

Hand Sanitizers Marketed in the Streets of Addis Ababa, Ethiopia, in the Era of COVID-19: A Quality Concern

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Abstract: Hand hygiene is one of the least expensive measures proven to be effective in preventing the transmission of coronavirus disease 2019 (COVID-19). When access to handwashing facilities is limited, hand sanitizers offer a viable alternative for hand hygiene. Since the appearance of the first case of COVID-19 in Ethiopia, the demand for hand sanitizers, especially alcohol-based handrubs (ABHRs), was found to be increased. In the country, more than 100 manufacturers are engaged in the production of ABHRs. Besides, there are similar products without labels available for sale in the streets of Addis Ababa for which their nature and source are not clearly known. Generally, hand sanitizers marketed in the streets of the city are against the country's regulatory requirement. The Ethiopian Food and Drug Authority should inspect manufacturers regularly and evaluate the quality of hand sanitizers in the market, especially those obtained from the streets of the city, and take appropriate measures on those products and manufacturers which fail to meet the regulatory requirements.

Keywords: alcohol-based handrubs, quality, COVID-19, Addis Ababa, streets

Introduction

The spreading of coronavirus disease 2019 (COVID-19) pandemic at a continuous pace worldwide and the lack of effective treatment for the disease yet has led to fear and agony for the healthcare professionals and the general public.¹ So, people mainly relied on preventive methods. Hand hygiene is considered an important preventive measure in response to the emergence of SARS-CoV-2, the virus that causes COVID-19. Hand decontamination by handwashing with soap and water or the use of hand sanitizers is necessary for reducing the transmission of the disease.^{2,3} When access to handwashing facilities is limited or water sources are insufficient, alcohol-based handrubs (ABHRs) offer a convenient, effective, and relatively low-cost alternative worldwide, especially for developing countries.⁴⁻⁶ Use of hand sanitizers as preventive measures is advocated by governments and health officials in the globe to combat the disease.⁷ Center for Disease Control and Prevention (CDC) recommends the use of alcohol-based hand sanitizer products that contain at least 60% ethyl alcohol (ethanol) or 70% isopropyl alcohol (isopropanol) in community settings.⁸

Alcohol-based hand sanitizers are regulated as over-the-counter (OTC) drugs by the US Food and Drug Administration (FDA) and others.^{9,10} Hand sanitizers have

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become an essential product in hospitals and the community in day-to-day life. They have gained much popularity and have become a highly accepted form of personal hygiene because of their effectiveness and ease of use.¹¹

A shortage of hand sanitizers in the global market has been observed due to a sudden outbreak of the COVID-19 pandemic.¹² World Health Organization (WHO) suggested local production of ABHRs by using either of the two formulations, one based on ethyl alcohol and the other is isopropyl alcohol-based to ensure the availability of the hand sanitizers.¹¹

Due to the COVID-19 pandemic, the drug regulatory authorities in some countries have relaxed legislation and provided temporary licenses for local companies to produce hand sanitizers rapidly to meet the increasing demand.^{13–15} Consequently, there has been a surge in the production of large quantities of ABHR products by various companies and attempting to respond to the unprecedented demand which may also be associated with some potential risks.⁶ Assuring the quality of these products will enhance compliance of healthcare providers and other individuals to these products and contributes in the containment of COVID-19 and other infections. Similarly, a rush in the production of sanitizers has been also observed in Ethiopia in the era of COVID-19 especially in the capital city, Addis Ababa.¹⁶

Hand Sanitizers in Addis Ababa Market

Ethiopia reported the first COVID-19 case on March 13, 2020,¹⁷ two days after it was declared as a global pandemic by WHO. As of October 22, 2020, the country has reported a total of 91, 693 confirmed COVID-19 cases and 1396 deaths.¹⁸ Among this, more than half of the cases were from the capital, Addis Ababa (46,570).

Before the sudden outbreak of this pandemic, the hand sanitizer market in Ethiopia was found to be dormant. However, the appearance of the first COVID-19 case in the country has resulted in an overwhelming, demand for hand sanitizers. The quest for hand sanitizers was intense in the capital city, Addis Ababa, as it was evidenced by long lines of customers in the city pharmacies especially in the first few weeks period. To address the demand for ABHRs during this pandemic, the Ethiopian Food and Drug Authority (EFDA) had prepared a guideline for the production of the sanitizers¹⁹ and given temporary production licenses for more than 100 manufacturers in the

country to produce ABHRs in which most are available for sale in Addis Ababa.²⁰ The authority had also advised these companies to join the market with products that meet the quality standards.²¹ Despite this, there are such products for sale in the streets of Addis Ababa where the sources are not clearly known.

The drug manufactures and small scale chemicals and cosmetics producers are the main sources of hand sanitizers for the city as well as the country at large. In addition, some beverage firms have reconfigured their operations to produce hand sanitizers. Small firms are also among the licensed ones to produce hand sanitizers for the local market.²⁰ Most of them are manufacturing hand sanitizers based on formulation 1 of the WHO guide in which ethyl alcohol is the main active ingredient.²² The relaxed legislation attracted many institutions to involve in the manufacturing of ABHRs which may raise the issue of quality of the products since most did not have adequate experiences of production of similar products. The increasing number of such products in the Addis Ababa market may also make the follow-up and quality assessment challenging.

Hand Sanitizers Marketed in the Streets of Addis Ababa: Do They Meet the Quality Standards?

