Off-label use of pharmaceutical drugs during the COVID-19 pandemic: Reflections from the English-Speaking Caribbean

“When men are most sure and arrogant they are commonly most mistaken, giving views to passion without that proper deliberation which alone can secure them from the grossest absurdities”

David Hume

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The philosopher David Hume, in his famous book, treatise of the Human nature, defended his thesis that humans, by nature, are slaves to passion and less inclined to reason. Hume, a well-known empiricist of his time, was observant that the nature of man was to not be inclined to knowledge by experience, but more so to be make judgements based on instinct and emotions. The behaviours of some health professionals during the COVID-19 pandemic could be an excellent example of this Hume’s observation. The pandemic evoked a lot of emotions—fear being the most dominant. The world was in lock-down and the virus kept mutating – there was great uncertainty about the future and how to mitigate against significant loss of life and a crippling economy. Health professionals, who once relied on the scientific method of knowledge generation, exhibited deviant behaviours by going against the recommendations of international, regional, and local public health and regulatory agencies.

A coalition of health professionals, known as Frontline Covid Critical Care Alliance, grew rapidly in numbers by establishing a web presence, conducting webinars, and publicly challenging government officials to support what they believe to be the most effective treatment protocol for COVID-19. The group notes on their website that they are a “non-profit organization dedicated to developing highly effective treatment protocols to prevent the transmission of COVID-19 and to improve the outcomes for patients ill with the disease.” The coalition established allies within the English-speaking Caribbean, including countries such as Jamaica, Trinidad, and St. Lucia, where experienced clinicians openly challenged health Ministries and promoted the widespread off-label use of the drug Ivermectin as the key to early treatment and prevention of COVID-19. Their websites and webinars discussed studies that proved that Ivermectin was not only effective in treatment but also essential to prevent individuals from being infected with the virus. Subsequently, several of the world’s leading drug agencies such as the US Food and Drug Agency, the European Medicines Agency, and the manufacturers of Ivermectin cautioned against off-label use, indicating

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2 Ibid
that there was insufficient evidence to prove its efficacy in COVID-19.\(^3\)\(^4\)\(^5\) Within the English-Speaking Caribbean, the Caribbean Public Health Agency (CARPHA), issued a directive to Ministries of Health across the Caribbean that Ivermectin should only be prescribed for officially indicated purposes and if it is to be used in the treatment of COVID-19, this should only be within clinical trial settings.\(^6\) Nevertheless, many practitioners in Jamaica, Trinidad, St. Lucia were able to source Ivermectin via the black market into their home countries which was prescribed, and supplied to their patients at exorbitant prices.\(^7\)\(^8\)\(^9\)\(^10\) During this period, the doctors became the importer, prescriber, dispenser-the clinician and the business professional. They assumed several roles in order to circumvent any interference in what they believed to be the best treatment for their patients. What a ‘passion’! What an ‘arrogance’!

**Off-label practices in St. Lucia, Jamaica, and Trinidad**

Laws, guidelines, regulatory systems and clinical trial protocols were established to protect vulnerable persons from the passion and arrogance of health professionals. We pause here to say that we are not asserting that doctors are not within their right to prescribe off-label medicines as they think is necessary. What is presented here is a genuine concern about the blatant disregard for established systems and the illegal and unethical practices that were abound during COVID-19, a time when persons were most vulnerable. The practitioners professed that the goal was to treat persons, however they failed to realise that they facilitated a black market via bypassing checks and balances that should identify counterfeit, harmful medicines and supplied experimental therapies without oversight. It was also alleged that their communications in the media may have frustrated

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5 WHO. 2021. *WHO advises that ivermectin only be used to treat COVID-19 within clinical trials.* https://www.who.int/news-room/feature-stories/detail/who-advises-that-ivermectin-only-be-used-to-treat-covid-19-within-clinical-trials
public health measures such as vaccination. The clinicians asserted that Ivermectin was safe and since the alternative was the possibility of death, they were within their right to try what they believed could benefit their patient. Many also did not believe that clinical trials were necessary as studies were already completed demonstrating the benefits of Ivermectin. The studies which were mentioned were based on posts on the website of FLCCC Alliance. The Health Ministries in Jamaica, St. Lucia, and Trinidad echoed the position of WHO and CARPHA. The Health Ministers and Chief Medical Officers were openly challenged with letters and position statements from medical doctors and even the Medical association of one country.

St. Lucia
In St. Lucia, a physician was suspended and fined for prescribing and supplying Ivermectin against the recommendation of the regulatory authorities. However, her impassioned plea was:

To disallow the use of Ivermectin and allow St Lucians to languish and even die is unconscionable and the Medical and Dental Council and the Chief Medical Officer must be held accountable for the actions in choosing to allow death instead of giving St Lucians a fighting chance against the COVID-19.

This plea indicates a sincere belief in the benefits of Ivermectin for the treatment of COVID-19. This belief was not based on traditional scientific consensus but on pre-printed literature published on a website of so-called “coalition of medical experts”. One wonders how this group garnered so much global influence in such a short time. To the extent that clinicians were willing to go against their own professional colleagues and established drug regulators. Was this fear-driven? Fear of the unknown? Fear of death? Emotions overpowered reason. The physician in this case, was of the opinion that the law makers were wrong and she had a higher moral obligation to her patients to use whatever she considers necessary to avoid harm. Hippocratic Oath does in fact say “Above all, do no harm”.

