

STATE AEFI TECHNICAL COLLABORATION CENTRE

MAULANA AZAD MEDICAL COLLEGE, NEW DELHI





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WELCOME NOTE ON THE INAUGURAL ISSUE

Vaccinations are usually administered to healthy persons and often are mandated as a condition for school attendance (with certain exemptions allowed); therefore, they are held to a higher standard of safety than other medical products. However, as with all medical products, no vaccine is perfectly safe or effective. Vaccines can cause minor adverse events (AEs) such as fever or local reactions at the injection site. Rarely, they can cause serious AEs such as anaphylaxis. Adverse events can also occur coincidentally after vaccines (i.e., they would have occurred in the absence of vaccination). Improving our understanding of vaccine safety is important to reduce the occurrence of vaccine AEs and maintain public confidence in vaccines. One way to enhance our understanding of vaccine safety is to improve surveillance for vaccine AEs. Robust vaccine safety monitoring may foster the discovery of adverse events associated with vaccination, and thus the development and use of safer vaccines and recommendations to minimize the risk of AE after vaccination (e.g., creating new recommendations, contraindications, and precautions).

The AEFI surveillance system in India, is a passive reporting system where any suspected adverse event following immunization informed to the health system (ANM, ASHA or AWW) should be recorded and reported as per the National AEFI Surveillance guidelines. Based on severity and for ease of recognizing events to be recorded and reported, any adverse event can be categorized as: Minor AEFI (common, self-limiting reactions, e.g. pain, swelling at the injection site, fever, irritability, malaise etc), Severe AEFI (disabling and, rarely, life threatening, however, not leading to long-term problems, e.g. nonhospitalized recovered cases of anaphylaxis, high fever (>102-degree F), hypotonic-hyporesponsive episodes, cellulitis, sepsis, etc) and Serious AEFI (death, persistent or significant disability, requiring inpatient hospitalization, are a part of AEFI cluster or evoke significant parental/community concern). The process involves timely notification of minor, severe and serious cases which are to be subsequently recorded in Block/ Planning unit AEFI recording register. Once the case investigation is completed and all the supporting documents are submitted to the state and national level, these cases are causally assessed by trained experts in state and national AEFI committee meetings. It is important that in events where program error is suspected suggestive actionable points are conveyed to the districts.

AEFI TCC will play a pivotal role for providing technical expertise for AEFI surveillance and capacity building.

- Dr. Pragya Sharma
Nodal Officer, State AEFI TCC

FROM THE DEAN'S DESK

Little did we know that, at the dawn of this decade there would emerge an uncertainty created by a global pandemic. This health crisis has created some extraordinary trials for our world. The safest way to fight this pandemic is to get vaccinated. The vaccine development rate, magnitude and accentuated vaccination drive are all the gifts of this millennium. As you read our news bulletin, I hope you feel inspired to engage with those around you to use vaccination to create a safer world. With this focus, I am confident that we will emerge from this time in our history as a stronger nation, and as better people and leaders.

- Dr. Ritu Arora Dean, Maulana Azad Medical Colleae

FROM THE DIRECTOR'S DESK

Setting up of Technical Collaboration Centre for AEFI in Maulana Azad Medical College (MAMC) along with Lok Nayak Hospital (LNH) and GB Pant Hospital is a novel initiative by Government of National Capital Territory of Delhi. The aim of this unit is to provide support to the Immunization Division of Directorate of Family Welfare in terms of capacity building of the state and district officials for investigation of adverse events following immunization, their causality assessment, the surveillance activities, monitoring of trends of adverse events and ensuring quality in data. Strengthening of this important component of Immunization program will lead to its more effective implementation.

- Dr Monika Rana
Director, Directorate of Family Welfare





TECHNICAL READS: THE SCIENTIFIC PERSPECTIVE

COVID-19 TRANSMISSION DYNAMICS IN THE COMMUNITY: SARS CoV-2 HT Study

Closed settings, such as households, have a defined population that may not mix readily with the larger surrounding community, and therefore such settings can provide a strategic way to track emerging respiratory infections and characterize virus transmission patterns because the denominator can be well defined. This study was conducted as a art of WHO Unity studies with the objective to understand the transmission dynamics of COVID-19 among the household contacts of laboratory-confirmed cases of COVID-19.

