rotasiil vaccines. It was informed that Both the vaccines have some advantages and challenges in terms of vaccine delivery, however, efficacy of both the vaccines is not significantly different. An update on Rotavirus vaccines Interchangeability study was provided. The study was conducted at two sites: KEM, Pune and NICED, Kolkata. Results of the study will be shared in the next STSC meeting.
JE Vaccines: It was informed that interim recommendation on dosage and schedule of JE vaccines in Routine Immunization (RI) and Campaigns has already been provided, which is as follows: -

- For RI, two doses of any of the three available JE vaccine formulations [LAJEV (SA-14-14-2), Jenvac, or Jeev (3 µg per dose)], administered at 9-12 months and 16-24 months, may be used.
- For campaigns in children (1-15 years of age) as well as in adults (above 15 years), one dose of any of the three vaccines (for Jeev, 6-µg dose) may be used.
- The NTAGI-STSC will monitor and review the evidence on implementation of the three JE vaccines formulations and see whether there is a need for changing or adopting the interim recommendation on dosage and schedule of JE vaccines in RI.

ICMR was requested to conduct a study on interchangeability and head-to-head comparison of the three JE vaccines available in India. The available data on efficacy of three JE vaccines were reviewed, which revealed that –

- An unpublished study showed highest GMT titers after 2 doses of the vaccine from Bharat Biotech India Limited (BBIL), followed by a mixed regimen with BBIL vaccine as prime (first dose) and SA-14-14-2 as boost (second dose), SA-14-14-2 prime and BBIL vaccine boost, and two doses of SA-14-14-2, in that order. However, this study included very few subjects.

A study outside India in adult subjects with IXIARO vaccine [6 µg doses; with technology transfer to Biological E Limited (Jeev) in India] showed only 26% sero-conversion on day 56 and only 9% seroconversion by end of 6 months. Due to ethical concerns, JE vaccine from M/s Biological E Limited (BEL) was dropped from interchangeability study protocol. JE vaccine interchangeability study protocol was presented in 25th NTAGI-STSC Meeting. The STSC opined that without JE vaccine from M/s BEL, the purpose of the study will be diluted.

STSC recommendations:

- The study can start with the two vaccines other than JE vaccine from M/s BEL to avert further delay.
- JE Working Group should re-discuss and decide on exclusion or inclusion of JE vaccine from M/s BEL (possibly with a different dose or schedule) in the study.

The Chairperson requested the NTAGI members to share their observations on the presentations.

The Chairperson, JE Working Group (JE WG), Dr Rakesh Aggarwal shared that three vaccines -- one live-attenuated (SA-14-14-2) vaccine from China and two killed vaccines which are made in India (Jenvac by BBIL and Jeev by BEL) – are available. The JE vaccine from BBIL has good long-term immunogenicity following a single dose. Some data suggest that the JE vaccine from BEL has a low immunogenicity following a single-dose, and that it requires 2 doses at an interval of 4 weeks. In the program, the first dose is administered at 9-12 months and the second dose at 16-24 months after a gap of almost 7 months. For the interchangeability study, this has led to a concern that the children receiving this vaccine may not be fully protected in the intervening period. For this, the WG had discussed whether the JE vaccine could be introduced at an earlier age to align with the existing RI program.

Some members felt that moving the JE vaccine to an earlier age may lead to an overcrowding of vaccines at early age (1.5, 2.5 and 3.5 months), and an additional injectable vaccine at this age might trigger vaccine hesitancy among parents. Another view was that a new time window for immunization as well as other health interventions could be opened up.

It was highlighted that the Jeev vaccine (BEL) is being used in the immunization programme (in two states) and its expansion in the program will be considered based on the final technical recommendations of the

STSC. Therefore, STSC should provide its recommendations on the concerned issue for taking immediate programmatic decisions.

One of the members expressed that the ICMR should be consulted to share its learnings from the work on adult JE vaccination in North-East region, JE vaccine coverage in central India, and at Gorakhpur region. It was suggested that the JE WG should also look at program implementation issues.

The Co-chairperson mentioned that interim recommendations were made on grounds of urgency and limited supply of SA-14-14-2 JE vaccine. The JE WG was requested to relook at the issue and submit an early report. A special meeting of the STSC will be held to come up with recommendations and send it to the Chairperson, and a special NTAGI meeting could be convened if required. It was mentioned that a timeline of maximum 6 weeks for providing recommendations should be considered.

Decision:

Based on the discussions the NTAGI endorsed STSC recommendations on JE interchangeability study with following points:

- There is a need for immediate recommendations from STSC for taking urgent programmatic decision on account of a study showing low efficacy of single dose JE vaccine from M/s BEL. The JE WG is required to deliberate on the issue in consultation with all stakeholders including Immunization Division, National Vector Borne Disease Control Program (NVBDCP) and subject matter experts within 2 weeks of time. A report of the deliberations and specific recommendations may be presented to NTAGI Chairperson and Co-chairpersons in 6 weeks of time.

