WHO has recommended a new vaccine, R21/Matrix-M, for the prevention of malaria in children

Greetings from Drug Information Bulletin!

Patient Safety Awareness Week has been celebrated during 17th-22nd September 2023 throughout the globe with a goal to inculcate the idea of collective responsibility to make healthcare safer to all. Medication error is one of the important issues in patient safety. Medication error is the third largest contributor in case of death after Heart diseases and cancer. The magnitude may be clear with a data that about 7.7 million patients hurt every year globally. It involves economic consequences like extended hospital stays, additional treatment. Medication errors may occur due to Prescription Errors, Administration error, Transcription error and Dispensing error. There are several causes of medication errors like illegible hand written prescription, wrong dose especially in case of child below 15 years and elder above 65 years. Sometimes half of the adult dose prescribed for children inspite of calculating dose on the basis of microgram or mg per Kg body weight leading to over dosage. Other examples are use of wrong abbreviation (confusion between microgram and mg), not using zero before decimal etc. Lookalike and sound alike drugs are also a common cause of confusion leading to medication error. Besides all stakeholders pharmacists can play an important role in reducing medication error in case of Dispensing, Compounding, Patient counseling and they are doing it efficiently specially in institutional setup but high patient load per pharmacists is a deterrent here. In our country a major portion of the drugs are being dispensed from retail medicine centre on prescription of registered medical practitioners or without prescription, where the role of Pharmacists are immense to reduce medication error. Therefore pharmacists should update themselves, serious in dispensing and be present in the community pharmacy as long as selling activities is continuing. Finally I would request all health care professionals and patients are careful about this issue as “Patient safety is everyone’s job”.

Dr. Subhash C. Mandal
Editor
WHO recommends R21/Matrix-M vaccine for malaria prevention in updated advice on immunization

The World Health Organization (WHO) has recommended a new vaccine, R21/Matrix-M, for the prevention of malaria in children. The recommendation follows advice from the WHO: Strategic Advisory Group of Experts on Immunization (SAGE) and the Malaria Policy Advisory Group (MPAG) and was endorsed by the WHO Director-General following its regular biannual meeting held on 25-29 September.

WHO also issued recommendations on the advice of SAGE for new vaccines for dengue and meningitis, along with immunization schedule and product recommendations for COVID-19. WHO also issued key immunization programmatic recommendations on polio, IA2030 and recovering the immunization programme.

The R21 vaccine is the second malaria vaccine recommended by WHO, following the RTS,S/AS01 vaccine, which received a WHO recommendation in 2021. Both vaccines are shown to be safe and effective in preventing malaria in children and, when implemented broadly, are expected to have high public health impact. Malaria, a mosquito-borne disease, places a particularly high burden on children in the African Region, where nearly half a million children die from the disease each year.

Demand for malaria vaccines is unprecedented; however, available supply of RTS,S is limited. The addition of R21 to the list of WHO-recommended malaria vaccines is expected to result in sufficient vaccine supply to benefit all children living in areas where malaria is a public health risk.

“As a malaria researcher, I used to dream of the day we would have a safe and effective vaccine against malaria. Now we have two,” said Dr Tedros Adhanom Ghebreyesus, WHO Director-General. “Demand for the RTS,S vaccine far exceeds supply, so this second vaccine is a vital additional tool to protect more children faster, and to bring us closer to our vision of a malaria-free future.”

Dr Matshidiso Moeti, WHO Regional Director for Africa, emphasized the importance of this recommendation for the continent, saying: “This second vaccine holds real potential to close the huge demand-and-supply gap. Delivered to scale and rolled out widely, the two vaccines can help bolster malaria prevention and control efforts and save hundreds of thousands of young lives in Africa from this deadly disease.”

Key features of the R21 malaria vaccine:
The updated WHO malaria vaccine recommendation is informed by evidence from an ongoing R21 vaccine clinical trial and other studies, which showed:

- **High efficacy when given just before the high transmission season**: In areas with highly seasonal malaria transmission (where malaria transmission is largely limited to 4 or 5 months per year), the R21 vaccine was shown to reduce symptomatic cases of malaria by 75% during the 12 months following a 3-dose series. A fourth dose given a year after the third maintained efficacy. This high efficacy is similar to the efficacy demonstrated when RTS,S is given seasonally.

- **Good efficacy when given in an age-based schedule**: The vaccine showed good efficacy (66%) during the 12 months following the first 3 doses. A fourth dose a year after the third maintained efficacy.

- **High impact**: Mathematical modelling estimates indicate the public health impact of the R21 vaccine is expected to be high in a wide range of malaria transmission settings, including low transmission settings.

- **Cost effectiveness**: At prices of US$ 2 – US$ 4 per dose, the cost-effectiveness of the R21 vaccine would be comparable with other recommended malaria interventions and other childhood vaccines.

- **Similarity of R21 and RTS,S vaccines**: The two WHO-recommended vaccines, R21 and RTS,S, have not been tested in a head-
to-head trial. There is no evidence to date showing one vaccine performs better than the other. The choice of product to be used in a country should be based on programmatic characteristics, vaccine supply, and vaccine affordability.