This was a prospective case ascertained study conducted among the household contacts of laboratory-confirmed COVID-19 cases residing in the Central and North East districts of Delhi between December 28, 2020 and June 28,2021. Baseline data collection and sample collection for RT PCR and serology from the primary case and the contacts were done on day 1 of visit and then they were followed for a period up till 28 days (Day 7, 14, 28) for development of symptoms as well as for nasopharyngeal and blood specimen along with a daily symptom diary maintained for all the primary cases and contacts for 28 days.

A total of 109 primary cases and their 202 household contacts were included in the study analysis. The secondary attack rate (SAR) estimated was 13.86% (9.71%,19.39%) and the secondary infection rate was 33.16% (26.97%, 40.00%). The proportion of secondary cases being symptomatic and asymptomatic was 24 (34.78%) and 45 (65.22%) respectively. On univariate analysis, the significant predictors/risk factors of the infection were location of household in Central district (SAR= 20% [13.75,28.16]) vs North East District (SAR= 4.87% [1.83-12.35]) p= 0.002, sharing of utensils (SAR= 42.85% [14.26-77.11], p=0.02), and using the room to sleep where case has been isolated (SAR= 25% [12.97-42.71], p=0.047). Other socio-demographic factors like sex, sharing of toilet, presence of comorbidity was not significantly associated. The serial interval and basic reproduction number within household were estimated to be 3.6± 5.73 days and 1.26.[95% C.I. 1.21-1.31] respectively.

Overall, the average infection produced by one infected case in a household is 1.26(R₀). The mean time taken for a household contact to develop symptoms after contact with the primary case was 3.6 days which is almost similar to that seen in the ongoing pandemic. A COVID-19 case will transmit infection to 33.16% of its household contact. Therefore, it is needed that the primary case and their contacts need to maintain COVID-19 appropriate behaviour at all times. Strengthening of testing capacity and early identification of primary case through active and passive surveillance will also help in further reduction in transmission.

Seroconversion was not seen as a 100% phenomenon for disease correlates in our study. Thus, a significant proportion of cases and their contacts remains susceptible to recurrent infection since antibodies against COVID-19 infection had not yet developed in them. *Thus, vaccination needs to be given in individuals despite their past history of natural infection.*

Investigators- Dr. Pragya Sharma, Dr. M.Meghachandra Singh, Dr. Shivani Rao, Dr. Sonal Saxena, Dr. Vikas Manchanda, Dr. Rohit Chawla, Dr. Warisha Mariam, Dr. Saurav Basu

Healthcare workers (HCWs) constitute a very high-risk group for contracting COVID-19 due to sustained occupational exposure to the virus and the risk of infection contraction and transmission. The real-world effectiveness of infection prevention and control measures in the prevention of COVID-19 especially non-pharmaceutical interventions such as masking, hand hygiene and social distancing measures can also be objectively evaluated in HCWs due to their risk profile Vaccination was initiated for HCWs from 16th January 2021 with introduction of Covishield at the beginning followed by Covaxin later.

In a study conducted by the Department of Community Medicine and Dept. of Microbiology, Maulana Azad Medical College, found that most of them 88% had received Covishield vaccine while remaining 12% had received Covaxin by May 2021. The incidence of seroconversion in the baseline seronegative cohort on follow-up after 21-28 days (median 24 days) was observed in 35 (14.9%) HCWs (n=245). The proportion of participants who seroconverted after receiving two doses of either COVID-19 vaccines (Complete Vaccination) was higher (36.2%) compared to those who had received only one dose (Partial Vaccination) (11.4%) of COVID-19 vaccine and this was statistically significant (p= 0.000).

The overall incidence rate of SARS-CoV-2 seropositivity was 5.9 (95% CI 4.2, 8.2) per 1000 person-days. Among the baseline seronegative HCWs on follow-up, complete vaccination with two doses of either Covishield (AZD1222) or Covaxin (BBV152) vaccine was the only factor that was significantly associated with seroconversion indicating the presence of detectable antibodies (p<0.001).

