



Guardian Consulting Services, Inc.

Consultant Pharmacists for Healthcare Organizations, Industry, and the Community.

To: All Administrators, Directors of Nursing, and Medical Directors

From: Dr. William C. Hallett, Pharm.D., MBA, BCGP, C-MTM

Date: April 27, 2020

Subject: COVID-19 UPDATE:

Revisiting Hydroxychloroquine: FDA Warning and Latest Study Findings

Continuing in our ongoing series on medication use issues COVID-19, our attention returns to Hydroxychloroquine (HCQ). For a complete list of our medication related COVID-19 memos and tools, [please click here](https://guardianconsulting.com/covid-19-updates/), or copy/click this link: <https://guardianconsulting.com/covid-19-updates/>

Background

Questions regarding the safety and efficacy of Hydroxychloroquine in COVID-19 emerged rapidly after early use trials in China were first reported in February, 2020. Of concern were the cardiac side effects, and in particular, QT interval prolongation, especially when used in combination with other medications that may cause this same effect. While studies continue on the drug's effect on viral load and potential mitigation of Cytokine Storm Syndrome, data has begun to emerge on clinical outcomes, including the results of 2 recent studies, highlighted below.

Discussion

FDA Warning: The FDA specifically warns against use of Hydroxychloroquine outside of the hospital setting or a clinical trial due to the *"risk of heart rhythm problems"*. [Click here](https://guardianconsulting.com/wp-content/uploads/2020/04/Hydroxychloroquine_FDA_Warning_24April2020.pdf) for the full warning, or copy/click this link: https://guardianconsulting.com/wp-content/uploads/2020/04/Hydroxychloroquine_FDA_Warning_24April2020.pdf. In addition, our Hydroxychloroquine fact sheet, highlighting [cardiac concerns and other precautions](https://guardianconsulting.com/wp-content/uploads/2020/04/Hydroxychloroquine_Memo_31March2020.pdf), can be found here: https://guardianconsulting.com/wp-content/uploads/2020/04/Hydroxychloroquine_Memo_31March2020.pdf

Recent Study Results: The results of 2 recent studies were recently released. In the first, [a retrospective analysis of 368 patients treated at the Virginia VA Hospital](#) showed significantly more deaths in the Hydroxychloroquine (HCQ) and HCQ + Azithromycin groups compared to the group that received neither. The second, [a retrospective analysis of 181 COVID-19 patients requiring oxygen at 4 hospitals in France](#) found no evidence of efficacy.

Utilization

It is again important to remind prescribers that while numerous clinical trials continue here in the United States and abroad, ***the FDA has not approved hydroxychloroquine for use for chemoprophylaxis or treatment of COVID-19 in the Long Term Care setting.*** We will continue to monitor the FDA status along with the clinical literature and emerging information. Additionally, we have tremendous information on many other potential therapeutic modalities, and we welcome your questions. Please do not hesitate to reach out to us if we can be of assistance!

Respectfully,

Dr. William C. Hallett, Pharm.D., MBA, CGP, C-MTM

President/CEO, Guardian Consulting Services, Inc.

New York - Albany/Syracuse/Southern Tier [\(518\) 708-8101](tel:5187088101)

New York - Downstate/NYC/Long Island [\(516\) 775-6235](tel:5167756235)

Connecticut and Rhode Island [\(203\) 889-4915](tel:2038894915)

Massachusetts/Vermont/New Hampshire [\(617\) 301-4147](tel:6173014147)

New Jersey, Pennsylvania and the Mid-Atlantic [\(732\) 719-1915](tel:7327191915)

Florida and the Southeast [\(772\) 403-8215](tel:7724038215)

Visit us on the web at GuardianConsulting.com