(JE Working Group and NTAGI Secretariat)

Agenda Item 1.3: Human Vaccines Interchangeability SOP at the time of licensure

The DCGI, informed that in this regard, CDSCO has prepared a SOP no. BIV-P-23 on 09.12.2019 for review of Clinical Trial applications including assessment of issue of Interchangeability of Human Vaccines used under National Immunization Programme. It was explained that subject expert committee (SEC) of vaccines reviews study design, primary and secondary endpoints, population details, result assessment criterion, study objective, Inclusion/exclusion criteria, sample size, study assessment, statistical analysis, study endpoints along with surrogate markers for vaccines used and assessment of interchangeability for vaccine in National Immunization Programme at the time of approval. Based on the evaluation recommendations are finalized as mentioned in the New Drugs and Clinical Trials Rules, 2019.

The Co-chairperson conveyed that the SOP will help in ensuring interchangeability aspect when a second candidate vaccine targeting same vaccine preventable disease goes for review of SEC of DCGI. The SOP will have implications on future vaccines, it should be accepted by the NTAGI.

The Chairperson noted that since the SOP has been devised by the regulator, so regulator is now bound to comply with the SOP as and when Indian version of different vaccines come up.

The members were informed that, it may not be applicable to trials already been completed, with regards to particular vaccine, if it fits interchangeability, a post approval or parallel recommendation is granted.

It was emphasized that COVID-19 vaccines are developed on different platforms and many of these platforms will be used for first time in humans. Interchangeability between different platforms need to be looked carefully. This will be a work in a progress as new information arises with time. Addition of type of study designs in the SOP of interchangeability of human vaccines was suggested. This may become relevant to COVID-19 and other vaccines which may come up in future.

Decision:

The NTAGI accepted the SOP on human vaccines interchangeability, with an advice to carefully examine feasibility of interchangeability of vaccines developed on different platforms. Further it was advised to include possible types of study designs in the SOP of human vaccine interchangeability.

(DCGI, CDSCO)

Agenda Item 2: Follow-up actions by MoHFW on carrying out 2 recommendations made by STSC

The Joint Secretary-RCH apprised the NTAGI on STSC's recommendations on JE vaccines and Rotavirus vaccines.

JE Vaccines: The interim recommendations of the STSC on dosing and schedule of the three JE vaccine in immunization program were shared with concerned stake holders- states, procurement division, and partner agencies. Training of trainers (ToT) on recommendations on JE vaccine interchangeability have been conducted in Orissa, Bihar, MP, Chhattisgarh, Meghalaya, and West Bengal which are undertaking JE vaccination campaign.

Rotavirus Vaccines: Globally there are 4 manufacturers of Rotavirus vaccine- 2 offshore and 2 indigenous. Rotavirus Vaccines in UIP: Rotavac: 25 states/UTs (covering 60% of the birth cohort); Rotasiil: 11 states/UTs (covering 40% of the birth cohort). Due to programmatic challenges, as recognized by NTAGI-STSC, these two vaccines are not being interchangeably used in the UIP.

Agenda Item 3: STSC Meeting Discussion and Recommendations

The Co-chairperson, Secretary, Department of Biotechnology (DBT) presented to the NTAGI, a detailed overview of the work undertaken by the STSC over past two years. In the past two years, the STSC met seven times and had deliberated on nine key issues: Five standing items as part of annual review [(i) VPD Surveillance, (i) IVRCB, (iii) UIP monitoring report for South-East Asia Region-Immunization Technical Advisory

Group (SEAR-ITAG), (iv) progress made by UIP and AEFI surveillance program, and (v) review of National certification committee polio eradication report] and four new topics identified for discussion by stakeholders [(i) leprosy, (ii) influenza, (iii) JE vaccines and (iv) COVID-19. Among new identified topics, work on influenza is delayed due to COVID-19 pandemic.

Tenth SEAR-ITAG Meeting Recommendations: MR-IEAG (Measles and Rubella-Indian Expert Advisory Group) recommendations should be fully implemented, which are as follows: -

- An evaluation of Mission Indradhanush (MI) and Intensified MI should be conducted.
- Lessons learned from urban immunization strengthening pilots and best practices should be implemented.
- Multi-antigen sero-surveys should be considered to help with: (i) identification of rubella immunity gaps in women of child-bearing age, (ii) decision-making and vaccine scheduling of Td booster doses, (iii) monitoring the progress for achieving the hepatitis B control goal.
- Reasons for outbreaks in areas that have introduced JE vaccination should be identified and corrected.

The Members were informed that MR campaigns have been conducted in 34 states/UTs and case-based surveillance has been implemented in all 36 states/UTs. Evaluation of MI had been conducted and the report shows that there is increase in coverage also there is decline in deaths due to measles. Detailed report will be shared with NTAGI-STSC once it gets approved in MoHFW. Urban immunization strengthening pilots are undergoing in 14 cities, its report is under review, based on the learnings, interventions will be scaled up in other cities. A sero-survey on rubella among pregnant women, recruited from six sentinel surveillance sites in India, showed 83.4% seropositivity. Td is part of RI at 10 years and 16 years as recommended by the NTAGI. Hepatitis-B vaccine birth dose is regularly being monitored by the program. A very high vector density and less than 50% JE vaccine coverage were two main reasons for outbreak in areas where JE vaccine has been introduced.