Even though the hand sanitizers should be prepared under similar conditions routinely followed to compound other non-sterile pharmaceutical preparations,²³ lack of adherence to the good compounding practice principle has been observed from some manufacturers which were exhibited in inferior strength for alcohol content; lack of packaging integrity; incomplete labeling information; and decreased consumer acceptability.¹⁶ Failure to adhere to such standard of ABHR production practice has negative consequences for users which includes failures in the effectiveness of the preparation in combating infections and posing the individuals at risk due to poor quality products.

In April 2020, EFDA reported that 10 hand sanitizers were banned from the market as they exhibited quality defects and some of them were marketed without a manufacturing license from the authority.¹⁶ Moreover, following the initial widespread availability of ABHRs in response to the first COVID-19 case report in the country, quality evaluation of 20 different ABHRs from the Addis Ababa market was done by the Ethiopian Standards Agency. The result revealed that 70% of

products were found to be below the WHO limit for alcohol strength (less than 75% v/v) and all products failed to meet the hydrogen peroxide (H_2O_2) content limit (0.125% v/v).²⁴ Such failures of products to meet the specifications may lead to loss of activity and microbial contamination of the products that can be sourced from the excipients and packaging materials which ultimately jeopardize the purpose of hand sanitizers. The people will not be benefited from the use of such substandard products that instead endanger users' safety.

By considering the unprecedented public demand and use of hand sanitizers, peoples engaged in selling different goods in the streets of Addis Ababa city included this product as one item from the menu. They also believed that some people prefer such market places due to the relatively cheaper price than products obtained from legal sources (eg pharmacies and supermarkets). Currently, so many ABHRs are being sold in the streets of different corners of the city along with other goods. Such marketplaces do not meet the proper storage conditions recommended for the product. Moreover, the sources of these products are not known as most are sold without labels in contrast to the country's regulatory requirement.²⁵ Such lack of labeling information (eg name of the product and its composition, direction for use, handling and storage conditions, expiry date, and batch number) on the product packaging containers makes users not follow the appropriate ways of ABHRs use and make them difficult to take necessary precautions during use. In addition, it is difficult to recall the sanitizers from the market when defects are observed from these products. Furthermore, these products may contain unacceptable active ingredients (eg methanol) other than the recommended alcohols (ethanol or isopropyl alcohol) that can be toxic to consumers because of respiratory and dermal exposure and may cause even death if swallowed.^{6,9} The Food and Drug Administration had reported the presence of some methanol containing hand sanitizer products in the United States market.²⁶ Cases of methanol poisoning in the era of COVID-19 pandemic were indicated elsewhere^{9,27-29} which created an additional burden for the health care system and caused people fatality. Even with the recommended formulations, the preparations may become toxic to human health when misused.³⁰ Though it is highly recommended to avoid ingestion of alcohol-based hand sanitizers, there may be unintentional swallowing that is life-threatening and the problem is worse for methanol containing products.

WHO recommends incorporating glycerol in the ABHRs to protect skin from dryness and contact dermatitis with repeated use.^{6,22} Consumers are raising the issue of skin dryness after using ABHRs obtained from the streets of the city. Even though these products are claimed to be hand sanitizers, there are no guarantees on the incorporation of other functional ingredients, like glycerol and hydrogen peroxide, to the preparation other than the alcohol. As the wide use of hand sanitizers is expected to continue for prevention of COVID-19 and beyond, the repeated use of such substandard products for long periods will make the skin drier and prevent the adherence of consumers for hand hygiene using ABHRs.

WHO advised not to incorporate other ingredients in the formulation which are not indicated in its guideline as the antimicrobial efficacy can be limited and the physicochemical properties of the product may be altered which otherwise their influence should be evaluated.²² But, most sanitizers marketed in the streets were colored and had specific flavors in which their nature and concentrations are not known. Such incorporations of coloring and flavoring agents may not be comfortable for some consumers due to allergic conditions as suggested by WHO.²²

There are also many risks associated with low-quality hand sanitizers which include harm to healthcare providers, patients, and the general public. Unless these quality issues are addressed and managed appropriately, the risks may outweigh the benefits of these products. Since ABHRs are considered as non-prescription drugs, appropriate regulatory control should be in place over the distribution of these products in the city.

Conclusion and Recommendations

Though the number of ABHRs in the streets seems less as compared with those available in the pharmacies, supermarkets, and other distinguished selling areas, a significant number of consumers are using sanitizers from the streets' source as they are relatively cheaper than other sources. Generally, hand sanitizers marketed in the streets of the city are against the country's regulatory requirement.

Hence, EFDA should take appropriate measures on such streets' products in which their nature and sources are not clearly known. Besides, appropriate information should be disseminated to the general public through different media about the potential risks of using ABHRs available in such market places and advising them to avoid using such products. Although hand sanitizers quality issues had been aired in some occasional

programs by local media, short messages regarding the health hazard resulted from substandard hand sanitizers shall be aired continuously on mass media to get the users alerted and encourage them to prefer products obtained from the known sources. Furthermore, the authority should undertake a regular inspection of manufacturers and quality testing of sample hand sanitizers from the market as their kind and number are increasing rapidly.²⁰

Relevance and Future Study

The current perspective can serve as an indicating study for researchers and other interested bodies to have a better outlook for understanding the problem. Besides, an overall quality assessment of hand sanitizers sourced from the streets of the city, using the current study as a baseline, can be conducted and forward the timely recommendations for the regulatory body of the country and other relevant stakeholders. Furthermore, the quality concern of such products pointed out by this study may call the attention of the regulatory body given for such products and take appropriate measures to safeguard the general public.

Disclosure

The author declares no conflicts of interest.

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