Editorial

Several groups of scientists are working hard for developing medicines and vaccines to combat COVID-19 round the world. They are either trying to develop new drug or vaccine for this purpose or some of them are trying to repositioning old drugs to combat COVID. As per the reports several groups are working on different type of drugs like- antivirals, antimalarials, Cardiovascular drugs, H2 receptors, anti psoriasis drugs etc. Already USFDA has given permission of use of Hydroxychloroquine and Chloroquine for emergency purpose and it is in use in full swing. On 1st May USFDA has cautioned against use of these drugs outside hospital and for clinical trial because of its serious adverse reaction i.e. QT prolongation. Indian people are eagerly waiting for the reaction of ICMR and CDSCO regarding use of Hydroxychloroquine and Chloroquine in this back drop.

USFDA extended EUA approval to Remdesivir for COVID treatment on 1st May 2020 for hospitalized patient and for clinical trial, which was tried earlier for several purposes without much positive result. In the mean time Gilead -the patent holder signs Voluntary Licensing Agreements with Cipla, Hetero Labs, Jubilant Lifesciences, Mylan for Remdesivir.

Favipiravir-a drug approved for the treatment of influenza in Japan since 2014 showed promising result in COVID-19 patient and several companies are conducting Phase III trial on it.

Several scientific groups are working for developing vaccines for COVID and their results are at different stages like- pre clinical, Phase I, Phase II and Phase III etc, but as per the report the Oxford University developed vaccine is much ahead and are expecting to market within a very short time. One of the Indian companies is also partnering with them in manufacturing of this vaccine.

However whole world has to wait for vaccine against COVID and curative drug of COVID patient. We strongly believe that we will overcome this crisis.

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Govt. of India Notifies Guidelines For Practising Telemedicine

The government has gazette notified guidelines to practice telemedicine in India, a significant step as telemedicine consultation was a grey area in India on 12th May vide No. MCI-211(2)/2019(Ethics)/100659.

The experts in the centre had been working on drafting standard guidelines that doctors could refer to because of the challenges posed for in-person consultation owing to the country’s large size and varied topography.

Telemedicine is referred to the delivery and facilitation of health and health-related services including medical care, provider and patient education, health information services, and self-care via telecommunication and digital communication technologies, a practice that has gained significance globally over the past few years with advances in technology.

In India it had been a somewhat grey area because there was no central guideline regulating the practice even though some states had come out with individual guidelines. The centre had been in the process of drafting these guidelines for sometime that got expedited because of the restrictions imposed by the sudden lockdown.

The Board of Governors in supersession of the Medical Council of India (MCI), has been working on the guidelines amended the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, to include telemedicine consultation. However, the guidelines prohibit use of digital technology to conduct surgical or invasive procedures remotely.

“We had already put in six months of work into the guidelines and, when the coronavirus pandemic happened, we expedited it. Technology platforms were something available and being used, but were not regulated, which exposed both patients and providers to challenges…” Dr Nikhil Tandon, head, department of endocrinology and metabolism, All India Institute of Medical Sciences, had explained earlier when the draft was out during March end. Dr Tandon is a member of the Board of Governors, MCI.

The release of guidelines that aim at protecting both patients and practitioners got expedited because of the restrictions on movement imposed during the national lockdown to contain the pandemic, as the practice provides patient’s safety, as well as health workers’ safety, especially in situations where there is risk of contagious infections.

“Disasters and pandemics pose unique challenges to providing health care. Though telemedicine will not solve them all, it is well suited for scenarios in which medical practitioners can evaluate and manage patients. A telemedicine visit can be conducted without exposing staff to viruses/infections in the times of such outbreaks. Telemedicine practice can prevent the transmission of infectious diseases reducing the risks to both health care workers and patients,” the guidelines say.

“...It can provide rapid access to medical practitioners who may not be immediately available in person. In addition, it makes available extra working hands to provide physical care at the respective health institutions. Thus, health systems that are invested in telemedicine are well positioned to ensure that patients with Covid-19 kind of issues receive the care they need.”

In the long run, there is a special focus on Health and Wellness Centres that provide preventive and primary healthcare within a 5 km radius at the grassroots level, especially in remote and largely inaccessible areas.

There are a number of benefits of telemedicine. It increases timely access to appropriate interventions, including faster access to services that may not otherwise be available.

One of the major advantages of telemedicine, say experts, can be saving cost and effort, especially of rural patients, as they need not travel long distances for obtaining consultation and treatment.

The practice can be particularly helpful for patients who need a follow up consultation but do not have to be physically present for a check-up, which will, in turn, reduce the burden on the secondary hospitals.

“There are a number of technologies that can be used in telemedicine, which can help patients adhere better to their medication regimens and manage their diseases better. Telemedicine can also enable the availability of vital parameters of the patient to the physician with the help of
medical devices such as for blood pressure, blood glucose, etc management,” the guidelines further mention.

The results from the home monitoring devices can be directly uploaded online for a physician to access, and advise accordingly.

The expert document has also provided a list of medicines that can be prescribed by doctors to treat patients.

Telemedicine includes all channels of communication with the patient that leverage information technology platforms, including voice, audio, text and digital data exchange. However, telemedicine services cannot be used for providing emergency care when alternative in-person care is available. Also, it should largely be limited to first aid, life-saving measure, counselling and advice on referral. Health care providers say it is a welcome move, not just the under current circumstances but also in the long run, when physical examination is not required.

