Original Article

A critical evaluation of contents, labeling, and cost of hand sanitizers marketed in India during COVID-19 pandemic

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Abstract

Background: Antiseptics were introduced a long time ago, but their significance was noteworthy during the COVID-19 pandemic. Hand sanitizer plays a pivotal role as a preventive measure. Multiple national authorities have advocated for the application of Alcohol-Based Hand Sanitizers (ABHS). During the pandemic, a surge in demand and limited supply prompted numerous manufacturers to ramp up production. Consequently, it is imperative to scrutinize the composition, labeling, and price of hand sanitizers. **Aims and Objective:** To assess the contents, labeling, and price of hand sanitizers available in the Indian market. **Methodology:** Hand sanitizers, both online and offline, marketed in India between May 2019 and May 2022 were included. Hand sanitizers by local manufacturers without labeling were excluded. Contents and labeling of hand sanitizers were evaluated as per World Health Organization (WHO) recommendations. Price was assessed as a percentage cost variation. **Result:** Out of 79, the majority (98.73%) were ABHS, and 28.20% of them met the recommended criteria for "Adequate" alcohol concentration. Ethyl alcohol emerged as the most prevalent (69.23%), often accompanied by emollients, humectants, fragrances, and color additives. Notably, 69.62% of the hand sanitizers featured comprehensive labeling, while incomplete labels lacked essential details under "Warning and Cautions." The average price of hand sanitizers was Rs 505.11 ± 255.36. **Conclusion:** Choosing ABHS with appropriate alcohol concentrations in line with recommendations is crucial. To ensure the proper and safe use of hand sanitizers, individuals should follow the instructions provided on the product labels; both manufacturers and regulators are responsible for adhering to standards for hand sanitizers made available to the public.

Keywords: ABHS, antiseptic, disinfectant, hand antiseptic, hand sanitizer, NABHS

Introduction

The pivotal role of hand sanitizers in mitigating the spread of infections was documented over 170 years ago by Semmelweis and Florence Nightingale.[1,2] The term "hand sanitizers" has replaced "antiseptic" and serves as a convenient substitute for handwashing with soap and water, particularly in healthcare and public settings.[1] Hand sanitizers are primarily categorized as "Alcohol-based hand sanitizers (ABHS) and Non-alcohol-based hand sanitizers (NABHS)."[1] National agencies, including the Central Drugs Standard Control Organisation (CDSCO), Centres for Disease Control and Prevention (CDC) and the World Health Organization (WHO) recommended ABHS.[2] The ABHS inactivates microorganisms or temporarily suppresses their growth.[3,4] Non-ABHS (NABHS) are less preferred by the CDC due to their lower efficacy and narrower spectrum compared to ABHS.[5] As the pandemic extended across the globe, a surge in demand for hand sanitizers resulted in shortages and surpassed production capacities.[2,6] The marketing and sales

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of hand sanitizers have grown tremendously worldwide in recent years, estimated at $919 million in 2016 and expected to reach $1.755 billion by 2023.[7] Despite established standards for hand sanitizer regulation by the Food Drug and Administration (FDA), WHO, United States Pharmacopeia (USP), and CDSCO, the soaring demand prompted WHO and local regulatory agencies to issue guidelines for expedited production, ensuring adherence to minimum manufacturing standards.[4,8,9] Correct and effective use of hand sanitizers necessitates adherence to content standards and following the instructions on the label, all while maintaining affordability. This study focuses on assessing the contents, labeling, and price of hand sanitizers in the Indian market during the COVID-19 pandemic.

Materials and Method

Study design

It was a cross-sectional study conducted after approval from the Institutional Ethics Committee (IEC).

Inclusion criteria

Hand sanitizers of various brands with labels were included for assessment, encompassing both online and offline sources spanning from May 2019 to May 2022 in India. Online data was sourced from various websites offering hand sanitizers, while offline information was gathered from published drug information and local pharmacies in Rajkot city.

Exclusion criteria

Hand sanitizers produced by local manufacturers without labels were excluded from the analysis.

Data collection tool

The data were collected in predefined case record form (CRF). The CRF was prepared from the scientific literature.[10]

Data collection process

The study was conducted after approval from IEC. Various online websites selling different brands of hand sanitizers were identified. For offline data, various pharmacy stores in Rajkot city were assessed by snowball technique and approached for information regarding hand sanitizers available at their stores. Various hand sanitizers published in drug information sources, i.e. Current Index of Medical Specialities (CIMS), Monthly Index of Medical Specialities (MIMS), and Drug Today, were also included. The data relating to contents, labeling, and price were collected in CRF.

