# Health Update

KITSAP PUBLIC HEALTH DISTRICT

May 18, 2020

# COVID-19 Updates: CDC COCA and HAN about MIS-C and new COVID-19 Outpatient Treatment Study

## Actions Requested

- **Participate in CDC Clinician Outreach and Communication Activity (COCA) Zoom call about Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease 2019 (COVID-19).**
  - **Tuesday May 19, 2020, 11am-1230pm, Pacific time**
  - Learn about clinical characteristics of multisystem inflammatory syndrome in children, how cases have been diagnosed and treated, and how clinicians are responding to recently reported cases associated with COVID-19.
  - https://emergency.cdc.gov/coca/calls/2020/callinfo_051920.asp?deliveryName=USCDC_1052-DM28644

- **Review the CDC HAN 432: Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease 2019 (COVID-19) -- May 14, 2020.**
  - Learn background information on several cases of a recently reported multisystem inflammatory syndrome in children associated with coronavirus disease 2019 and a case definition for this syndrome.
  - https://emergency.cdc.gov/han/2020/han00432.asp

- **Be aware of a COVID-19 Outpatient Treatment Study your patients may be interested in.**
  - A5395 is a phase IIb, double-blinded, placebo-controlled, randomized trial designed to compare the efficacy of low dose hydroxychloroquine (HCQ) plus azithromycin (Azithro) versus placebo to prevent hospitalization and death in symptomatic adult outpatients with COVID-19.
  - See attachment: ACTG A5395 Provider Summary Sheet.

- **Continue to report all positive COVID-19 test results immediately** to Kitsap Public Health Communicable Disease staff at 360-728-2235. If you report via KPHD secure fax, 360-813-1168, provide the lab result, patient name, date of birth, and phone number, and indicate if the patient has been notified of their positive result.

  **Report the following:**
  - **RT-PCR positive results**
  - **point of care PCR positive and negative results**
  - **repeat positive results** for an individual but please be aware that repeat testing is not generally recommended by Washington State Department of Health.
  - **serology positive results,** Kitsap Public Health Communicable Disease staff will investigate all serology positive results to determine if a case can be classified as probable based on clinical evidence and/or epi-linkage.

- **Advise all patients when you test for COVID-19, that if their test is positive, Kitsap Public Health will be following up with them by phone.**

- **Notify Kitsap Public Health Communicable Disease staff within 24 hours of any death associated with a positive COVID-19 test** by calling 360-728-2235.

- **Notify Kitsap Public Health Communicable Disease staff of any suspected cases of Multisystem Inflammatory Syndrome in Children (MIS-C) associated with COVID-19** by calling 360-728-2235.

## Kitsap Public Health District: Health Update, May 18, 2020

### Background

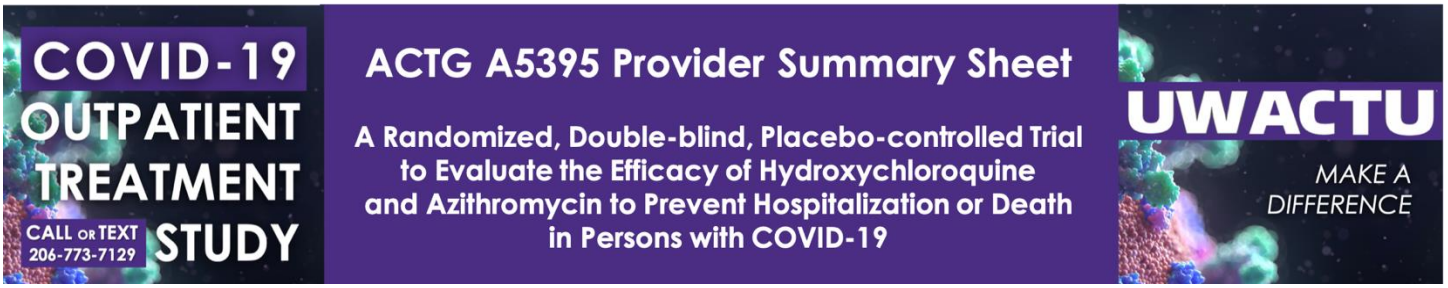
160 Kitsap County residents have tested positive for COVID-19 and 2 Kitsap County resident deaths have been associated with COVID-19 as of 2PM on May 18, 2020.

### Attachment

ACTG A5395 Provider Summary Sheet

### Resources

- CDC COVID-19 page: https://www.cdc.gov/coronavirus/2019-nCoV/
- DOH COVID-19 page: https://www.doh.wa.gov/Emergencies/Coronavirus
- KPHD COVID-19 page: https://kitsappublichealth.org/CommunityHealth/CoronaVirus.php
- Questions? Please contact our Communicable Disease staff at 360-728-2235




**Background:**
There are no Food and Drug Administration (FDA)-approved drugs for the treatment of COVID-19. There is an urgent need for well-designed clinical trials to inform patient care.

**Brief Summary**:
A5395 is a phase IIb, double-blinded, placebo-controlled, randomized trial designed to compare the efficacy of low dose hydroxychloroquine (HCQ) plus azithromycin (Azithro) versus placebo to prevent hospitalization and death in symptomatic adult outpatients with COVID-19.

This study was designed to address the toxicity concerns seen with hydroxychloroquine +/- azithromycin in hospitalized patients with COVID-10. Safeguards include using doses that are commonly used in out-patients (e.g. rheumatoid arthritis, respiratory infections) without intensive monitoring, excluding participants with pre-existing conditions that increase the risk of these medications, excluding use of medicines that prolong the QTc, frequent communications with the research team, and weekly data monitoring committee review.

**Primary Objective:**
To determine if low-dose HCQ and Azithro will prevent hospitalization or death by 21 days after study entry.

**Inclusion Criteria:**
- ≥18 years of age
- Positive test from the nose or throat for COVID-19 RNA from any respiratory specimen collected within 96 hours prior to when the first dose of study treatment is expected to be taken
- Experiencing at least one of the following symptoms: fever, cough, or shortness of breath
- Agree not to participate in another COVID-19 study during the study. (Participants may participate in another COVID-19 study if they get hospitalized.

**Treatment:**
Participants will be randomized 1:1 to receive active/placebo study treatment as follows:
HCQ/Placebo 400 mg (two 200 mg capsules) orally for 2 doses starting on Day 0, followed by 200 mg orally twice daily for 12 doses (6 days)
*PLUS:*
Azithro/Placebo 500 mg (two 250 mg capsules) orally as a single dose on Day 0, followed by 250 mg orally once daily for 4 doses (4 days).

**Study Visits**
The study is designed to minimize in-person contact between participants and study staff. The informed consent process, screening, and randomization may be performed remotely.

Most participants will have telephone visits. If eligible and someone agrees to participate at a screening phone call, participants will be shipped or dispensed study treatment, a symptom and adherence diary (i.e. Study Diary), study instructions, and contact information for the study staff. Participants will be asked about medical and medication histories and their contact information. Study staff will confirm that participants take their first dose of study treatment.

Participants will be contacted via phone by study staff on Days 2, 4, 6, 9, 13, and 17 and at 3 and 6 months after they enter the study. At Day 20, an in-person or remote visit will occur for assessment of disease course and hospitalization, collection of the symptom diary, and participant reimbursement.

**Duration of Study:**
Study participants will be followed on study for 24 weeks. Treatment will be for 7 days with 23 weeks of follow up.

**Compensation:**
$50 provided at Day 20