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Editorial

COVID-19 has made significant changes in everyday life throughout the world and education system is not an exception. In a recent survey conducted by the FIP regarding impact on education technology reveals that 3% institutions have not shifted to online mode, 75% have switched to online mode in the month of March 2020, 16% have switched over to online in April 2020, remaining institutions have switched over to online mode on May 2020 onwards. In this Rapid Response survey 211 responses were received from 63 Universities round the globe. WHO region wise, Europe is on the forefront, followed by the Western Pacific and North America.

India is also adopted digital technology in Pharmacy Education. But with some limitations like other parts of the globe, that include-lack of internet access, lack of computers/Laptops/smart hone and sometimes low internet speed. Though faculty members were not trained in using digital platform in teaching, but they have picked up very quickly during this COVID pandemic. This is one of the better sides of the COVID pandemic. Hope this digital technology will be used in teaching simultaneously with class room teaching in future also.

Dr. Subhash C. Mandal
Editor
E mail: subhash.mandaldr@gmail.com
Mob. 9830136291
USFDA Issues Emergency Use Authorization for Convalescent Plasma as Potential Promising COVID–19 Treatment

U.S. Food and Drug Administration issued on 23rd August an emergency use authorization (EUA) for investigational convalescent plasma for the treatment of COVID-19 in hospitalized patients as part of the agency’s ongoing efforts to fight COVID-19. Based on scientific evidence available, the FDA concluded, as outlined in its decision memorandum, this product may be effective in treating COVID-19 and that the known and potential benefits of the product outweigh the known and potential risks of the product. Today’s action follows the FDA’s extensive review of the science and data generated over the past several months stemming from efforts to facilitate emergency access to convalescent plasma for patients as clinical trials to definitively demonstrate safety and efficacy remain ongoing. The EUA authorizes the distribution of COVID-19 convalescent plasma in the U.S. and its administration by health care providers, as appropriate, to treat suspected or laboratory-confirmed COVID-19 in hospitalized patients with COVID-19.

Scientific Evidence on Convalescent Plasma

Based on an evaluation of the EUA criteria and the totality of the available scientific evidence, the FDA’s Center for Biologics Evaluation and Research determined that the statutory criteria for issuing an EUA criteria were met. The FDA determined that it is reasonable to believe that COVID-19 convalescent plasma may be effective in lessening the severity or shortening the length of COVID-19 illness in some hospitalized patients. The agency also determined that the known and potential benefits of the product, when used to treat COVID-19, outweigh the known and potential risks of the product and that there are no adequate, approved, and available alternative treatments. The EUA is not intended to replace randomized clinical trials and facilitating the enrollment of patients into any of the ongoing randomized clinical trials is critically important for the definitive demonstration of safety and efficacy of COVID-19 convalescent plasma. The FDA continues to recommend that the designs of ongoing randomized clinical trials of COVID-19 convalescent plasma and other therapeutic agents remain unaltered, as COVID-19 convalescent plasma does not yet represent a new standard of care based on the current available evidence.

Terms of EUA

The EUA requires that fact sheets providing important information about using COVID-19 convalescent plasma in treating COVID-19 be made available to health care providers and patients, including dosing instructions and potential side effects. Possible side effects of COVID-19 convalescent plasma include allergic reactions, transfusion-associated circulatory overload, and transfusion associated lung injury, as well as the potential for transfusion-transmitted infections. For details: https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment

Status in India: CDSCO has approved A Phase II, Open Label, Randomized Controlled Trial to Assess the Safety and Efficacy of Convalescent Plasma to Limit COVID-19 Associated Complications in Moderate Disease on 17.04.2020.

US FDA removes boxed warning about risk of leg and foot amputations for the Canagliflozin: Janssen Pharmaceuticals, Inc.

Based on a U.S. Food and Drug Administration (FDA) review of new data from three clinical trials, we have removed the Boxed Warning about amputation risk from the diabetes medicine canagliflozin (Invokana, Invokamet, Invokamet XR) prescribing information.

We required the Boxed Warning in 2017 based on our assessment that the risk of amputations was very serious in relation to the potential benefit of canagliflozin, which was initially approved to be used with diet and exercise to lower blood sugar in adults with type 2 diabetes. Subsequent FDA reviews of new clinical trial data demonstrated additional heart- and kidney-related benefits, which led to additional approved uses.
Specifically, in 2018, canagliflozin was approved to reduce the risk of major heart-related events such as heart attack, stroke, or death in patients with type 2 diabetes who have known heart disease; and, in 2019, it was approved to reduce the risk of end-stage kidney disease, worsening of kidney function, heart-related death, and being hospitalized for heart failure in certain patients with type 2 diabetes and diabetic kidney disease.