Content adequacy of hand sanitizer

The antiseptic effectiveness of hand sanitizer is attributed to the presence of alcohol in the recommended concentration. Therefore, the adequacy of hand sanitizer content was evaluated based on the alcohol strength present in the formulations. Hand sanitizers containing alcohol at the recommended concentration (ethanol 80% v/v, or isopropyl alcohol 75% v/v) according to WHO guidelines were classified as "Adequate."[10]

Label score for hand sanitizer

The assessment of label adequacy for both ABHS and NABHS was conducted in accordance with WHO recommendations. Each hand sanitizer label was examined for the presence of eight specified items, with the presence of each item scored as "1" and the absence as "0." Consequently, the total label score could range from 0 to 8.[10]

The price of each hand sanitizer was calculated per liter. The percentage cost variance is calculated as follows[11]:

$$\text{Percentage cost variation} = \frac{(\text{Maximum Cost - Minimum cost}) \text{ X } 100}{\text{Minimum Cost}}$$

Data analysis plan: Hand sanitizers were categorized as "ABHS" and "NABHS." Alcohol content adequacy was calculated among ABHS. Label score and price were assessed among total hand sanitizers (ABHS and NABHS). The data were entered in a Microsoft Excel sheet 2016. Descriptive statistics were expressed as percentages and means ± SD.

Results

A total of 79 distinct brands of hand sanitizers fulfilled the inclusion criteria and underwent analysis. The majority (98.73%) of these were ABHS, and the rest (1.27%) were NABHS [Table 1]. The majority of hand sanitizers (93.58%) were rinsed and foam formulations in this study.

The predominant alcohol types observed in ABHS in this study were ethyl alcohol (69.23%) and isopropyl alcohol (16.66%), followed by absolute alcohol (7.69%). Only a small proportion of hand sanitizers (6.41%) had a combination of more than one type of alcohol. Additionally, glycerol (62.82%) and hydrogen peroxide (53.85%) were identified as supplementary components in the ABHS formulations in this study. The recommended concentration of H_2O_2 and glycerine was observed in 16.66% and 21.79% of total ABHS, respectively [Table 2].

Additional contents observed in hand sanitizers included fragrance (75.94%), color (20.24%), emollient (13.92%), and antiseptics (14.10%) in this study. Fragrances such as lemon, rose water, jasmine, sandalwood, and orange were identified in ABHS. As an alternative to traditional fragrances, some ABHS contains clove oil, essential oil, tea tree oil, and rosemary oil. Among the colored hand sanitizers, brilliant blue (13.92%)

Table 1: Category of hand sanitizers

Categories of Hand sanitizer	No. (%), *n*=79
Alcohol Base Hand Sanitizer (ABHS)	78 (98.73)
Non-Alcohol Base Hand Sanitizer (NABHS)	1 (1.26)

was the most prevalent, followed by sunshine yellow (5.06%) and green (1.26%). A limited number of sanitizers (13.92%) incorporated emollients (e.g. carbomer, castor oil, propylene glycol, aloe vera, extracts of neem, tulsi, lemon, clove, lotus) and antiseptics (e.g. benzalkonium chloride, chlorhexidine gluconate, silver, betadine). Chlorhexidine was the most common (7.59%) antiseptic observed in hand sanitizers [Table 2].

Alcohol content adequacy was observed in 28.20% of total ABHS. Total content adequacy (all specified components at the recommended concentrations according to WHO guidelines) was observed in 16.66% of the total ABHS analyzed [Table 3].

69.62% of hand sanitizers had a "complete" label (scored 8) in accordance with the Drugs and Cosmetics Act of 1945, Section 96 [Figure 1].

"Three" was the lowest label score observed in 13.92% of the hand sanitizers analyzed in this study [Table 4].

Deficiencies in the labeling of hand sanitizers were observed, with "Warnings for children" (24.35%), "Flammability precautions" (12.82%), and "For external use only" (10.25%) in this study [Table 5].

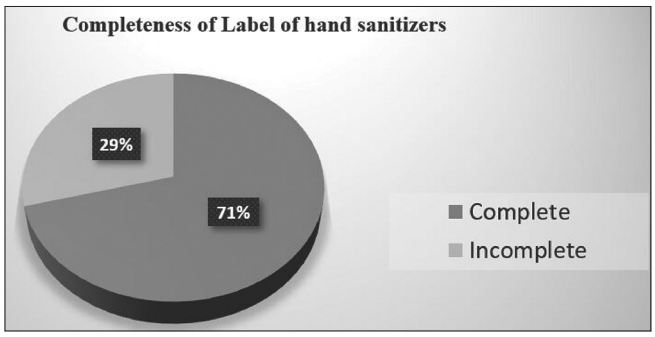

Figure 1: Completeness of label of hand sanitizers

The cost of hand sanitizers per liter ranged from Rs. 100 (minimum) to Rs. 2160 (highest), with an average price of Rs. 505.11 ± 255.36. The observed percentage cost variation of hand sanitizers was 2060 in this study [Table 6].