SWG-VPD Surveillance: Existing outbreak-based, case-based surveillance data, and sentinel surveillance data from different organizations should be integrated to get meaningful inferences.

The members were apprised that the SWG-VPD surveillance is working on framework of three vaccine preventable diseases. Based on review, recommendations for all VPDs will be developed. This process may take 8-12 weeks.

STSC recommendations

- Draft a report explaining the details of mechanism, methodologies, necessary systems, data points, manpower and support require for developing a platform/data warehouse which will help in harmonizing data from various agencies, relevant for NTAGI.
- Capacity building of NTAGI Secretariat in terms of additional human resources & trainings.

SWG-IVRCB: Identification of gaps & priorities in vaccine related research and programme & maintaining a database of ongoing vaccine related research and track their progress, & mapping of capacity building opportunities. Key areas identified: (i) Maternal Immunization, (ii) Vaccine Confidence and (iii) Life course Immunization.

STSC recommendations

- Review and Identification of the best fit for maternal Immunization into the existing ANC schedule (4+1 visits) and WHO recommended ANC schedule (8 visits).
- Effect of maternal Tdap vaccination on the whole cell pertussis containing vaccine administered in RI.
- A PhD Program in Vaccinology, under institutions like PGI, Chandigarh & JIPMER or AIIMS, New Delhi. Program will involve training from various mentors with a clear curriculum & outcomes. The Program will be funded by DBT and ICMR in the form of an award or fellowship.

Leprosy WG: A working group was formed under the Chairpersonship of Dr J P Muliyil. The WG was comprised of members from the STSC and independent subject matter experts for undertaking detailed technical review. A report of the WG was submitted in 21st and 23rd STSC meetings. The report of the WG is going to be presented

Vaccine Cost Effectiveness Analysis (VCEA) WG: The need to have a group which will look into SOPs for adopting CEA for vaccines was highlighted in 23rd NTAGI-STSC Meeting. A note on convening of a working group to consider socio-economic impact and economic cost analysis was circulated among members. A working group on CEA of vaccine was formed under the Chairpersonship of Dr Indrani Gupta. 1st meeting of the WG was convened on Oct 5, 2020. Overview of relevance of economic evaluation and general steps involved in CEA were discussed.

The members were informed that CEA WG will identify best methodologies and protocol for doing CEA of vaccines. The VCEA WG will also help in vaccine economics analysis capacity building, under the leadership of the NTAGI. Along with vaccine CEA, risk benefit assessment was also suggested.

COVID-19 WG: The need was felt to discuss development of COVID-19 vaccines, disease burden, program preparedness and other technical aspects in the 24th NTAGI-STSC Meeting. A working group on COVID-19 was formed under the Chairpersonship of Dr N K Arora. Eleven WG meetings have been convened from Aug-24 to Dec 09, 2020. Part-1 of the preliminary guidance report of the WG has been shared with the MoHFW and NEGVAC, NITI Aayog.

Co-chairperson, Secretary-DBT, summarized that the STSC meets almost once in a quarter of a year, proactively looks at issues which may concern the vaccine development and the uptake in the immunization program. Working Groups have been constituted so that they can supplement and support the data which is coming from vaccine development so that it can facilitate program implementation. She reiterated that STSC strongly recommends capacity building of critical human resources both in terms of vaccine research aspects and more importantly within the secretariat. As lots of research and analysis is needed for NTAGI-STSC work.

The Members felt that over a period of time the NTAGI secretariat is doing exceptional quality work under the guidance of both the Co-chairpersons of the NTAGI-STSC. There has been substantial increase in number of working groups. The secretariat provides techno-managerial support to all working groups, STSC and NTAGI. Now with COVID-19, there is a clear need for strengthening of the NTAGI Secretariat in terms of extra technical human resources and advanced trainings.

Most of the members welcomed idea of PhD in vaccinology with constructive feedback from a few other members on research and trainings. It was explained that the idea of PhD in vaccinology program evolved from the idea of young leaders training program, during the discussions in various STSC. It was felt that young leaders invited for few months training may not be worth to fulfil the long-term capacity building goal of developing future champions of vaccinology. Therefore, the idea started from young leaders and then converted to PhD. It was also felt that in addition to PhD in vaccinology there is need of leaders in immunization program operation, for that context internship position at NTAGI secretariat could be opened for public health professional, who are pursuing MPH or MD for a period of 3-6 months. This will give them operational hands.

It was mentioned that there is a need of modeling capacity building at NTAGI Secretariat. It would be multidisciplinary and interdisciplinary training and research involving medical school, statistics, and business school.

One of the members mentioned that IIPH has a program on MSc-PhD in health informatics. Modeling expertise can be developed there as well. It was emphasized that the capacity building should be done utilizing all the opportunities provided.

Suggestions were made to build capacity by conducting training and research while incorporating multidisciplinary areas including biology of vaccination, epidemiology, mathematical modeling, and social acceptance. It was also suggested to create research professor position for vaccine research and training of

PhD students as it is seen in Oxford and Harvard Universities. At the end of the year, research professor can demonstrate what research they have guided.