Thus, the evaluation of antibody response in HCWs post-vaccination, detection of neutralizing antibodies in seropositive HCWs, and the possibility of considering booster doses in the absence of adequate immune response warrant urgent consideration in this high-risk cohort.

COVID-19 VACCINES AND THEIR SIDE EFFECTS

VACCINE CANDIDATES	ADVERSE REACTIONS
ChAdOx1 nCoV-19 vaccine (AZD1222)	 Pain after vaccination (Mild to moderate intensity) (67%) Tenderness (mild intensity) (83%) Fatigue and Headache (70%) Fever (18%)
BNT162b2 (Pfizer)	 Pain at the injection site Fatigue and headache Fever (temperature, ≥38°C) (16%)
BBV152 COVAXIN	 Pain at the injection site Fatigue and headache
SPUTNIK V Vaccine	 Pain at injection site, [58%] Hyperthermia [50%] Headache ,[42%] Asthenia, [28%] Muscle and joint pain [24%]
ZyCoV D	Pain at the injection site Fatigue and headache





OPINION PIECE

MAMC COVID VACCINATION SITE:

FROM VACCINE HESITANCY TO VACCINE EAGERNESS

In the early months of 2021, countries had started deploying the administration of newly developed COVID-19 vaccines. These vaccines were chosen to be delivered to masses in a campaign mode. The earliest vaccine to be used across the world was AstraZeneca, a recombinant viral vector vaccine.

Similar to the AstraZeneca vaccine, India also introduced the Covishield vaccine by Serum Institute of India from January 16 onwards. At that time the other vaccine which was introduced for emergency use in India was the Covaxin, an inactivated indigenous COVID-19 vaccine, developed by Bharat Biotech. Maulana Azad Medical College, New Delhi being the largest Medical College under the Delhi Government along with its associated hospital had been the largest (2000 bedded) COVID hospital in Delhi, and had been instrumental in managing the maximum number of COVID patients during the two waves of pandemic.

The department of Community Medicine played an active role in the pandemic by working as a partner along with the Delhi Government for contact tracing and surveillance, developing training material for RWAs/community volunteers/recovered patients, research in epidemiology and carrying out the population based seroprevalence studies for generating evidence for policy decisions in NCT of Delhi.

So, with the launch of the COVID vaccination drive, the responsibility of vaccine delivery to the health care workers initially and the general population subsequently was shouldered with the Central Delhi district administration. The sites accepted the challenge of introducing the Covaxin vaccine, through the mass campaign approach. Since, this was a newer vaccine which was still under phase three of clinical trial development, thus, was viewed with a lot of suspicion and thus the most important challenge in this mass vaccination drive that awaited was that of vaccine hesitancy due to a large consent form citing an exhaustive list of possible adverse effects, that refrained most of the beneficiaries to take the vaccine after going through the consent process.

Dr. Shivani Rao, Assistant Professor











GLIMPSES FROM COVID-19 VACCINATION

SITE, MAMC

Fear from COVID-19 Vaccination- A hinderance to herd immunity?

Since ages, there has been less realization in mindset of people when it comes to prevention from diseases, not just limiting to uneducated class or rural community. The people have a general tendency to seek healthcare only when they become ill from any acute or chronic ailments. In today's digital era, there is rampant use of various digital technologies to disseminate information in least possible time frame. The use of various social media platforms/applications like Facebook, WhatsApp, LinkedIn, Telegram, Twitter, etc are being used to spread messages either in a constructive or criticizing manner. There is utmost need to sensitize masses through various digital technologies in a very responsible and not with half-baked knowledge.

Often, benefits versus harms need to be weighed with regard to any intervention planned in a community like the use of vaccines to prevent SARS CoV-2 (most commonly referred as COVID-19) infection after clinical trial phases. It needs to be emphasized and reiterated especially for antivaccine lobby and uneducated/illiterate class who exaggerate either more frequent with mild intensity or less frequent severe/serious side-effects after vaccination (more appropriately referred to as Adverse Events Following Immunization-AEFI).