Discussion

"Hand hygiene" is one of the most important preventive measures during the COVID-19 pandemic. ABHS is advocated as an important means of reducing transmission of infectious disease.[12] The majority of hand sanitizers available in the market are alcohol-based, leveraging alcohol's broad spectrum of germicidal activity against various organisms, including vegetative bacteria, viruses, and fungi.[6,13] Ethanol and isopropanol emerge as the most commonly utilized alcohols in hand sanitizers.[14] Isopropanol is acknowledged for its superior activity against bacteria, whereas ethanol is deemed more effective against viruses. However, the efficacy level hinges on the percentage concentrations of alcohol and the physical properties of the target microorganism.[13]

85.89% of ABHS had an alcohol concentration greater than 60% (v/v) in this study. Ethanol concentrations ranging from 60% to 95% (v/v) are recommended by the US FDA and CDC for safe and effective disinfectant properties, including efficacy against severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). ABHSs have lower ethanol content than current regulatory standards, potentially rendering them less effective in preventing SARS-CoV-2. ABHSs with alcohol concentration below the recommended standards (<60%) were not observed in this study. In March 2022, the US FDA, on compassionate grounds, temporarily

Table 2: Content analysis of Alcohol-based hand sanitizers (ABHS)

Contents	Present *n* (%)	Concentration % (v/v)	*n* (%) *n*=78
Alcohol			
Absolute alcohol	6 (7.69)	60-80	6 (7.69)
Ethyl alcohol	39 (50)	>60 to<80	
	15 (19.23)	≥80*	54 (69.23)
Isopropyl alcohol	2 (2.56)	≥75*	13 (16.66)
	11 (14.10)	<75	
Ethyl alcohol plus isopropyl alcohol	3 (3.84)	60,76*	3 (3.84)
2-Propanol and 1-Propanol	2 (2.56)	45g, 30g*	2 (2.56)
Glycerol	17 (21.79)	≥1.45*	49 (62.82)
	19 (24.35)	<1.45	
	13 (16.66)	Not mentioned	
Hydrogen peroxide	13 (16.66)	≥0.125*	42 (53.84)
	9 (11.53)	<0.125	
	20 (2.56)	Not mentioned	
Other contents ¥			*n* (%), *n*=79
Fragrance			60 (75.94)
Color			16 (20.25)
Emollients			11 (13.92)
Antiseptics			6 (7.59)

*As per WHO recommendation. ¥ Other contents were analyzed from total hand sanitizers, *n*=79

Table 3: Content adequacy of ABHS

Content adequacy	Adequate No. (%), *n*=78	Inadequate No. (%), *n*=78
Alcohol content adequacy	22 (28.20)	56 (71.79)
Total content adequacy (alcohol, glycerol, hydrogen peroxide, and water)	13 (16.66)	65 (83.33)

Table 4: Scoring of label on hand sanitizers

Label score (1-8)	No. (%), *n*=79
8	55 (69.62)
7	5 (6.32)
6	6 (7.59)
5	1 (1.26)
3	11 (13.92)

Table 5: Incomplete labeling of hand sanitizers, *n*=79

Missing items in label of hand sanitizer as per WHO recommendation	Number (%)
Keep out of reach of children	19 (24.35)
Flammable: keep away from flame and heat	10 (12.82)
For external use only	8 (10.25)
Avoid contact with eyes	7 (8.97)
Name and address of manufacture	6 (7.69)
Direction of use	3 (3.84)
Composition not mentioned	3 (3.84)

Table 6: Price of hand sanitizers

Hand sanitizer	Price (Rs./Liter), *n*=79
Range (lowest – highest)	100-2160
Percentage cost variation	2060
Average price (mean±SD)	505.11±255.36
(median, IQ)	500 (350-500)

allowed the use of hand sanitizers with an alcohol content exceeding 60%, citing a study demonstrating the efficacy of such sanitizers in inhibiting the growth of microorganisms. This temporary measure was implemented to address the significant surge in demand, but it was rescinded in March 2022.[15] The majority of hand sanitizers (93.58%) were foam and rinse formulations in this study. The foam, rinse, and gel hand sanitizer formulations contained 70%, 80%, and 90% alcohol, respectively. These formulations exhibit comparable antimicrobial activity, but their efficacy is significantly influenced by application volume and drying time.[16]