Emphasis was made on applied research, and alliance between the SWG-IVRCB and program divisions. As program divisions regularly monitor the data which is collected from the field. A suggestion was made to include a representative of NCDC in the SWG-IVRCB.

The members were informed that an external evaluation of all 11 NITAGs in WHO-SEAR countries was conducted and It is a matter of pride that Indian NITAG and Srilanka NITAG were found one of the best ones. It was mentioned that, these capacity building inputs will help India in becoming one of the global leaders in field of vaccinology.

The Co-chairperson thanked the members for suggestions and mentioned that SWG-IVRCB will consider them. Further, it was mentioned that regarding PhD in Vaccinology, DBT will proactively work with premier institutions to come up with the program and present the progress to STSC and NTAGI.

The Chairperson thanked, Co-chairperson for comprehensive presentation and showcasing work undertaken by different WGs.

Decisions

The NTAGI endorsed STSC recommendations on VPD surveillance and IVRCB:

- A report on mechanism, methodologies, necessary systems, data points, manpower and support require for developing a platform/data warehouse for harmonizing data from various vaccine preventable disease surveillance agencies may be developed in 12 weeks' time.

  (SWG-VPD Surveillance and NTAGI Secretariat)

- In view of surge in the work of NTAGI secretariat and requirements of NTAGI-STSC, a proposal for strengthening of the NTAGI Secretariat in terms of additional human resources and advanced trainings will be processed. Additionally, efforts will be made to establish national capacity to model disease burden and the impact of vaccination.

  (MoHFW)

- Conducting two research studies on maternal immunization: (i) Review and Identification of the best fit for maternal Immunization into the existing ANC schedule (4+1 visits) and WHO recommended ANC schedule (8 visits) and (ii) Effect of maternal Tdap vaccination on the whole cell pertussis containing vaccine administered in RI.

  (SWG-IVRCB, DBT, ICMR and NTAGI Secretariat)

- A PhD Program in Vaccinology, under premier institutes offering multidisciplinary and interdisciplinary research pertaining to the domain of vaccinology is to be established. An effort must be made to

consider capacity building of MPH & MD students on operational aspects of immunization in form of internships at the NTAGI Secretariat.

(SWG-IVRCB, DBT, ICMR, MoHFW and NTAGI Secretariat)

Agenda 4: Report of Leprosy Working Group

The Chairperson, Leprosy WG, made a detailed presentation on work carried out by the working group.

Cardinal Observations of Leprosy Disease: Majority of the individuals heal on their own, and if there is a lesion early on, then it is a good sign of protection. On the other hand, those with unstable immunity would have more serious forms of the disease which leads to deformities which is the basis of the public health burden.

Burden of Disease: Trends in new case detection top 17 countries, who were using multi drug therapy as an attempt to eradicate leprosy, was presented. It was observed that there was not significant difference in case of new case detection annually till 2005 in all countries, except India. In India, a sharp decline in new case detection was observed between 2002-2005. Now at least 200,000 new cases are detected annually and almost 5,000 cases become deformed because of leprosy.

Safety and Efficacy of MIP Leprosy Vaccine: The public health importance of leprosy rests solely on the risk of disability and consequent physical & social handicaps**.** Role of a candidate vaccine can be viewed from the following angles: a) Does the vaccine reduce disease transmission in the community? b) Does the vaccine reduce the incidence of deformity causing types of disease? Major question is whether the MIP vaccine prevents deformities, or at least can it prevent the more serious forms of the disease. Unfortunately, the disease has long incubation period, usually 25 years and no study has gone that long to demonstrate protection. No evidence supporting protection against borderline disease emanated from these studies on MIP vaccine. Increased incidence of cases happens early on, among vaccinated, showing immunogenic potential. When administered to borderline cases as therapy, it surprisingly showed reduction in granuloma, redness, and other cardinal signs of leprosy disease, which implies its immunosuppressing action. It is the opposite of what is expected from a vaccine. **Based on leprosy working group deliberations and view on the economic analysis. The working group felt that the available evidence is inconclusive to recommend introduction of MIP vaccine in public health program.**

One of the members informed about 2 major leprosy vaccine trials in India, one was along with TB and second one was conducted in 300,000 subjects in South India. It was informed that in all leprosy vaccine trials around the world, new cases were non-lepromatous, single patch cases were around 70-80%, multibacillary cases were negligible.

It was mentioned that MIP vaccine is not preventing borderline or lepromatous cases. In general population, MIP vaccine had efficacy equal or less than BCG. It was observed that MIP vaccine prevents more cases in

contacts of leprosy patients. However, it is important to consider that less than 10% of new cases of leprosy come from the contacts. It was highlighted that use of MIP vaccine in the program will not reduce the incidence of leprosy cases significantly.

Decision:

- The NTAGI endorsed the findings of the STSC on MIP Leprosy vaccine and did not recommend its inclusion in the national immunization program at this time, as the existing evidence is inconclusive for a large-scale adoption of the MIP vaccine in the public health program.

