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Uncovering COVID-19 Treatments: An Update on the SOLIDARITY Trial

Announcer:
You're listening to *The Drug Report* on ReachMD, hosted by Linda Bernstein, Pharm.D., Clinical Professor on the Volunteer Faculty of the School of Pharmacy, University of California, San Francisco.

Dr. Bernstein:
Welcome to *The Drug Report*, with special focus on the COVID-19 pandemic.

The World Health Organization and partners recently announced it was launching an international clinical trial with the goal of generating significant worldwide data from thousands of patients to find the most effective treatments for COVID-19. The SOLIDARITY trial will offer clinicians simplified procedures to enable even overloaded hospitals to participate. Tedros Adhanom, Director-General of the World Health Organization stated, “This is a historic trial which will dramatically cut the time needed to generate robust evidence about what drugs work. More than 45 countries are contributing to the trial, and more have expressed interest. The more countries who join the trial, the faster we will have results. Ten countries have already committed to the project. Those countries are Argentina, Behrain, Canada, France, Iran, Norway, South Africa, Spain, Switzerland, and Thailand, and I trust many more will join. In the meantime, we call on individuals and countries to refrain from using therapeutics that have not been demonstrated to be effective in the treatment of COVID-19.”

According to a recent Science Magazine article describing the trial, researchers and public health agencies are looking to repurpose drugs already approved for other diseases and known to be largely safe. They’re also looking at unapproved drugs that have performed well in animal studies with the other two deadly coronaviruses, which cause severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS).

WHO is focusing on what it says are the four most promising therapies based upon existing data from case reports and early studies: an experimental antiviral compound called remdesivir; the malaria medications chloroquine and hydroxychloroquine; a combination of two HIV drugs, lopinavir and ritonavir with and without interferon-beta. Some data on their use in COVID-19 patients have already emerged—the HIV combo failed in a small study in China—but WHO believes further study is needed in a broader cohort of patients. This trial will not be double blind as WHO is balancing the desire for quick answers vs. scientific rigor.

Patient enrollment in the SOLIDARITY trial will be easy. The physician can enter an eligible patient’s data into a WHO website, including any underlying condition that could change the course of the disease, such as diabetes or HIV infection. The patient’s consent form is scanned and sent to WHO electronically. The website will randomly assign the patient to one of the study drugs available at the patient’s hospital or to the local standard care for COVID-19.

According to Ana Maria Henao Restrepo, Medical Officer, Department of Immunization Vaccines and Biologicals at WHO, once enrolled, no more measurements or documentation are required. Physicians will record the day the patient left the hospital or died, the duration of the hospital stay, and whether the patient required oxygen or ventilation, she says. “That’s all.”

Additional studies within other countries may piggyback onto the WHO trial, Heneo-Restrepo says. For example, INSERM, the French biomedical research agency, announced it will conduct an add-on trial in Europe, named Discovery, that will follow WHO’s example and will include 3,200 patients from at least seven countries, including 800 from France. That trial will test the same drugs, with the exception of chloroquine.

The WHO will be continually monitoring the trial’s progress and may make adjustments as required to the trial’s “adaptive design” and in

the medications under study.

For *The Drug Report*, I'm Pharmacist Dr. Linda Bernstein.

Announcer:
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