“It will help to have a standard operating guidelines in place as earlier different guidelines were emerging from different states. Apollo has a telemedicine programme running for long, and through our network we cater to states such as Andhra Pradesh, Jharkhand, and higher reaches of Himachal Pradesh such as Kaza and Keylong. The formal notification will help us scale up and reach out to a larger population base. It anyway doesn’t make sense for a patient to come all the way to a health facility just to show, say, blood reports,” says Dr Anupam Sibal, group medical director, Apollo Hospitals.

“Also, telehealth is definitely going to be a key component of the new normal that we are going to see in the post-pandemic world,” he added.

Source: Hindusthan Times

Gilead signs Voluntary Licensing Agreements with Cipla, Hetero Labs, Jubilant Lifesciences, Mylan for Remdesivir

Under the licensing agreements, the companies have a right to receive a technology transfer of the Gilead manufacturing process for Remdesivir to enable them to scale up production more quickly

Gilead has signed non-exclusive voluntary licensing agreements with Cipla, Hetero Labs, Jubilant Lifesciences, Mylan and Ferozsons Laboratories, a Pakistan based pharma firm, to manufacture remdesivir for distribution in 127 countries including India. Remdesivir has been issued an Emergency Use Authorization (EUA) by the US Food and Drug Administration (FDA) to treat COVID-19 patients.

Under the licensing agreements, the companies have a right to receive a technology transfer of the Gilead manufacturing process for Remdesivir to enable them to scale up production more quickly. The licensees are also allowed to set their own prices for the generic product they produce. According to Gilead, the licenses are royalty-free until the World Health Organization declares the end of the Public Health Emergency of International Concern regarding COVID-19, or until a pharmaceutical product other than remdesivir or a vaccine is approved to treat or prevent COVID-19, whichever is earlier.

Commenting on the partnership, Umang Vohra, MD and Global CEO, Cipla said, “As the world is faced with the COVID-19 crisis, it is imperative that we collaborate and fight this virus together. We are pleased to partner with Gilead for this cause and take this treatment to patients across countries after the required regulatory approvals. At Cipla, it is our continuous endeavour to ensure that no patient is denied access to life-saving treatments. Our partnership with Gilead represents this unwavering commitment and is a significant step towards saving millions of lives impacted by the pandemic.”

Evoking similar notions, Shyam S Bhartia, Chairman and Hari S Bhartia, Co-Chairman & Managing Director, Jubilant Life Sciences said, “We are very happy to strengthen our partnership with Gilead to license remdesivir, which, based on initial data, shows promise to be a potential therapy for COVID-19, a pandemic creating unprecedented health and economic crisis globally. We will be monitoring the clinical trials and regulatory approvals very closely and would be ready to launch the drug shortly after the required regulatory approvals. We also plan to produce the drug’s Active Pharmaceutical
Ingredient in-house, helping its cost effectiveness and consistent availability.”

"Hetero is pleased to partner with Gilead to enable access for this important drug to India and other developing countries at this crucial time. This agreement also illustrates the significance of global collaboration and the need for coming together to fight the health crises impacting humanity. Hetero has developed this product in India and has already been working with the government, ICMR, and DCGI for necessary studies and approvals to bring this product to treat COVID-19 patients in India,” commented Dr B Partha Saradhi Reddy, Chairman, Hetero Group of Companies.

The EUA is based on available data from two global clinical trials – US National Institute for Allergy and Infectious Diseases’ placebo-controlled Phase 3 study in patients with moderate to severe symptoms of COVID-19, and Gilead’s global Phase 3 study evaluating Remdesivir in patients with severe disease. Multiple additional clinical trials are ongoing to generate more data on the safety and efficacy of Remdesivir as a potential treatment for COVID-19. Remdesivir continues to be an investigational drug that has not been approved by the FDA.

Source: Pharmabiz

No Benefit In Hydroxychloroquine COVID-19 Virus Treatment: Two Studies

Treating COVID-19 patients with the malaria drug hydroxychloroquine (HCQ) had no positive effect and caused other health complications, two new studies showed recently.

The anti-malarial has been touted by US President Donald Trump among others as a potential "game changer", after initial studies in lab settings showed it may be able to prevent the virus replicating.

But several subsequent studies -- including one funded by the US government -- appear to have doused hopes that HCQ can help patients hospitalised with COVID-19.

In the first study released Friday, researchers in France monitored 181 patients hospitalised with pneumonia due to COVID-19 and who needed oxygen.

Eighty-four were treated with HCQ and 97 were not.

They found no meaningful difference between the groups for either transfer to intensive care, death within seven days or developing acute respiratory distress syndrome within 10 days.

"Hydroxychloroquine has received worldwide attention as a potential treatment for COVID-19 because of positive results from small studies," said the authors of the research, published in the BMJ journal.

"However, the results of this study do not support its use in patients admitted to hospital with COVID-19 who require oxygen." A second study saw researchers in China split 150 COVID-19 patients in to two groups, one of which received HCQ.

After four weeks tests revealed similar rates of sustained infection among both groups, though adverse reactions to treatment were more common in the HCQ group.

Nor did the severity or duration of symptoms differ between each group. Hydroxychloroquine and a related compound chloroquine have been used for decades to treat malaria, as well as the autoimmune disorders lupus and rheumatoid arthritis.

Last month the European Medicines Agency warned that there was no indication HCQ could treat COVID-19 and said some studies had seen serious and sometimes fatal heart problems in patients.

Source: AFP