The WHO recommends the inclusion of hydrogen peroxide in ABHS.[2] The presence of a low concentration (3%, 0.125% v/v) of H_2O_2 aims to eliminate contaminating spores, as alcohol alone may not effectively kill spores.[17] Hydrogen peroxide generates free hydroxyl radicals that target membrane lipids, DNA, and other essential cellular components, thereby disrupting and destroying the microorganism.[18] However, the use of higher concentrations (3-6%) is prohibited due to their corrosive nature.[19]

The WHO recommends incorporating glycerine into ABHSs to improve the overall acceptability of ABHS and capitalize on their humectant properties.[2] Emollients, including glycerine, have demonstrated effectiveness in mitigating the drying effects of alcohol on the skin, promoting skin hydration and scare.[4,20] Glycerine, being cost-effective and readily available, is the most frequently utilized emollient. However, studies have indicated that glycerine may diminish the efficacy of isopropanol-based disinfectants, forming agglomerates scaling skin cells in the sticky glycerine.[20] This impact of glycerol was acknowledged in the FDA guidelines issued for the temporary formulation of ABHS by the industry during the COVID-19 pandemic. Adjusting the glycerol content from the WHO-recommended 1.45% to 0.5% was found to strike a better balance between antimicrobial efficacy and skin tolerability.[20,21] The lowest concentration of glycerol observed in this study was 1%. The emollients other than glycerine, such as carbomer, aloe vera gel, and propylene glycol, were observed in various hand sanitizers in this study.[22] The commonly observed antiseptics in this study were chlorhexidine, benzalkonium chloride, triclosan, silver, and betadine. Among them, chlorhexidine gluconate (0.12%) exhibits an antiviral activity against coronavirus, including its effectiveness against other enveloped viruses.[23]

Additional contents, such as color and fragrance, are provided to enhance the acceptability of hand sanitizers among consumers. Fragrances are added to mask the odor arising from alcohol or other components in ABHS.[24] Adding fragrance increases the cost and risk of allergy to the product. The purpose of adding dyes is to distinguish hand sanitizers from other liquids, but they must be safe and compatible with the essential contents of the hand sanitizer.[22] The fragrances and dyes may be added for aesthetic improvement, but WHO does not recommend them due to the potential for allergic responses.[10,25] According to the WHO, ABHS with fragrances might be poorly tolerated by healthcare workers with respiratory allergies, and it strongly suggests that mild or no added fragrances would be more acceptable.[22] In fact, the most common causes of contact allergies are fragrances and preservatives and, less frequently emulsifiers.[26]

As per US FDA, hand sanitizers are classified as over-the-counter (OTC) drugs and must follow the same labeling requirements as other OTC medicines.[27] The main objective of labeling is to furnish essential information for the proper utilization of a product. It is crucial to emphasize the importance of safety precautions when it comes to hand sanitizers, especially given the increased use during the COVID-19 pandemic. In the case of hand sanitizers, individuals are recommended to adhere to the instructions specified on the label, encompassing guidance on usage, cautions, potential risks, and details of other inactive ingredients present within the product.[8]

Missing information about warnings for children on hand sanitizer labels poses a significant risk as children are more susceptible to accidental ingestion of hand sanitizer due to the

allure of colored liquids. Accidental ingestion of hand sanitizers has become more prevalent among children below 12 years old and younger during the COVID-19 pandemic.[28] Recent reports have recognized serious concerns, including apnea, acidosis, and coma in young children who ingested ABHS.[29,30] Accidental contact of sanitizer with the eye can cause burning, blurry vision, and even vision loss.[31] Hand sanitizers should be kept away from the children and should be used carefully under supervision.[32] A notable percentage cost variation exists among different brands of hand sanitizers, and this variation cannot be explained by specific factors.

Conclusion

Selecting ABHS with the recommended alcohol concentration is crucial. For the safe and effective use of hand sanitizers, complete labeling according to standards is essential. Pharmaceutical products must be available in formulations as specified to ensure their intended effect. Both manufacturers and regulators bear the responsibility of adhering to standards for hand sanitizers made available to the public during the COVID-19 pandemic.

Abbreviation

ABHS: Alcohol-Based Hand Sanitizers
CDSCO: Central Drugs Standard Control Organisation
CDC: Centres for Disease Control and Prevention
CIMS: Current Index of Medical Specialities
CRF: Case Record Form
FDA: Food and Drug Administration
IEC: Institutional Ethic Committee
MIMS: Monthly Index of Medical Specialities (MIMS)
NABHS: Non-Alcohol-Based Hand Sanitizers
OTC: Over The Counter (OTC)
SARS-CoV-2: Severe Acute Respiratory Syndrome Coronavirus-2
USP: United States Pharmacopeia
WHO: World Health Organization

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Conflicts of interest

There are no conflicts of interest.

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