STATE AEFI TECHNICAL COLLABORATION CENTRE
DEPARTMENT OF COMMUNITY MEDICINE
MAULANA AZAD MEDICAL COLLEGE, DELHI

e-newsletter

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From the Editor's Desk

Dear readers, New year is a great time to act! Let us make our world healthier and make sure that no matter where someone lives, they should have access to something as simple as a vaccine that can save the lives of children. As we navigate the evolving landscape of global health, the importance of maintaining an open channel of communication cannot be overstated. It is with immense pleasure and commitment that we present to you the latest edition of our Newsletter.

This newsletter serves as a cornerstone of our collaborative efforts to promote awareness, share insights, and foster a culture of safety within the realm of immunization. In these pages, you will find a curated blend of critical updates, research findings, expert perspectives, and practical guidance related to Immunization, Vaccines and AEFI surveillance. By staying informed and engaged, we collectively plan to contribute to enhancing the safety, efficacy, and public trust in immunization programme in the country.

We invite you to immerse yourself in the content and together, let us champion the cause of immunization safety, ensuring that every individual receives the protection they deserve without compromising on quality or integrity.

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NEXT STEPS IN THE FIGHT AGAINST TYPE 2 VARIANT POLIOVIRUS: AN UPDATE FROM GPEI

To better address the evolving risk of type 2 variant poliovirus (cVDPV2), Global Polio Eradication Initiative (GPEI) partners together with countries have developed and deployed the novel oral polio vaccine type 2 (nOPV2). The vaccine is a next-generation version of the type 2 monovalent OPV (mOPV2), which is safe to use and provides comparable protection against poliovirus as per the results of clinical and field trials. It is also genetically much more stable and therefore less likely to be associated with new cVDPV2 outbreaks. Development of nOPV2 began in 2011, it was rolled out in March 2021 for outbreak response after which it was granted WHO Emergency Use Listing (EUL) approval to enable its rapid field availability. As of December 2023, approximately 1 billion doses of the vaccine have been administered across 35 countries, providing protection to millions of children against illness and debilitating paralysis. In December 2023, nOPV2 earned full licensure from Indonesian regulatory authority (Badan POM) as well as WHO Prequalification (PQ) after rigorous reviews of safety, effectiveness, and genetic stability data, as well as quality assurance checks of manufacturing sites. This marked the end of its EUL use phase, making it easier for more countries to access and use nOPV2 for outbreak response. nOPV2 is the first EUL-approved vaccine to achieve prequalification. The vaccine will continue to be an important tool to help stop variant poliovirus outbreaks more sustainably.

As on 3 January 2024, 325 cases of cVDPV2 had been reported in 2023, compared to 689 cases in 2022. While nOPV2 has played a key part in this reduction, its success, like any polio vaccine, depends on the ability to rapidly implement high-quality immunization campaigns that reach every child. A prequalified nOPV2 will help to make important headway against cVDPV2 outbreaks, and with renewed support from global partners, donors and leaders of polio-affected countries to fully implement the program's strategy, we can stop all forms of polio for good.

Source: ***GPEI press release on nOPV2 prequalification – GPEI (polioeradication.org)***

Outsmarting Malaria: Prevention through Vaccination

The World Health Organization (WHO) approved the R21/Matrix-M vaccine in October 2023 for the prevention of malaria among children in high-transmission areas. This vaccine, based on a virus-like particle that incorporates the circumsporozoite protein from the Plasmodium falciparum strain NF54, uses Matrix-M as its proprietary adjuvant. A major phase 3 trial conducted across Burkina Faso, Kenya, Mali, and Tanzania involved 4,800 children aged 5 to 36 months. Participants were randomly assigned to receive either a three-dose series of the R21 vaccine or a placebo. After 12 months, the vaccine demonstrated a 75 percent efficacy (95% CI 71-79) in areas with seasonal malaria transmission and 68 percent efficacy (95% CI 61-74) in regions with year-round transmission. The vaccine was well-received, with injection site pain and fever being the most common adverse effects. The recent advances in malaria vaccine development, particularly with RTS,S/AS01 and R21/Matrix-M, alongside innovative monoclonal antibody therapies like L9LS and CIS43LS, represent significant strides in combating this global health challenge.

