How long Covid-19 vaccines will protect a person already vaccinated? It is a million dollar question. In a recent article published in Springer Nature Andreas Radbruch and Hyun-Dong Chang tried to find out the answer. They have opined that the duration of protective immunity to infection by SARS-CoV-2 is crucial for understanding and predicting the course of the COVID-19 pandemic. Clinical studies now indicate the immunity will be long-lasting. In another study available stated that some vaccines may offer COVID-19 immunity for years, especially for those who contracted and recovered from the virus before immunization.

Scientists in a recent article published in Nature reported that mRNA Covid vaccines like those produced by drug companies Pfizer and Moderna induced a persistent immune response in humans that indicate long lasting immunity against the virus. It is learnt that the mRNA vaccines impacted humans’ memory cells, which are called memory “B cells”.

Let us wait for more stud data on other types of vaccines made available by scientists to come to a conclusion on the period of protection offered by different types of Covid vaccines.

Dr. Subhash C. Mandal
Editor
E mail: subhash.mandaldr@gmail.com
Mob. 9830136291
New Drug: Trientine dihydrochloride for Wilson's disease

Approved indication: Wilson’s disease
250 mg capsules

Wilson’s disease is an autosomal recessive disorder. This genetic defect affects the transport of copper. Free copper is toxic so it causes cell damage as it accumulates, firstly in the liver and then in the brain. The disease is therefore also known as hepatolenticular degeneration.

The treatment of Wilson’s disease aims to keep copper concentrations low. This can include using zinc, to reduce the absorption of copper from the gut, and chelating agents, such as penicillamine, to increase excretion. Treatment is lifelong but, in the absence of advanced liver disease, life expectancy can be normal.

Trientine dihydrochloride is a chelating agent which forms a complex with copper. It is taken orally, but is not well absorbed and should not be taken with food. The absorbed portion of the dose is widely distributed. The molecule is metabolised and its main metabolites can also chelate copper. Absorbed trientine has a half-life of 13.5 hours and is excreted with its metabolites in the urine. The dose is determined by the serum concentration of free copper.

Various forms of trientine have been available for a number of years. The approval of trientine dihydrochloride in Australia appears to be mainly based on a retrospective observational study. This used data from 405 children and adults with Wilson’s disease who had been followed for an average of 13.3 years. As patients could change treatment, the analysis involved 326 treatments with penicillamine and 141 with trientine. Most patients took trientine as a second-line therapy. In second-line therapy stable liver disease was achieved with 25% of penicillamine treatments and 22.2% of trientine treatments. The corresponding figures for stable neurological disease were 69.2% and 33.3%.1

During the study 28.8% of the treatments with penicillamine were stopped because of adverse events, compared with 7.1% for trientine. The adverse effects of trientine include nausea, arthralgia and rashes. Neurological symptoms may get worse at the start of treatment. Trientine can reduce serum iron so some patients may develop anaemia. As trientine and zinc may interact, they should not be used together. Trientine is teratogenic.

The approved indication for trientine dihydrochloride in Australia is for adults and children with Wilson’s disease who are unable to tolerate penicillamine.

References:

Source: Australian Prescriber

Status in India:
Trientine Hydrochloride Bulk and 250 mg capsule approved by CDSCO for the treatment of Wilson’s disease (hepatolenticular degeneration) in patients intolerant to Penicillamine. It should be used when continued treatment with Penicillamine is no longer possible because of intolerable or life endangering side effect approved on 11.06.2018. Presently available in Indian market.

India and UK jointly Conduct Clinical Trials on 'Ashwagandha' for COVID-19 Recovery

The Ayush ministry’s All India Institute of Ayurveda (AIIA) in collaboration with the United Kingdom’s London School of Hygiene and Tropical Medicine will conduct a study on ‘Ashwagandha’ for promoting recovery from COVID-19 in a boost to the traditional Indian medicine system.

The London School of Hygiene & Tropical Medicine is a public research university in Bloomsbury, central London, and a constituent college of the University of London that specialises in public health and tropical medicine. Both the institutions signed a Memorandum of Understanding to conduct the clinical trials of Ashwagandha on 2,000 people in three UK cities - Leicester, Birmingham, and London (Southall and Wembley), said the ministry in a statement.

Ashwagandha (Withania Somnifera), commonly known as 'Indian winter cherry', is a traditional Indian herb that boosts energy, reduces stress, and makes the immune system stronger. It is an easily accessible, over-the-counter nutritional supplement in the UK and has a proven safety
profile. The positive effects of Ashwagandha have been observed in COVID-19, which is a multi-system disease with no evidence of its effective treatment or management.

The successful completion of the trial can be a major breakthrough and give scientific validity to India’s traditional medicinal system. While there have been several studies on Ashwagandha to understand its benefits in various ailments, this is the first time the Ministry has collaborated with a foreign institution to investigate its efficacy on COVID-19 patients.