Agenda Item 5: Preliminary Report of COVID-19 Working Group

The Chairperson, COVID-19 WG, presented a brief timeline of activities of the COVID-19 working group. The NTAGI was informed that WG had deliberations on epidemiology of COVID-19 disease, sero-survey studies, at risk population characteristics, sensitivity and specificity of COVID-19 testing kits, different vaccine development platforms, immediate expectations from the COVID-19 vaccines, vaccination delivery, logistics, data management and recipient tracking system, cold chain requirement, regulatory guidelines for vaccines, prioritization of vaccine recipients, program preparedness for rolling out COVID-19 vaccines, preparedness of National AEFI surveillance program for post-licensure surveillance of COVID-19 vaccines, challenges in preparation of AEFI surveillance program, strategy for strengthening or modifying existing vaccine safety surveillance, a framework on active AEFI/AESI surveillance system. It was informed that the COVID-19 working group had presentations from 4 manufacturers on vaccine development and trials. Discussions were also held on serology testing kits specificity, and emergency use authorization of candidate COVID-19 vaccines.

STSC Recommendations:

- Development of new facilities having international standard bioassay assessment capacity.

Prioritization of vaccine Recipients: The NTAGI was apprised that globally accepted principles of human wellbeing (Equal respect, National equity, Reciprocity, and Legitimacy) were used in development of priority recipient list which has been shared with MoHFW and NITI Aayog.

STSC Recommendations on priority recipients list:

- **High Risk of Exposure (Stage I)**

  First Responders: Health providers; Security personnel; Municipal workers

  Next line of responders: Pre-school and Primary school teachers and caregivers; Maintaining other essential services

- **High Risk of Poor Outcome (Stage II):** Persons with age > 60 years; age > 50 years; Younger individuals with co-morbidities

Framework for an advanced procurement agreement of COVID-19 vaccines: A suggested generic guidance framework for advanced procurement agreement for COVID-19 vaccines by Government of India was developed.

STSC Recommendations:

- Suggestions were made to consider vaccines that are currently under different phases of clinical trials in India.
- A close scrutiny of pre-clinical and available clinical data indicating promising serological responses with appropriate neutralizing vis-à-vis total antibody response to vaccine was advised.
- Consider vaccines if there were no safety signals in the early clinical data or in animal studies.
- It was suggested that the vaccines that fulfil the programmatic feasibility considerations based on the existing immunization infrastructure (e.g., storage, transport and administration) may be considered.
- It was mentioned that manufacturer's capacity and delivery schedule versus the country's/program's requirements also need to considered.

The Part 1 of preliminary guidance document on COVID-19 vaccine use has been shared with MoHFW and NITI Aayog.

Discussions on Emergency Use Authorization, Compassionate Use and Other Options: The following are important to consider: -

- Current state of the COVID-19 pandemic & associated mortality, burden on the health system and impact on the economy.
- Country's prowess to manufacture COVID-19 vaccines in quantities required for the India.
- Development in vaccine R&D, evaluation and readiness to enter the market.

Current state of different vaccines either developed in India or under manufacturing license (as on 7th December 2020). *COVISHIELD (SII)***:** Bridging study (1575 received 2nd dose. *COVAXIN (BBL)***:** Phase I (375); Phase II (390); Phase III (5000 received 1st dose). Both the manufactures had submitted their dossiers for EUA.

The NTAGI was informed that deliberations were held on EUA versus compassionate use versus MEURI (monitoring emergency use of unregistered & experimental interventions aligned with ICMR Ethics guideline 2017). It was informed that compassionate use and MEURI are for serious illness in an individual. There were certain concerns while considering them for vaccination program for a large population. It was felt that balance between the principals of science and accelerated vaccine rollout should be seen with lenses of public health benefits. As vaccines will be administered to a large apparently healthy population. It was also highlighted that at present, correlates of protection are not yet confirmed.

Concern were raised in handling of vaccine candidates that are later on found to be ineffective or significantly less effective or have safety concerns as they might give rise to challenges for health system as well as at regulatory level. Concern over public trust on vaccines and immunization in general were shared. Therefore, it is important that all regulatory guidelines are followed for EUA of a candidate COVID-19 vaccine.

It was shared that DCGI expects sufficiency of data from sufficient number of subjects (Phase III or bridging trial); assessment of risk-benefit ratio; durability of protection and overall discernment of Subject Expert Committee (SEC) of DCGI.

It was mentioned that safety and adverse event monitoring in the 4-6 weeks after completing the immunization schedule among pre-specified sample size is critical in making decision on EUA of a particular vaccine as it is accepted globally.

Further it was informed that credibility and standing of Indian regulatory authorities are very high particularly in context of vaccines as India has emerged as a vaccine-manufacturing hub.

Agenda of forthcoming meetings of the COVID 19 WG: A brief information on forthcoming work to be undertaken by COVID-19 WG was presented. It included a) Finalization on approaches to: i) Emergency Use Authorization and ii) Compassionate use or MEURI, b) vaccine specific contraindications of use of the COVID-19 Vaccine(s), and c) Decisions on the vaccination of COVID-19 antigen and serology positive individuals.
These recommendations may change with availability of new information and change in course of SARS-CoV2 pandemic.

