

BC PROVINCIAL ANTIMICROBIAL CLINICAL EXPERT GROUP (PACE) POSITION STATEMENT:

INVESTIGATIONAL THERAPEUTICS FOR COVID-19 IN HOSPITALIZED PATIENTS

MARCH 2020

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COVID-19 is caused by the novel coronavirus SARS-CoV-2, which was first identified in December 31, 2019. It causes a wide range of illness from asymptomatic infection to acute respiratory distress syndrome. There are no licensed therapies for COVID-19 or other related coronaviruses.

A vaccine for COVID-19 is unlikely to be available for another 12-18 months. In the interim, researchers and funders have rapidly mobilized to initiate clinical trials of existing therapeutic agents. A number of potential antiviral and immunomodulatory therapies have become prominent in medical discussion and social media, including chloroquine, hydroxychloroquine, lopinavir-ritonavir, remdesivir and tocilizumab.

There is much excitement amongst clinicians to use investigational agents before results of clinical trials are available. The urge to “do something” is understandable. However, **none of the agents has any published evidence of clinical benefit**. It is completely unknown if prophylaxis or treatment of COVID-19 with these agents is beneficial, neutral, or even harmful. Provision of investigational agents without a proper ethical framework to identify magnitude of potential benefit versus harm goes against the core principle of medicine – “do no harm”. Furthermore, diversion of drug supply to COVID-19 without evidence can cause great harm or concerns about availability to those who take these medications for Health Canada approved, evidence-based, indications.

These recommendations are in line with the World Health Organization; BC Provincial Clinical Guidance (<http://www.bccdc.ca/health-professionals/clinical-resources/covid-19-care/clinical-care>); and the College of Physicians and Surgeons of BC, College of Pharmacists of BC, and BC College of Nursing Professionals (<https://www.bcpharmacists.org/readlinks/joint-statement-unproven-therapies-covid-19>).

RECOMMENDATION

1. Investigational therapeutics for COVID-19 should only be used in the setting of an ethically approved clinical trial.
2. Chloroquine/hydroxychloroquine should only be used for approved indications (rheumatoid arthritis, systemic lupus erythematosus, treatment and prevention of malaria). Chloroquine/hydroxychloroquine should not be used for prophylaxis or treatment of COVID-19 outside of a clinical trial.
3. Lopinavir-ritonavir (Kaletra) is formulary restricted to the approval of the Centre for Excellence (CFE) in HIV/AIDS. Lopinavir-ritonavir should not be used for the prophylaxis or treatment of COVID-19 outside of a clinical trial.
4. Remdesivir has no approved indication in any country and is not available on hospital formulary. Remdesivir has limited availability through the Health Canada – Special Access Program and the manufacturer.
5. Tocilizumab is non-formulary and should only be used to treat rheumatoid arthritis, juvenile idiopathic arthritis and giant cell arteritis. It should not be used to treat COVID-19 outside of a clinical trial.

These recommendations will be reviewed as properly conducted clinical trials are published.

ENDORSED BY BC PACE GROUP