On one hand, it can be considered ethically justifiable to act in the best interests of one’s patients (beneficence) especially if the alternative is death (non-maleficence). However, the regulators offered a middle ground permitting the use of Ivermectin in clinical trial settings which would have more oversight. The doctors pushed back on this suggestion stating that clinical trials were already done in other countries and published in peer-reviewed journals. Some of the cited

11 Aleem, Z. 2021. The anti-Covid vaccine crisis is all about mistrust. Ivermectin is a case in point. MSNBC. https://www.msnbc.com/opinion/anti-covid-vaccine-crisis-all-about-mistrust-ivermectin-case-point-n1278327
published articles were actually pre-prints and eventually retracted. The suspended doctor in St. Lucia claimed victimization and unfair treatment by the Regulators. A similar sentiment was expressed by a medical doctor in Jamaica because of his advocacy for Ivermectin but his accusation was directed at social media networks such as Facebook.

Jamaica

In Jamaica, the two main off-label drugs used were hydroxychloroquine during early to mid-2020 and Ivermectin in 2021. During the hydroxychloroquine frenzy, there was hoarding and misuse of the drug by many because of the perceived benefits that the drug could prevent or treat COVID-19. This drug was readily available locally for the approved use of treating lupus and Rheumatoid arthritis patients. These persons were at a disadvantage due to shortages. The Ministry of Health in Jamaica, unlike the USA and Europe did not agree with the use of Hydroxychloroquine for the treatment of COVID-19. In 2021, the Health Ministry faced a greater challenge because the support for off-label use of Ivermectin was greater than that for hydroxychloroquine. A group of doctors openly challenged the Health Ministry by publishing a series of articles in newspapers as well as several television, radio and social media appearances lobbying for the government to authorize Ivermectin for use in the treatment of COVID-19. These doctors referenced frontline alliance (FLCCC Alliance) as their source of clinical information and their own practice. Implicit in their statements is that they have been supplying ivermectin which would have been obtained on the black market and prescribed off-label. One article notes that a “limited supplies of ivermectin are available in Jamaica at black-market high prices and being used without adequate medical supervision” while another has a doctor who said “Early treatment works. I have treated many patients with Ivermectin, Zithromax™, (antibiotic), Xarelto™ (blood thinners) and with steaming, and they have all lived.” There is no evidence that the doctors were reprimanded or disciplined compared to what took place in St. Lucia.

The Ministry of Health of Jamaica was adamant that Ivermectin was only to be used in clinical trial settings. However, the Ministry eventually issued permits for the importation of Ivermectin with a caveat that it was not to be used for the treatment of COVID-19. While this addressed the concern of ivermectin being sourced via the black market and was not available from legitimate sources, it did not address the patients who had already been treated with Ivermectin.

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sources, it would not address the concerns regarding off-label use, although it could be implied in the following statement by the Jamaican Minister of Health:

The drug is used for parasitic treatment and the advisory of the ministry remains that there is no evidence that it will benefit COVID-19 patients. While it is not being offered in the public healthcare system,…, doctors and patients can decide how they choose to use it.  

22

Trinidad and Tobago

In the twin island state of Trinidad and Tobago, a similar situation ensued. Some drugs such as Ivermectin, although unavailable in the country, was smuggled into the country and was sold in pharmacies for exorbitant prices. Hydroxychloroquine, which is a long-term prescription drug for autoimmune disorders, was hoarded by some to be used in COVID-19, depriving the regular patients of their medication.  

A senior consultant physician shared this experience:

A colleague of mine at the University called and informed me that she was tested ‘positive’ for COVID-19, and she consulted a General Practitioner (GP). To my surprise, she had been prescribed a grocery list of medications which included Intravenous Meropenem, Azithromycin, Hydroxychloroquine, and Ivermectin as antimicrobial agents among others. None of the above medications were indicated for a COVID-19 patient, who was in fact otherwise normal and was not even hospitalized with a severe illness. Even in a severely ill COVID-19 patient admitted to a hospital or critical care unit, none of the above medications may be of any benefit. The dilemma was that, when I said to discontinue all the medications, the patient was not convinced and told me that she was afraid that her condition may deteriorate if she stops those medications.  

The COVID-19 pandemic was marred with numerous unethical practices in the healthcare sector, prescribing, dispensing and consuming off-label medications being one of the leading in the list. The most important factor during this pandemic, which led to such indiscriminate and inappropriate use of off-label medications was the ‘infodemic’ spread by the social media (and sometimes even the mainstream media). Science and evidence-based medicine were discarded by leaders as well as the public. Politics, demagoguery, internet influencing, fake information dominated the landscape. Academicians were ‘influenced’ by the pseudoscience propagated in social-media and started expressing their views, which further confused general public. High dose Vitamin C was one such drug, which studies established no benefit in COVID-19. The arm-flexing of the antivaxxers groups throughout the world, promoted drugs such as hydroxychloroquine and ivermectin in lieu of vaccines, despite undeniable scientific evidence discrediting their use. In this internet era, there has been a blatant lack of ethical journalism and dissemination of scientific


information. Every Tom, Dick and Harry became a virologist, vaccinologist, immunologist and epidemiologist! Ethical reporting of the facts and editorial censorship of fake news were missing. Competing with the COVID-19 virus, this fake news messages became ‘viral’, circulating and causing immeasurable damage in the minds of the people. In addition, many healthcare providers also lost their ethical and moral conviction to refrain from unethical practices; they were influenced by not only this fake literature, but also by short-term financial gains, which complicated the whole scenario.

A lot of lessons in ethics have to be learnt from the COVID-19 pandemic.

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