The following discussions were held:

- The members raised concern over considering use of COVID-19 vaccines on compassionate ground. It was mentioned that compassionate criteria should not be used for COVID-19 disease, as it is not a severe life-threatening illness which is looked at compassionate use of drugs. Further, it was mentioned that vaccines will be administered in healthy people, compassionate clause is for individual drug treatment, it should not be brought to vaccine domain. Further evidence would be needed with time on the issue of prevention of transmission by COVID-19 vaccines.

- Some of the members suggested to consider people with high risk of severe illness like elderly and comorbidity should be kept bit higher in priority order above primary school teachers.

- It was suggested that COVID-19 WG should also look into community level perspective, e.g., areas with high prevalence, how infection behaves in community group what vaccination strategy would be needed to reduce high burden and transmission. One of the members suggested expedited guidance on EUA as the pandemic is still ongoing.

- Information on identification and tracking of individual beneficiaries was solicited by members. As lot of disinformation is floating around. It was suggested that public could be informed that it is a complicated exercise and concisely designed, and vaccine will be freely available once it comes in the program. It will avoid issues of disinformation. Suggestion was made for exceptional transparency to tell everything to all the communities to every beneficiary by various channels.

Chairperson Remarks:

The Chairperson mentioned that exceptional transparency is critically important and all facts will be shared with priority group as well as with the public at large. Further, it was mentioned that serology testing prior to vaccination is an open question and evidence is being reviewed by the COVID-19 WG.

It was also remarked that MoHFW is actively working with State governments, databases are getting created and uploaded on digital platform which will enable a real time tracking of every individual beneficiary. Further, it was informed that MoHFW has formulated a communication strategy, focusing on COVID-19 vaccination in collaboration with all stakeholders and this communication strategy will be shared with State governments in next few days. Trainings for field level functionaries, have been scheduled on communication. It included training on how, whom and when to communicate, and how to counter disinformation and rumors. The members were apprised that a COVID- 19 vaccine communication dashboard is being planned and pertinent information will be placed on website as well. The work presented by the COVID-19 WG is work in progress, an account of all the suggestions shared by the members will be undertaken.

Recommendations:

Decision:

The NTAGI endorsed the STSC recommendations on development of bioassay assessment capacity, suggestions on the prioritization of the vaccine recipients and suggestive framework on advanced purchase agreement of COVID-19 vaccines with following points:

- A report on (i) emergency use authorization of COVID-19 vaccines, including informed consent component (ii) literature review findings on conducting a serology testing prior to vaccination, and (iii) product specific contraindications of COVID-19 vaccines may be shared with the Chairperson and Co-chairperson in a time-bound deadline.

(COVID-19 WG and NTAGI Secretariat)

Agenda Item 6: Annual Work Plan of NTAGI 2021

The Joint Secretary RCH, shared annual work plan of the NTAGI for the year of 2021. The annual work plan was developed in consultation with the Co-chairpersons (Secretary DBT and Secretary DHR & DG-ICMR). Following additional activities were suggested to be included in the annual work plan of 2021:

- A discussion on Controlled Human Infection Model (CHIM) studies human by STSC.
- Six-monthly NTAGI meeting for expedited decisions.
- Formal documentation, presentation and publication of the experience of COVID-19 vaccine rollout.
- Discussion on safety signals which emerge during the course of population vaccination.
- Ascertain the effectiveness of communication strategy, in terms of sustaining the demand and debunking the vaccine rumors and disinformation.
- Vaccine hesitancy: Review the strategies to counter misinformation related to adverse events effectively.

An updated annual work plan of 2021 has been annexed as Annexure-3.

Chairperson Remarks and Vote of Thanks

The Chairperson thanked all the participants for their invaluable contribution to all the six agenda items considered in the meeting. He also thanked the members for approving the annual work plan (AWP) for 2021 with significant suggestions which would be incorporated in the AWP-2021 to enrich overall interventions. Further, he mentioned that in future more frequent NTAGI meetings will be conducted and concluded the meeting.

JS (RCH) finally proposed vote of thanks.

15th National Technical Advisory Group on Immunization (NTAGI)
Meeting (Through Video Conferencing)
December 10, 2020, Thursday, 12:00 PM to 2:00 PM
1st Floor Nirman Bhawan, MoHFW, New Delhi

