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FIRST UPDATE ON THE SAFETY MONITORING OF MEDICINES FOR THE TREATMENT OF COVID-19 FROM 1ST TO 30TH APRIL 2020

BACKGROUND

The Food and Drugs Authority has put in place a safety monitoring plan to guide healthcare professionals to follow up patients with COVID-19 being treated with any of the medicines issued with "Emergency Use Authorization" in line with the Provisional Standard Treatment Guidelines (STG) for Novel Coronavirus Infection, 2020. This is to ensure that local data on the safety of these medicines is gathered to facilitate early detection of safety signals to promote patient safety.

Information being collected from the Treatment Centres include cumulative positive cases reported, cumulative number of patients treated with medicines recommended by the STG for Novel Coronavirus Infection and number of adverse drug reactions including therapeutic failure.

REPORTING FACILITIES

Information was received from 18 Treatment Centers across the country with 3 reporting adverse drug reaction and the remaining 13 reported none (i.e. zero reporting).

Facilities reporting adverse drug reactions are:

- University of Ghana Medical Centre (2)
- Greater Accra Regional Hospital (2)
- Ga East Municipal Hospital (1)

SUSPECTED DRUGS AND ADVERSE DRUG REACTIONS

Five adverse drug reaction reports were received for the suspected drugs listed below:

- Hydroxychloroquine
- Hydroxychloroquine with azithromycin
- Zinc

Adverse drug reactions reported were:

- supraventricular tachycardia, chest discomfort and epigastric pain.[1]
- palpitations
- mild dizziness
- breathlessness
- rashes
- weakness

[1] These reactions occurred in one patient and considered serious (life-threatening)

OUTCOME OF THE ADVERSE DRUG REACTIONS

All patients who had adverse drug reactions fully recovered.

CALL TO REPORT

All healthcare professionals should report adverse drug reactions including therapeutic failures for drugs being used in the treatment of patients with COVID-19.

In addition, information on patients treated with any of the medicines during pregnancy should also be reported with follow up on the outcome of the pregnancy.

The reports should be submitted through the following means:

- Complete Adverse Reaction Reporting Form (which can be obtained from all health facilities)
- Download the Med Safety App from the Apps Store or Google Play
- Submit report online using the link http://adr.fdaghana.gov.gh
- Call mobile No: 024 431 0297
- Send email to drug.safety@fda.gov.gh or safetymonitoring220@gmail.com

REPORTING TIMELINE

All suspected adverse drug reactions including therapeutic failure should be reported within 24 hours.