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Off-Label Use of Hydroxychloroquine in COVID-19: Analysis of Reports of Suspected Adverse Reactions From the Italian National Network of Pharmacovigilance

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Why is this article important to you?

This study aimed to characterize adverse drug reactions (ADRs) to hydroxychloroquine (HCQ) in the setting of COVID-19, occurring in Italy in the period March to May 2020. The analysis of the combination therapy with azithromycin or/and lopinavir/ritonavir, as well as a comparison with ADRs reported throughout 2019, was performed. Adverse drug reactions collected by the Italian National Network of Pharmacovigilance were analyzed for their incidence, seriousness, outcome, coadministered drugs and Medical Dictionary for Regulatory Activities classification. A total of 306 reports were gathered for the quarter of 2020: 54% nonserious and 46% serious, and half of the latter required either the hospitalization or its prolongation. However, most of them were either completely recovered (26%) or in the process of recovery (45%), except for nine fatal cases. Learners that complete this activity will be able to explain the ADRs associated with HCQ therapy with/without adjunct therapies targeting SARS-CoV-2 and practice evidence-based medicine in the setting of COVID-19 pandemic.



ACPE Accreditation Statement

The American College of Clinical Pharmacology® is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.

UAN: 0665-0000-22-027-H01-P– ACPE 1 Contact Hours

Activity Type: Knowledge-based **Format:** Home-study **Target Audience:** 'P'



ACCME Accreditation Statement

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ACCME Designation Statement

The Accreditation Council for Continuing Medical Education designates this journal CE activity for 1 *AMA PRA Category 1™* credit. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Target Audience

Interprofessional team of Physicians, Pharmacists and PhDs.

Learning Objectives

After completing this activity, the learner will be able to:

1. Identify the place of therapy of HCQ for autoimmune diseases and in treating SARS-CoV-2;
2. Explain the key safety concerns associated with HCQ alone, as well as in combination therapy;
3. Recognize the clinical covariates independently predicting categorical serious adverse events associated with HCQ treatment regimen(s) and the clinical implication.

Requirements to Receive Credit

To receive continuing education credit, the learner must register for the educational activity, study the provided journal article and complete the online learning Post-event Self-assessment, as well as the

online course Evaluation and CME/CPE Certificate. Credits and CME/CPE Certificates must be claimed within thirty (30) days of completing the article, Post-event Self-Assessment and Evaluation. Contact CE@ACCP1.org with any questions.

Disclosures:

Article Selection: Joseph S. Bertino Jr, PharmD, planner for this educational activity, has no relevant relationship(s) with ineligible companies to disclose.

Planners: Jianjun Liu, PharmD, MSc, planner for this educational activity, has no relevant relationship(s) with ineligible companies to disclose.

CE Reviewer: Jonathan Constance, PhD, reviewer for this educational activity has no relevant relationship(s) with ineligible companies to disclose.

Schedule & Fees

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Home Study Initial Release and Expiration Dates

Date of Issuance: 05/01/2022

Expiration Date: 05/01/2025

Helpful Tips

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