Annexure -1

List of Participants

S.No.	Name	Designation
Chairperson		
1	Shri Rajesh Bhushan	Secretary, Department of Health & Family Welfare
Co-chairperson		
2	Dr Renu Swarup	Secretary, Department of Biotechnology
Core Members, Ex-officio		
3	Dr Sunil Kumar	Director General of Health Services
4	Ms Vandana Gurnani	Additional Secretary & Mission Director, NHM
5	Dr Sujeet Singh	Director, National Centre of Disease Control
6	Dr Priya Abraham	Director, National Institute of Virology
Core Members, Independent Experts		
7	Dr J P Muliyil	Professor, CMC Vellore
8	Dr Gagandeep Kang	Professor, CMC, Vellore
9	Dr Indrani Gupta	Professor, Institute for Economic Growth, Delhi
10	Dr Rakesh Aggarwal	Director, JIPMER, Puducherry
11	Dr Mathew Varghese	Head of the Dept, Orthopedics, St. Stephan's Hospital, New Delhi
12	Dr Satinder Aneja	Professor and Head, Dept. of Pediatrics, Sharda University
13	Dr Neerja Bhatla	Professor, AIIMS, New Delhi
14	Dr M D Gupte	Former Director, NIE, Chennai
15	Dr Arun Kumar Agarwal	Professor, PGI, Chandigarh
16	Dr Lalit Dar	Professor, AIIMS, New Delhi
17	Dr Dilip Kumar Das	Professor, Burdwan Medical College, Burdwan
18	Dr Parvaiz Koul	Professor, Sher-i-Kashmir Institute of Medical Sciences, Srinagar
19	Dr Surinder Jaswal	Professor, Tata Institute of Social Sciences
20	Dr F U Ahmed	Pro-Vice Chancellor, Khaja Bandanawaz University, Gulbarga
Liaison Members		
21	Dr Manohar Agnani	Additional Secretary, MoHFW
22	Ms Preeti Pant	Joint Secretary-RCH, MoHFW
23	Dr Pradeep Haldar	Advisor-RCH, MoHFW
24	Dr M K Aggarwal	Additional Commissioner-UIP, MoHFW
25	Dr V G Somani	Drugs Controller General of India, CDSCO, MoHFW
Professional Organization Representatives		
26	Dr Bakul Jayant Parekh	President, Indian Association of Paediatrics
27	Dr Rajan Sharma	President, Indian Medical Association
28	Dr K Srinath Reddy	President, Public Health Foundation of India
International Partners Representatives		

29	Dr Roderico Ofrin	Country Representative, WHO, India
30	Dr Pankaj Bhatnagar	National Professional Officer & Deputy Team Lead, WHO, India
31	Mr Lugi D Aquino	Chief of Health, UNICEF
32	Dr Rija Andriamihantanirina	Immunization specialist, UNICEF
33	Dr Bhrigu Kapuria	Health Specialist (Immunization), UNICEF
State Representatives		
34	Dr Arundhati Chandrashekhar	MD-NHM, Karnataka
35	Dr B N Rajani	Deputy Director, Karnataka
36	Mr Amit Singla	Secretary, Delhi
37	Dr Monika Rana	Director, Govt of NCT of Delhi
Indian Council of Medical Research		
38	Dr Samiran Panda	Scientist 'G', ICMR, New Delhi
39	Dr Nivedita Gupta	Scientist 'F', ICMR, New Delhi
Department of Biotechnology		
40	Dr Alka Sharma	Adviser / Scientist 'G', Department of Biotechnology, New Delhi
41	Dr Jyoti Logani	Scientist 'E', Department of Biotechnology, New Delhi
Immunization Division, MoHFW		
42	Dr Indu Grewal	Joint Commissioner-UIP, MoHFW
Special Invitees		
43	Ms Rekha Sharma	Joint Secretary, MoHFW
44	Dr N K Arora	Chair COVID-19 Working Group, Executive Director, INCLEN International
45	Dr Rajat Ranjan	Lead Consultant, MoHFW
NTAGI Secretariat		
46	Dr Dinesh Paul	Advisor-cum-Manager
47	Dr Awnish Kumar Singh	Research Analyst
Co-chairperson Apologized		
48	Dr Balram Bhargava	Secretary, Department of Health Research & DG-ICMR
Member Apologized		
49	Dr Y K Gupta	Principle Adviser THSTI-DBT
50	Dr Veena Dhawan	Joint Commissioner-Immunization, MoHFW

15th National Technical Advisory Group on Immunization (NTAGI)
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Annexure -2

Agenda

Chairperson: Shri. Rajesh Bhushan, Secretary (H&FW), MoHFW	***Co-chairperson: Dr Renu Swarup, Secretary DBT***	***Co-chairperson: Prof Balram Bhargava, Secretary DHR & DG-ICMR***
12:00 PM-12:05 PM	General Business	NTAGI Secretariat
12:05 PM-12:10 PM	Welcome and Introduction Submission of minutes of the NTAGI meeting held on December 17, 2018	Chairperson and Co-chairpersons NTAGI
Agenda no. 1: Action Taken Report		
12:10 PM-12:15 PM	Agenda no. 1.1: Action taken report on the minutes of previous meeting of NTAGI held on December 17, 2018	JS-RCH
	Agenda no. 1.2: Summary of ATR on previous NTAGI recommendations 1.2.1: Dosage and schedule of JE Vaccines and plan of Interchangeability study of JE Vaccines 1.2.2: Indigenous Rotavirus Vaccines Program Implementation Review	Co-chairpersons
	Agenda no. 1.3: Human Vaccines Interchangeability SOP at the time of licensure	DCGI
Agenda no. 2: Follow-up Action on carrying out NTAGI-STSC Recommendations		
12:15 PM-12:20 PM	Agenda 2: Follow-up action on STSC recommendations by MoHFW 2.1: JE Vaccines 2.2: Indigenous Rotavirus Vaccines	JS-RCH
12:20 PM-12:25 PM	Discussion	NTAGI Members
Agenda no. 3: STSC Meeting Discussion and Recommendations (closed session)		
12:25 PM-12:35 PM	Agenda 3.1: Vaccine Preventable Disease Surveillance Agenda 3.2: Immunization & Vaccine Research & Capacity Building Agenda 3.3: Introduction & Background Leprosy WG Agenda 3.4: Introduction & Background Vaccine Cost Effectiveness Analysis WG Agenda 3.5: Introduction & Background COVID-19 WG	Co-chairpersons
12:35 PM-12:40 PM	Discussion	NTAGI Members
Agenda no. 4: Leprosy Vaccines (closed session)		
12:40 PM-12:50 PM	Agenda 4: Report of Leprosy Working Group	Chair, Leprosy WG
12:50 PM-01:00 PM	Discussion	NTAGI Members
Agenda no. 5: COVID-19 Vaccines (closed session)		
01:00 PM-01:20 PM	Agenda 5: Preliminary Report of COVID-19 Working Group	Chair, COVID-19 WG
01:20 PM-01:45 PM	Discussion	NTAGI Members
01:45 PM-01:50 PM	Recommendations	Chairperson and Co-chairpersons
Agenda no. 6: Annual Work Plan of NTAGI 2021 (closed session)		
01:50 PM-01:55 PM	Agenda no. 6: Annual Work Plan of NTAGI 2021	JS-RCH
01:55 PM-02:00 PM	Concluding Remarks	Chairperson and Co-chairpersons