There is a growing confusion in communities including educated classes when certain diseases still manifest despite of its specific vaccination in an individual. There is a dire need to maintain trust among public and ensure correct information is put forth in public domain at the correct time through various means of mass communication by authorized Government officials. Till today, there is lack of awareness related to potency of vaccines and lack of availability of correct information on AEFI, as a result of which fear and vaccine hesitancy is bound to occur in populations. For this, there is urgent need for government will and policy makers to ensure AEFI Surveillance is strengthened along with ensuring more budgetary outlay in research activities.

Till date, more than 95 crore doses of COVID-19 vaccine have been administered in India, with more than 50 lakh vaccine doses on a daily basis in every part of the country. The concept of herd immunity cannot be achieved with antibodies formed through natural infection, rather immunity can be achieved only by immunizing about 60% - 80% individuals in population of every part of the country.

The COVID-19 Pandemic has taught each one of us as how important it is to maintain COVID Appropriate Behavior at all times including hand hygiene (with soap and water/sanitizer), face cover (with face mask/face shield), cough/sneezing etiquettes, physical distancing (maintaining 6 Ft distance), COVID-19 Vaccination and avoiding overcrowded places. It is reminding once again to all of us what we were taught in nursery class as toddlers-'Prevention is better than cure'!

Dr. Sahil Goyal, Senior Resident, Dept. of Community Medicine





AEFI TECHNICAL COLLABORATION CENTRE: THE GAME CHANGER

IMMUNIZATION AND ADVERSE EVENTS (AEFI) & THE WAY FORWARD: KEYNOTE

As established by World Health Organization, any untoward medical event that follows immunization and that does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

In this context of the vaccine AEFI surveillance, a systematic review of data about the AEFI case(s) to determine the likelihood of a causal association between the event and the vaccine(s) received is done as a causality assessment.

The State AEFI Technical Collaboration Centre at MAMC envisages to provide technical support to the Immunization Division, GNCT of Delhi and, hand holding along with the State for providing quality causality assessment, investigation of adverse events and quality assurance. Monitoring of AEFI processes, capacity-building activities and providing feedback to districts and making corrective actions.

The activities carried out will be looking into the trend analysis of AEFI related to vaccines under Universal Immunization Program and COVID-19 vaccination and database surveillance. This State AEFI Technical Collaboration Centre would also provide expertise and a pool of resource persons for carrying out capacity building and periodic review meetings and workshops related to AEFI.

This newsletter is an initiative under the TCC which will be released quarterly and will provide latest information and updates on the activities done by the State AEFI TCC as well as scientific and technical updates related to vaccine development and related adverse events.

Dr. Amod Laxmikant Borle
(Assistant Professor)
Dr. Shivani Rao
(Assistant Professor)
AEFI TCC



क्यों टीकाकरण है ज़रूरी?
पोलियो तपेदिक खसरा हो अथवा होवे टेटनस
कुक्कुरखांसी गलाघोंट्र यकृतदाह या हेपेटाइटिस
ये कुछ बिमारियाँ हैं बच्चों की ले सकती हैं जान
पोलियो से बच्चा जीवन भर रह सकता विकलांग
इन रोगों से बचने हेतु मुफ्त उपलब्ध हैं टीके
पोलियो की दो बूँद बाकी सुई से लगते टीके
बीसीजी खसरा पोलियो जीवित रोगाणुयुक्त टीके
रोगाणुओं के अंग से बनते बाकी रोगों के टीके
शरीर में रोगों से लड़ती अंदरूनी रोग निरोधक
क्षमता

टीके लगवाने से बढ़ जाती पुन: रोग निरोधक क्षमता

इसीलिए जरूरी है बच्चों को लगें सभी टीके टीके लगने में देर न हो समय से लगें टीके सुरक्षित होगा बच्चा और बीमारी न होगी मृत्यु दूर रहेगी उससे विकलांगता न होगी टीकों से बीमारी न होगी घटेगा धन नुक्सान खुशहाली संग देश चढ़ेगा उन्नति के सोपान

> -डा.पन्ना लाल निदेशक प्रध्यापक सामुदायिक चिकित्सा विभाग मौलाना आज़ाद मेडिकल कॉलेज