- **Safety**: The R21 vaccine was shown to be safe in clinical trials. As with other new vaccines, safety monitoring will continue.

Next steps for the second recommended malaria vaccine, R21/Matrix-M, include completing the ongoing WHO prequalification which would enable international procurement of the vaccine for broader rollout.

Ref. WHO

India had world’s highest number of preterm births in 2020: Lancet

India recorded 3.02 million preterm births in 2020 -- the highest worldwide -- accounting for over 20 percent of all preterm births globally, according to a study published in the The Lancet journal. The research by authors from the World Health Organization (WHO), the United Nations Children’s Fund (UNICEF) and the London School of Hygiene and Tropical Medicine, UK, showed that over 50 percent of all preterm births in 2020 occurred in just eight countries. India was followed by Pakistan, Nigeria, China, Ethiopia, Bangladesh, Democratic Republic of the Congo and the US, the researchers said.

The high numbers of preterm births in these countries and areas are, in part, a reflection of their large population sizes, high numbers of total births, and weaker health systems that are unable to deliver high-quality family planning, antenatal care, and childbirth services to all individuals who need them, they said. Globally, an estimated 13.4 million babies were born early in 2020, with nearly one million dying from preterm complications, the authors said. The data is equivalent to around 1 in 10 babies born early, before 37 weeks of pregnancy worldwide, they said. “Since prematurity is the leading cause of death in children’s early years, there is an urgent need to strengthen both care for preterm babies as well as prevention efforts -- particularly maternal health and nutrition -- so as to improve childhood survival,” the authors said.

“For those who live, preterm birth also significantly increases the likelihood of suffering major illnesses, disability and developmental delays, and even chronic diseases as adults like diabetes and heart conditions,” they said. The study derives estimates from population-based and nationally representative data to generate internationally comparable country-level estimates for 2020. It found that India had the highest number of preterm births in 2020 -- 3.02 million -- accounting for over 20 percent of all preterm births worldwide. Although most of the high preterm birth rates occur in low-income and middle-income countries and areas, rates of 10 per cent or higher were also observed in high-income countries such as Greece and the US, according to the researchers. In south Asia, Bangladesh had the highest rate of preterm births in 2020 (16.2 per cent), followed by Pakistan (14.4 per cent and India (13.0 per cent). In Latin America, country-level preterm birth rates ranged from 5.8 per cent in Nicaragua to 12.8 per cent in Suriname. As birth registration and facility-based deliveries have increased, data on the prevalence of preterm birth has improved. Gaps remain, however, with 92 countries lacking adequate nationally representative data.

Ref. Milleniumpost

Esomeprazole is associated with Hyperprolactinaemia: PvPI

The preliminary analysis of Adverse Drug Reactions (ADRs) from the PvPI database revealed that Esomeprazole indicated for -

- GERD, erosive reflux esophagitis, prevention of relapse of esophagitis & helps in eradication of H. Pylori associated peptic ulcer.
- For the treatment of GERD, gastric and duodenal ulcer, Zollinger-Ellison syndrome is associated with adverse Drug Reaction of Hyperprolactinaemia.

PvPI release requested that Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADR associated with the use of above suspected drug. If, such reaction is encountered, please report to
COVID-19 vaccine Janssen (Ad26.COV2-S)
Potential risks of myocarditis and pericarditis, and facial paralysis

The US Food and Drug Administration (FDA) has announced that the product information for COVID-19 vaccine Janssen (Ad26.COV2-S) was revised to include a Warning conveying that adverse events following use of the vaccine reported suggest increased risks of myocarditis and pericarditis, particularly within the period 0 through 7 days following vaccination. An additional revision to the product information includes facial paralysis (including Bell’s Palsy) that have been reported during post-authorization use.

Reference: US FDA

Ibuprofen Potential risk of renal tubular acidosis

The SFDA has released a safety signal concerning ibuprofen and its potential risk of renal tubular acidosis. Ibuprofen is a non-steroidal anti-inflammatory medication that indicated for its analgesia and antiinflammatory effects. In 2023, the SFDA has detected a signal of ibuprofen and renal tubular acidosis and reviewed all the evidence available on the association between them. The SFDA reviewed VigiBase and found 116 ICSRs internationally at that point of time. The SFDA has extracted cases with completeness score of 0.5 (n=10 cases) in order to apply the causality assessment criteria on them. As a result, all the assessable cases of renal tubular acidosis were either probably or possibly linked to ibuprofen. Data mining of this drug/ADR has been estimated using Information component (IC=4.2) which reflect strong positive statistical association. The SFDA’s investigation concluded that the current available evidence from assessment of the ICSRs, class effect and literature might support a relationship between of ibuprofen and renal tubular acidosis. This signal needs further investigation to confirm the risk, and health-care professionals should be aware of this potential adverse reaction.

Reference: Safety Alert, SFDA, 21 March 2023