Annexure-3

Work plan of the NTAGI 2021

This document presents the activities planned by NTAGI for the year 2021

1. Scientific production

Activity 1.1: Collate, review and grade evidence on COVID-19 disease burden, COVID-19 Vaccines efficacy, safety and immunogenicity as part of **COVID-19 WG work.**

Activity 1.2: Daft a Final guidance document for use of COVID-19 vaccines in India as part of **COVID-19 WG work.**

Activity 1.3: Develop a report explaining the details of mechanism, methodologies, necessary systems, data points, manpower and support require for developing a platform/data warehouse which will in harmonizing data from various agencies, so that it can help in NTAGI work, as part of **SWG-VPD Surveillance work**

Activity 1.4: Identifying the priority research areas pertaining to COVID-19 vaccines program implementation and policy decision-making as part of **Standing Working Group on Immunization and Vaccine Research and Capacity Building (IVRCB) and COVID-19 WG work.**

Activity 1.5: A cost-effectiveness modelling exercise to ascertain at what cutoff point pre-vaccination serology may be effective as part of **vaccine CEA WG and COVID-19 WG work.**

Activity 1.6: Starting of PhD Programme in Vaccinology in AIIMS, New Delhi, PGI, Chandigarh or JIPMER, Puducherry with financial support from ICMR, and DBT.

Activity 1.7: Review of the data of maternal seasonal influenza vaccination data in Maharashtra as part of **Influenza working group work**.

Activity 1.8: A review of seasonal Influenza infection rates during pregnancy and its impact on maternal mortality, morbidity and fetal outcomes as part of **Maternal Immunization sub-group work.**

Activity 1.9: Identifying the priority areas of capacity building relevant to vaccine research and immunization policy decision-making as part of **Standing Working Group on Immunization and Vaccine Research and Capacity Building (IVRCB) work.**

Activity 1.10: Scoping Review on the burden of Respiratory Syncytial Virus in India as part of **Standing Working Group (SWG) on Vaccine Preventable Diseases (VPD) Surveillance and Maternal Immunization sub-group work**.

Activity 1.11: Review the surveillance data on Cholera and planned research studies on Cholera disease and OCV as part of **Cholera WG work**.

Activity 1. 12: Provide guidance on research studies on program costing, cost effectiveness, cost benefit, additional cold chain space requirement, vaccine wastage, cost for vaccination, training and capacity building of healthcare workers, and pilot implementation of vaccines as part of **Cholera WG work and Vaccine CEA WG work.**

Activity 1.13: A brain storming workshop to discuss the issue of vaccine confidence with different stakeholders and subject matter experts as part of **vaccine confidence sub-group work**.
Activity 1.14: Review of Rotavirus interchangeability study data by **NTAGI-STSC**.
Activity 1.15: Review of Typhoid surveillance study and TCV implementation study data by **NTAGI-STSC**.

Activity 1.16: A discussion on Controlled Human Infection Model (CHIM) studies human by **NTAGI-STSC**.

Activity 1.17: Formal documentation, presentation and publication of the experience of COVID-19 vaccine rollout by **COVID-19 WG.**

Activity 1.18: Discussion on safety signals which emerge during the course of population wide COVID-19 vaccination by **NTAGI-STSC.**

Activity 1.19: Ascertain the effectiveness of communication strategy, in terms of sustaining the demand and debunking the vaccine rumors and disinformation. **SWG-IVRCB**

Activity 1.20: Vaccine hesitancy: Review the strategies to counter misinformation related to adverse events effectively. **SWG-IVRCB**

2. Strengthening the Secretariat and committee's technical and scientific capacities

Activity 2.1: Access to multiple scientific articles databases for systematic literature review on VPDs by Secretariat.
Activity 2.2: Recruitment of additional technical human resource for facilitation of NTAGI work.