-Dr Vinay Khanna, M.D, Associate Professor, Deptt. Of Microbiology, KMC, Manipal

Activity Update on Sub-National Immunization Day (SNID) under Intensified Pulse Polio Immunization

(10th to 15th December 2023)

- Govt. of NCT of Delhi organized Sub-National Immunization Day (SNID) under Intensified Pulse Polio Immunization Programme (IPPIP) on 10th December 2023, which was followed by five days of House to House (HTH) 'Search & Immunize activity' from 11th December to 15th December 2023, as per recommendations of GoI.
- The Programme was implemented in a complete decentralized manner, under the direct control of District Magistrates (DMs) and Chief District Medical Officers (CDMOs), who managed the manpower, logistics, IEC, vaccine distribution, Cold Chain & location of booths, which was granularly planned and coordinated by the respective District Immunization Officers (DIOs).
- The overall programme was conducted under the supervision of Directorate of Family Welfare (DFW), Govt. of NCT of Delhi, at Vikas Bhawan – II, Civil Lines, and coordinated by the Immunization Section.
- Booths were organized at all Government health facilities including hospitals, Anganwadi centers, and other government & private institutions / establishments like selected metro stations, railway stations, religious places, schools etc.
- Extensive IEC and mobilization were conducted during the round, along with wide Media Coverage, from State level, as well as, at the level of Districts.
- The SNID was actively launched by the respective District Administration in all the 11 districts on 10th December 2023.
- Two drops of Oral Polio Vaccine (bOPV) were given orally to all children under 5 years of age at the pulse polio booths on 10th December 2023 and the left little fingernail of these beneficiaries was marked with indelible ink marker as per guidelines, for identification, supervision and monitoring.
- A total number of 6,39,707 children were vaccinated against Polio in 5840 no. of booths, on Sunday, 10th December 2023 SNID round. Further, 11,35,005 children were vaccinated against Polio during the HTH activity from 11th to 15th December 2023 during the SNID round, by visiting more than 47 lac households using HTH Polio Teams.
- Thus, more than 17.7 lakh children have been given Oral Polio Vaccine during this Pulse Polio Round SNID under IPPIP (from 10th to 15th of December 2023).

Dr Ruchir Rustagi

Medical Officer, Immunization Section,

Directorate of Family Welfare (DFW)

A Vaccine Wheel In Uttar Pradesh Helps ASHA Workers Track Newborn Immunisation

THE SIMPLE TOOL HELPS THE HEALTH PROPONENTS WORK WITH GREATER EFFICIENCY AT THE VILLAGE LEVEL, WITH THE AIM BEING TO ACHIEVE MORE THAN 90% VACCINE COVERAGE

The immunization wheel, called a **teekakaran chakra** in Hindi, is a simple plastic-laminated cardboard construction developed and funded by the Clinton Foundation, under the Clinton Health Access Initiative (CHAI). It consists of two discs, placed one on top of the other, one bigger than the other, and attached with a rivet. The smaller one has details of the vaccines and arrows; the larger one has a calendar with days and months. Introduced as a pilot in U.P. just after COVID-19, the tool was rolled out to 1,66,975 ASHA workers across 75 districts in August 2022; 1,83,600 wheels were distributed. The U.P. health department has been working with the foundation in pursuit of at least 90% immunization coverage. Health workers register a child's birth in what they call the ASHA diary. They use the wheel to match a birthdate to the first vaccine. The rest of the dates for year one of an infant's life (for immunization at 1.5, 2.5, 3.5, and 9 months) fall into place, without the need for manual calculation. There is a pictorial indication of whether the vaccine is a jab (syringe vector) or will be orally administered (drop vector). The vaccine wheel also has details of the vaccines for pregnant women and for babies from 16 months to 24 months, leading up to the fifth year. There is information about the benefits of timely vaccination that health workers can give parents.

