

# Envisaging the Off-Label use of Drugs in the Treatment of Coronavirus Disease 2019 Cases

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## Abstract

The coronavirus disease-2019 (COVID-19) pandemic continues to claim lives of the affected cases, as no therapeutically proven treatment option has been internationally approved. Till date, none of the used pharmaceutical products have been found to be safe and effective in the treatment of the disease. However, a wide range of medicines has been used in treating the patients and the process of using the same in clinical trials is also underway. In other words, those medicines which have not been yet approved for the treatment of COVID-19 disease by the national drug regulatory authorities are being used in different nations. This practice has been termed as off-label use and is permissible provided the national laws and regulations have approved the same. In conclusion, the COVID-19 pandemic is a global problem and it requires unprecedented global solutions as we cannot allow people to die from the disease-related complications. Thus, the off-label use of medicines has been recommended, provided it falls within the national regulations and till the time no safe and effective treatment option is available.

**Keywords:**

COVID-19 pandemic. Off-label. Treatment. World Health Organization

## Introduction

The coronavirus disease-2019 (COVID-19) pandemic continues to claim lives of the affected cases owing to the disease related complications, as no therapeutically proven treatment option has been internationally approved [1]. As of now, a total of 15581009 cases and 635173 deaths have been reported in the affected 216 nations and territories [2]. It is worth noting that gradually but definitely the global case fatality ratio is on the rise and has now reached to 4.1%, owing to the health system being overstretched beyond their capacities and shortage of medical equipment like ventilator and development of serious complications [1-3].

## Ground reality & Off-label use

In the ongoing pandemic, as of now, none of the used pharmaceutical products have been found to be safe and effective in the treatment of the disease. However, a wide range of medicines has been used in treating the patients and the process of using the same in clinical trials is also underway [3-6]. In other words, those medicines which have not been yet approved for the treatment of COVID-19 disease by the national drug regulatory authorities are being used in different nations [1]. This practice

has been termed as off-label use and is permissible provided the national laws and regulations have approved the same, and thus it is a must that all the health professionals should be aware of the same and it should not be done for everyone, but to only those cases who really do require drug intervention [1].

Moreover, due to the practice of off-label use of a medicine which has been recommended primarily for some other condition, the problems of needless stocking or unavailability of the medicine for its primary indication have to be avoided [1]. It has to be understood that the employment of medicines on an emergency basis without waiting for the results of clinical trials can be considered as ethical, as long as no proven effective treatment is available; it is not possible to start clinical trials promptly; the fact that informed consent has been given either by the patients or their legal representatives; the therapeutic off-label use is monitored stringently; and the obtained treatment results are carefully recorded and shared with the medical fraternity on a timely basis [1].

It is important to remember that the decision to offer an unproven treatment strictly depends on the agreement achieved between the confirmed case and the treating physician, provided it has been also approved by the national regulations [2,3]. However, the idea should be to offer this treatment as a part of clinical trials, so that eventually the scientific community can be benefited, but this all will depend upon the consent given by the patients or their relatives. Under all circumstances, the treatment options which show encouraging results have to be further studied in a clinical trial to eventually reach reliable conclusions about the safety, efficacy, potential risks and the associated benefits [3-6].

## Solidarity trial

In this regard, till date, more than 90 nations have agreed for being the part of a multi-national Solidarity trial, which will be sponsored by the World Health Organization and these participating nations [4]. The goal of this trial is to recognize the medicines which can save the lives of humans in this ongoing battle. As of now, it has been decided to assess the effectiveness of four different drugs or their combinations (viz. lopinavir, ritonavir, interferon beta and chloroquine) and compare the same with the standard care which is being employed currently (control arm) [4].

## Treatment modalities

At the same time, a wide range of treatment options has been employed under heterogeneous settings in different nations. In-fact, in a non-randomized clinical trial, the use of hydroxychloroquine has been associated with a significant decline in the viral load and these results are also reinforced by azithromycin [3]. In India, the national authorities have approved the combination of lopinavir and ritonavir, but at the same time the off-label use of hydroxychloroquine and azithromycin has also been recommended for serious patients or those requiring management in intensive care units [5]. Likewise, in some of the settings, Acetazolamide, Nifedipine and Phosphodiesterase Inhibitors have been employed as adjunctive therapy in the treatment of the diagnosed cases [6].

## Conclusion

In conclusion, the COVID-19 pandemic is a global problem and it requires unprecedented global solutions as we cannot allow people to die from the disease-related complications. Thus, the off-label use of medicines has been recommended, provided it falls within the national regulations and till the time no safe and effective treatment option is available.

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