Collectively, these newly identified effects of canagliflozin on heart and kidney disease show significantly enhanced benefit of this medicine. Safety information from recent clinical trials also suggests that the risk of amputation, while still increased with canagliflozin, is lower than previously described, particularly when appropriately monitored. Based upon these considerations, we have concluded that the Boxed Warning should be removed. The amputation risk with canagliflozin remains and is still described in the Warnings and Precautions section of the prescribing information.

Health care professionals and patients should continue to recognize the importance of preventative foot care and monitor for new pain, tenderness, sores, ulcers, and infections in the legs and feet. Risk factors that may predispose patients to the need for amputation should be considered when choosing antidiabetic medicines. Canagliflozin belongs to a class of medicines called sodium-glucose cotransporter-2 (SGLT2) inhibitors. It lowers blood sugar by causing the kidneys to remove sugar from the body through the urine. Untreated, type 2 diabetes can lead to serious problems, including blindness, nerve and kidney damage, and heart disease.

SOURCE: US FDA DRUG SAFETY COMMUNICATION

Estrogen may lessen severity of Covid-19 symptoms in women, says study
North Carolina: In an effort to understand why men are at greater risk for more severe symptoms and worse outcomes from Covid-19 regardless of age, scientists at Wake Forest School of Medicine conducted a review of published preclinical data on sex-specific hormone activity, especially estrogen. The review has been published in the September online issue of the journal Current Hypertension Reports. “We know that corona virus affects the heart and we know that estrogen is protective against cardiovascular disease in women, so the most likely explanation seemed to be hormonal differences between the sexes,” said the lead author of the review, Leanne Groban, M.D., professor of anesthesiology at Wake Forest School of Medicine, part of Wake Forest Baptist Health.

SOURCE: The Times of India

Extract of two webinars sponsored by the Partnership for Quality Medical Donations (PQMD) about Covid-19 vaccines: Interesting findings, said Richard Laing
The first webinar included the following participants.
1. Arnaud Bernaert Head of Health And Healthcare, Member Of The Executive Committee, World Economic Forum. He reported that previously the world's production of vaccines amounted to 3.5 billion doses and that 2.5 billion doses had already been purchased in advance by high-income countries for when the first vaccines are registered. He also pointed out that when they are registered no one can know how long the vaccine will be effective.
2. Sophie Mathewson, Specialist, Vaccine Policy & Investment, GAVI: The Vaccine Alliance. She talked about a number of practical issues they are facing and discussed the effect of Covid on existing highly effective existing programs have been affected and then issue of vaccine hesitancy.
3. Dawn O'Connell, USA Director, Coalition for Epidemic Preparedness Innovations (CEPI). This is the relatively new organization that was created to promote research into vaccines.
4. Dr. Tolullah Oni, Clinical Senior Research Associate, MRC Epidemiology Unit, University of Cambridge. Although she spoke last, she was very interesting. She is a clinical epidemiologist who has worked in South Africa on TB vaccine trial but clearly knows a lot about a lot of different things.

One comment she made which was not discussed as the panel ran out of time was "What will an effective Covid vaccine do? Will it reduce mortality? Will it prevent transmission? Will it do both or just one of these functions?" Thinking about her question, you can imagine that a vaccine that prevents mortality will be popular with the general public but if it does not prevent transmission governments may be much less willing to purchase it. If it only prevents transmission will the general public be willing to take it? Interesting questions.

The second panel had three participants, two from big pharma industry and the third from a Brazilian government supported institution with a lot of experience in bringing vaccines to market.
1. Dr. Isabelle Deschamps, Head of Global Vaccines and Public Affairs, Sanofi Pasteur. She explained how Sanofi and GSK have formed a consortium that will build on the two different companies' expertise in developing vaccine antigens and adjuvants and will jointly produce vaccines that may be better than the first round vaccines that are currently in Phase 3 trials.
2. Prof. Raul Machado Neto, Director of Institutional Strategy, Instituto Butantan. He talked about how institutions like his in Latin America were open to establish partnerships with big pharma companies based on mutual respect and trust. Clearly he has had a lot of positive and negative experiences.
3. Dr. Julia Spencer, Associate Vice President, Global Vaccines Public Policy, Partnerships, & Government Affairs at Merck. She talked about the importance of ensuring that any vaccine that was produced should be safe, of assured quality and efficacious. I got the strong impression from the industry speakers that they would not be seeking any Emergency Use Authorizations as has happened with chloroquine and convalescent plasma.

There was some discussion about financing and pricing and the case was made that companies needed these Advance Market Commitment payments to do the research now and that if they did not agree to these pre-registration contacts they would not be able to get the work done.
I was worried that when the vaccines do come out especially if a number of the initial Phase 3 trials fail will there not be any vaccine left for high-risk individuals in LMICs. I think they may have a long wait.
Source: E drugs