Source-https://www.thehindu.com/news/national/a-vaccine-wheel-in-uttar-pradesh-helps-asha-workers-track-newborn-immunisation/article67339245.ece

New presentation of Rotavirus Vaccine: Rotasiil

Orally administered Rotavirus Vaccine- 2 dose Rotasiil ® Liquid will be launched in the following states i.e. Gujarat, Karnataka, West Bengal, Jharkhand, Punjab, Delhi, Haryana and Rajasthan) under the Universal Immunization Programme (UIP). The vaccine comes in a bundle (1+1+2) which vaccine vial, adapter and 3ml syringe. Each dose of the new presentation of the Rotavirus vaccine is 2 ml. This will be administered orally with the 3 ml oral syringes supplied with the vaccine for the administration. The syringes provided for oral use are not to be used for injection. Storage and transportation: The 2 dose Rotasiil ® Liquid should be stored between +2°C to +8°C at all levels. In the ILRs, it should be stored at or above BCG level. It should be transported in cold boxes with conditioned ice-packs along with other UIP vaccines. The new presentation should be transported to session sites along with other vaccines in vaccine carrier with 4 conditioned ice packs. The vaccination schedule will remain the same i.e., 3-dose schedule at 6 weeks, 10 weeks and 14 weeks.The vaccine should be used within 4 hours of opening the vial as open vial policy is not applicable. No session site should have two different products of Rotavirus vaccine at the same time.

Source: UIP Programme Update

Updates on Revised Operational AEFI Surveillance Guidelines

The role of vaccines in preventing infectious diseases has become more important than ever after the aftermath of the COVID-19 pandemic. With the advent of newer vaccine introduction like the COVID-19 vaccines, Pneumococcal vaccines, Rotavirus vaccines and many more we have come a long way and so the need for an improved surveillance mechanism. The AEFI surveillance encompasses reporting, recording, investigation and finding a causal association of any adverse event to that of the administered vaccine. The Global Vaccine Action Policy recommends that for every 1,00,000 live births at least 10 adverse events need to be reported. Therefore, it is our collective responsibility for collaboration with all the stakeholders for increasing the reporting. I urge all the healthcare professionals, professional bodies like IAP, IMA, both private and government medical colleges and all the hospitals to report adverse events, provide the necessary support for investigations, and ensure that the information is disseminated widely.

The journey to strengthen the AEFI surveillance in the country is a learning process, building on with addition of new evidence from COVID-19 vaccination and experience sharing from various stakeholders. The revised Operational Guideline was released on 10th January 2024 which has evolved over the years from the experiences of the states and districts. Through these guidelines we have embarked on improving the robust system of reporting, recording and investigation following any adverse event post vaccination. These efforts help us to reaffirm our efforts to gain trust with the citizens and progress in public health.

Some of the key changes are:

- Use of digital vaccination recording software (SAFE-VAC, U-WIN) to increase reporting of all AEFIs, including minor ones.
- Timeline for submission of CIF increased to 21 days from 10 days.
- Vaccinators allowed to administer one dose of adrenaline intramuscularly in a suspect case of anaphylaxis and dispensing of syrup paracetamol in place of tablet paracetamol at vaccination session sites for managing minor AEFIs.
- Updated post-mortem guidelines for AEFI death investigations in adults and children, new verbal autopsy form for adults.
- Expansion of Quality Management System for AEFI surveillance to the states, districts, PHCs and session sites.
- Inclusion of physicians, neurologists, cardiologists, respiratory medicine specialists and obstetrician-gynaecologists in AEFI committees.
- Greater role of state AEFI committees and state AEFI technical collaborating centre in medical colleges in investigations, causality assessments, capacity-building, and monitoring activities at the district level.
- Strengthening the AEFI surveillance system for introduction of adult vaccinations and new vaccines in the UIP and introduction of new vaccines under Emergency Use Authorization as part of pandemic preparedness.
- Use of signal management processes for vaccines.

Source: UIP Programme Update

Quality Management System (QMS) in AEFI in India- Nascent but promising endeavor!