AILA director Dr. Tanuja Manoj Nesari, who is also a co-investigator in the project along with Dr. Rajgopalan, Coordinator - International Projects, said that the participants have been randomly selected. Dr. Sanjay Kinra of LSHTM is the principal investigator of the study. The participants will have to take the 500mg tablets twice a day. A monthly follow-up of self-reported quality of life, impairment to activities of daily living, mental and physical health symptoms, supplement use, and adverse events will be carried out.

"For three months, one group of 1,000 participants will be administered Ashwagandha tablets while the second group of 1,000 participants will be assigned a placebo, which is indistinguishable from Ashwagandha in looks and taste. Both patients and the doctors will be unaware of the group’s treatment in a double-blind trial," Dr. Nesari said.

Source: Zee News

NPPA Directs Manufacturers and Importers of Five Medical Devices to Submit Data Every Quarter

The National Pharmaceutical Pricing Authority (NPPA) has directed the manufacturers and importers of the five medical devices it has recently imposed a trade margin cap of 70 per cent to submit quarterly stock details within 10 days from the completion of the quarter, till the time the notification is in force.

The drug price regulator said that the revised maximum retail prices of 1034 brands of medical devices has been received by the authority, from the importers and manufacturers.

The Authority, through a Gazette Notification issued on July 13, 2021 has capped the trade margin of pulse oximeter, blood pressure monitoring machine, nebuliser, digital thermometer and Gluck meter, at 70 per cent at the Price to Distributor (PTD) level. It was further notified that the prices are to be revised by the manufacturers or importers as per the formula prescribed in the notification and the revised prices shall be effective from July 20, 2021.

The quarterly stock details, including units manufactured, imported, sold and exported, have to be submitted in the prescribed format, in order to assess the availability of these devices in the country.

“...manufacturers/importers of these five medical devices are hereby directed to submit requisite quarterly stock details, for every quarter, in the prescribed format within 10 days from the completion of the quarter till the time notification mentioned above is in force,” said an NPPA notification.

According to the new list of medical devices released by the Authority, a total of 260 pulse oximeter brands, 307 blood pressure monitoring device brands, 217 nebulisers, 150 digital thermometers, and 100 glucometer brands submitted their data including the existing/old MRP and revised MRP with effect from July 20, 2021, to the authority.

Source: Pharmabiz

5 percent of Covaxin Royalty to ICMR Raises Questions

Bharat Biotech will pay a royalty of 5% on net sales of its Covid-19 vaccine Covaxin to Indian Council of Medical Research, prompting concerns from public health and IP experts.

They have questioned the need for the payout, to be done on a half-yearly basis and the basis for the calculation. The pay-out reflects in the cost of the vaccine, and hence impacts affordability, they told TOI. While the Centre has revised the price to Rs 225 per dose for Covaxin for the fresh order placed in July, it is the most expensive jab in the private market at Rs 1,410.

Junior health minister Bharati Pravin Pawar told Parliament that the royalty “clause is governed by
the MoU executed between the two parties (Bharat Biotech and ICMR) for the development of Covaxin”.

As per the CoWin website, when the vaccination was launched on January 16, a little over 5 crore doses of Covaxin have been administered in the overall 45 crore immunisation so far. The government had invested in pre-clinical studies for Covaxin, and Rs 35 crore was spent on its clinical trials, according to the Centre’s affidavit filed in Supreme Court in May.

“The government should also verify the investments made by Bharat Biotech. If ICMR gets a royalty of 5% on Rs 35 crore funding, can the government verify that BB invested upwards of Rs 650 crore for development of Covaxin?” Murali Neelakantan, principal lawyer at Amicus said. Amulya Nidhi of Jan Swasthya Abhiyan alleged that there appeared to be a nexus between government and company for earning profits.

“Rather than giving 5% royalty to ICMR, the Centre should order technology transfer and a compulsory licence be given to not only the government-owned companies, but to all potential manufacturers.”

“The royalty should have been used instead to reduce the price of the vaccine by 5% for the citizens during the pandemic, and not as a source of revenue by a government body like ICMR, entrusted for disaster management of Covid-19,” added Rohit Jain, a doctor working on patient issues. Queries mailed by TOI to ICMR went unanswered.

Source: The Times of India

**Propofol Risk of green breast milk**

The Medsafe has announced that the CARM received a report of a patient who expressed green breast milk post-surgery after using propofol as an anesthetic agent. Propofol is indicated for induction and maintenance of general anesthesia in adults and children. It has been reported that propofol may discolor urine. Internationally, there are other case reports of green breast milk following administration of propofol. Health-care professionals are reminded to check the data sheet for information on breastfeeding following administration of propofol.

Reference: Prescriber Update, Medsafe, March 2021 (www.medsafe.govt.nz/)

---

**Reader's Column………**

Dear Dr. Subhash Mandal,

Publishing a newsletter fortnightly continuously for 15 years is no child’s play and takes serious efforts, passion and patience. Heartiest Congratulations to you for achieving this rare feat.

With regards.

C K Katiyar  
CEO Health Care (Technical)  
Emami Ltd  
687, Anandpur  
EM Bypass  
Kolkata-700107

---

**Forthcoming Event………**