India has developed a sensitive AEFI Surveillance System to ensure vaccine confidence through Quality immunization services with safe vaccines. The surveillance system monitors and investigates any adverse reactions or events related to vaccination. Robust AEFI surveillance and analysis facilitates ongoing improvements in vaccine safety, effectiveness, and public health policies. The main objective of AEFI Surveillance is to dent morbidity and mortality due to AEFI and minimize the negative impact of AEFI on public health. Having established AEFI surveillance system in as early as 1988, with the ever-increasing scope of immunization and expanding the basket of vaccines available, Ministry of Health & Family Welfare in consultation with NHSRC, introduced the National Quality Assurance Standards for Quality Management in AEFI in 2016. It was another milestone in terms of having QMS in a specific component of a public health program as not much has been done to develop standards and tools that enable measuring quality of public health programmes that runs beyond the well-defined boundaries of health facility but also in outreach session sites. The NQAS guidelines provide a framework and standards for implementing a QMS for AEFI surveillance. The QMS focuses on continuous quality improvements in AEFI detection, reporting, investigation, and causality assessment.

However, the following gaps are in implementation at sub-national levels due to lack of adequate staff, funds, and training. Resource constraints affecting QMS rollout. Inadequate training and capacity building of health staff at all levels on AEFI surveillance, reporting, investigation, and causality assessment as per NQAS guidelines.

More efforts are needed to build capacities, strengthen supervision, utilize data, and address health system challenges to establish robust QMS for AEFI in India. Under-reporting of AEFIs from the private health sector and their limited involvement in QMS processes needs immediate redressal. Data quality issues like incomplete information, errors, and delays in reporting also impacts its use for quality improvements. Weak supportive supervision and data monitoring also impacts the quality of implementation. Overall, while systems and processes as per NQAS guidelines are in place, more efforts are needed to build capacities, strengthen supervision, and use data for improvements. In summary, QMS implementation for AEFI as per NQAS is ongoing but sub-optimal in many states and districts due to various health systems challenges that need to be addressed. The extent of QMS implementation varies across these states. Most other states are still in the early stages of QMS roll-out for AEFI surveillance. Only two states, Goa and Chandigarh have implemented it across their territories. Delhi has piloted in two districts and intends to roll out in other districts soon. QMS in AEFI is still in its evolving stage. With Quality being the focus in every aspect of health, it is important that critical dimension of quality is added to AEFI as well, to further enhance the immunization services. Implementation of QMS in AEFI surveillance programme can help in improving efficiency, quality, and safety and assure standardization of its processes, transparency, role clarity and accountability at levels of implementation.

Dr Amita Raoot,
Program Officer-Immunization, (DFW)

RESEARCH BYTES

Study Title: The predictors of Incidence, Reinfection and Severity of disease in a cohort of SARS-CoV-2 antibody positive cases - A Prospective study (RIF STUDY)

Background- The role of antibodies and the titer of neutralizing antibodies, as well as the time interval between infection and a fall in antibody titers to a level indicating decreased protective power, have yet to be determined. Considering the high infection to case ratio for COVID-19, the assessment of reinfection in a population cohort showing the presence of IgG antibody against the SARS-CoV-2 can provide crucial evidence as to understand the epidemiological burden of reinfection and their determinants.

Objectives

1.To determine the incidence of reinfection of COVID-19 in a cohort of seropositive IgG SARS-CoV-2 study participants.
2.To determine the proportion of SARS-CoV-2 with ILI/SARI in a cohort of seropositive IgG SARS-CoV-2 study participants.
3.To find out the epidemiological predictors of incidence and severity of COVID-19 reinfection among a cohort of seropositive IgG SARS-CoV-2 study participants.

Methodology

This was a prospective cohort study which was conducted across the 11 districts of Delhi for a period of twelve months. The study population was a cohort of SARS CoV-2 IgG antibody seropositive participants irrespective of their antigen status identified during the 6 th round of serosurvey conducted by Delhi in 2021. Purposive sampling was done and a total of 7572 seropositive individuals could be contacted out of which 7418 study participants gave their consent and were enrolled for follow up while remaining 154 (20%) did not give consent.

Result

The mean age of study participants was 37.45 ± 15.42 years. Majority of them were women 4322 (58.3%) while men were 3094 (41.7%) and two of them identified themselves as transgender. The study participants were mostly literate 5913 (79.7%). Overcrowding was present among 53% of the households. Over a period of 2606125 person days, 163 reinfections developed. The incidence density was 6.25 per one lakh person days. The median time to reinfection was 348 days. The KM survival curve for equality of survivors showed a significant difference in probability of survival among covariates of age groups, education status, occupation status, socioeconomic class, overcrowding, previous history of COVID-19 infection, increase in BMI and infrequent following of COVID appropriate behaviour (log rank test p<0.05). The predictors of time to reinfection multivariate cox proportional hazard model were middle age, being literate, being employed, overcrowding, upper SES, previous history of COVID-19 infection and taking of booster doses (p< 0.05).

Conclusion

The reinfection of SARS CoV-2 virus envisages the measure to continue the preparedness and prevention of public health and social measures for reduction in disease transmission. Natural infection from SARS CoV-2 and vaccination may provide short term protection and reduce in severity but is solely not protective against the varied strains.

Authors: Dr Amod Laxmikant Borle, Dr Warisha Mariam, Dr Shivani Rao, Dr Ekta Gupta, Dr Reshu Aggarwal, Dr Pragya Sharma, Dr M.Meghachandra Singh, Project Implementation Team

Revitalizing TB Elimination in India: Harnessing BCG Vaccination in Adults

Study Title: "Effect of BCG Vaccination amongst Vulnerable Adult Population on Reducing TB Disease: A Programmatic Study."

Background: The Ministry of Health and Family Welfare, in collaboration with various esteemed institutes, has meticulously formulated a comprehensive protocol for Adult BCG Vaccination under Programmatic Conditions. A recent official release from the Ministry has disseminated a formal document titled *"Standard Operating Procedures for Adult BCG Vaccination under Programmatic Implementation Study in India"*. The primary focus of this study is to evaluate the effectiveness and safety of administering the BCG vaccine to adults, with the overarching goal of reducing the incidence of tuberculosis (TB) within vulnerable populations.

Study Design and Objectives: The study adopts a programmatic stratified cluster randomized parallel arm design. The primary objective is a comprehensive evaluation of the effectiveness of adult BCG vaccination, measured through changes in notified TB cases over a post-intervention period of 36 months. Secondary objectives include annual assessments of BCG vaccination effectiveness against active TB and the vigilant monitoring of Adverse Events Following Immunization (AEFI).

Study Settings: Covering 23 states and union territories (UTs) in India, the study involves 547 National Tuberculosis Elimination Program (NTEP) districts that underwent a careful randomization process, resulting in 274 intervention districts and 273 control districts. This expansive coverage ensures a diverse representation of the population, enhancing the generalizability of study findings.

Inclusion and Exclusion Criteria: Individuals aged 18 years and above, meeting specific criteria such as a history of TB, close contacts, low Body Mass Index (BMI), age over 60, and a history of smoking or diabetes, are eligible for adult BCG vaccination. Conversely, exclusion criteria encompass individuals who are unable to communicate or provide consent, individuals with immunodeficiency or HIV-positive status, pregnant or lactating women, and those currently experiencing illness.

Randomization and Blinding: The study employs a restricted randomization strategy to ensure a balanced distribution of adult population size, TB case notification rate, and socio-economic factors between intervention and control clusters. While the study population and investigators are aware of group allocations, the statistician remains blinded during the data analysis phase, upholding the integrity of the study.

Study Procedures: The study involves a meticulously planned sequence of preparatory activities, including protocol finalization, ethical approval, and training of stakeholders. Intervention districts initiate BCG vaccination following a district assessment based on a standardized checklist, while control districts continue routine TB prevention activities. Adverse events following immunization (AEFI) are monitored and reported in intervention districts, ensuring a comprehensive safety evaluation. Data analysis is conducted using the Ni-kshay portal, providing valuable insights into the program's impact.

Source:

Rodrigues LC, Diwan VK, Wheeler JG. Protective effect of BCG against tuberculous meningitis and miliary tuberculosis: a meta-analysis. Int J Epidemiol. 1993 Dec;22(6):1154-8.

Standard Operating Procedures for Adult BCG Vaccination under programmatic implementation study in India. Central TB Division. Ministry of Health and Family Welfare. 2023. Available from: http://surl.li/oqjdy .