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Original Research Article

Physicochemical Evaluation of the Potency and Viability of Alcohol-Based Hand Sanitizers

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Abstract: ***Background:*** Frequent hand washing with soap and antiseptics is vital to prevent the spread of infectious agents, but can also result in chronic skin dermatitis. This could change the skin's normal flora, leading to infectious pathogens colonization. Thus, the use of alcohol-based hand sanitizers, which may be less irritating to the skin, and improve hygiene. ***Objective:*** The study aimed to produce alcohol-based hand sanitizers following WHO guidelines, and quantify the effects of temperature on their potency and concentrations after exposure to different environmental conditions. ***Method:*** The WHO guidelines for the production of hand sanitizer formulation were carefully followed; Ethanol (96%) was diluted to 70%, Carbomer and valina with banana flavor were used as thickening and fragrance agent receptivity. Twenty (20) products (250 mL each) selected at random were grouped into four categories – 10 bottles were subjected to Room Temperature (at 25-28°C); 5 samples with lids (unexposed) and 5 without lids (exposed), respectively while the other 10 samples were stored in the car (at 28 - 38°C); 5 samples with lids (unexposed), and 5 samples without lids (exposed), respectively. The alcohol concentration was quantified respectively with the aid of the alcohol meter daily, up to a period of 30 days (one month), and was properly recorded. ***Results*** There were significant statistical differences in the exposed hand sanitizer preparations compared to the standard at p-value ≤ 0.05. Reduction of ethanol concentration was observed from 70 - 53% of the exposed preparation. Also, for the ones exposed and unexposed in the car, the ethanol concentration dropped from 70 - 68% of the well-corked product while there was an alcohol content reduction from 70 - 41% of the exposed product in the car. ***Conclusion:*** Temperature conditions directly affect the concentration, potency, and efficacy of hand sanitizer preparations.

Keywords: Ethanol, Antiseptics, Alcohol, Hand Sanitizer, Temperature.

INTRODUCTION

Hand sanitizer is a liquid, gel, or foam generally used to decrease infectious agents on the hands [1, 2]. In most settings, hand washing with soap and water is generally preferred [3- 5]. Hand sanitizer is less effective at killing certain kinds of germs, such as norovirus and *Clostridium difficile,* and unlike soap and water, it cannot remove harmful chemicals. People may incorrectly wipe off hand sanitizer before it has dried, and some are less effective because their alcohol concentrations are too low [3]. In most healthcare settings alcohol-based hand sanitizers are preferable to hand washing with soap and water [6, 7] because they may be better tolerated and is more effective at reducing bacteria [2]. Hand washing with soap and water; however, should be carried out if contamination can be seen, or following the use of the toilet [8]. The general use of non-alcohol-based hand sanitizers has no recommendations [6]. Alcohol-based versions typically contain some combination of isopropyl alcohol, ethanol (ethyl alcohol), or n-propanol, with versions containing 60% to 95% alcohol being the most effective [2]. Care should be taken as they are flammable [6]. Alcohol-based hand sanitizer works against a wide variety of microorganisms but not spores [2]. Compounds such as glycerol may be added to prevent the drying of the skin [2]. Some versions contain fragrances; however, these are discouraged due to the

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risk of allergic reactions [9]. Non-alcohol-based versions typically contain benzalkonium chloride or triclosan; but are less effective than alcohol-based ones [10- 12].

Alcohol has been used as an antiseptic at least as early as 1363 with evidence to support its use becoming available in the late 1800s [13]. Alcohol-based hand sanitizer has been commonly used in Europe since at least the 1980s [14]. The alcohol-based version is on the World Health Organization (WHO) essential medicines list, the safest and most effective medicines needed in a health system [15]. Some hand sanitizer products use agents other than alcohol to kill microorganisms, such as povidone-iodine, benzalkonium chloride, or triclosan [2]. WHO and the Centre for Disease Control (CDC) recommend persistent antiseptics for hand sanitizers [16]. Persistent activity is defined as the protracted or extended antimicrobial activity that, following the administration of the substance, prevents or inhibits the proliferation or survival of microorganisms. By sampling a site many minutes or hours after treatment and comparing bacterial antimicrobial efficiency with a baseline level, this activity can be proven. Remaining activity is another name for this quality. If they significantly reduce the quantity of germs during the wash phase, both active substances with substance and those without substance can exhibit a permanent impact [17]. Laboratory studies have shown lingering benzalkonium chloride may be associated with antibiotic resistance in *Methicillin-Resistant Staphylococcus aureus* (MRSA) [18, 19]. Tolerance to alcohol sanitizers may develop in fecal bacteria [20]. Where alcohol sanitizers utilize 62%, or higher, alcohol by weight, only 0.1 to 0.13% of benzalkonium chloride by weight provides equivalent antimicrobial effectiveness.

In 2002, the CDC released an updated hand hygiene guideline and, for the first time, endorsed the use of alcohol-based hand rubs for the majority of clinical interactions, provided that hands are not visibly soiled. For many reasons, alcohol hand sanitizers are increasingly being used as disinfectants over hand washing with soap and water. Their ease of availability, no need for water or plumbing, and their proven effectiveness in reducing microbial load are just a few. Consumer alcohol-based hand sanitizers and healthcare hand alcohol or alcohol hand antiseptic agents exist in liquid, foam, and easy-flowing gel formulations. Products with 60% to 95 %v/v alcohol are effective antiseptics. Lower or higher concentrations are less effective; most products contain between 60% and 80% alcohol [21]. In addition to alcohol (ethanol, isopropanol, or n-propanol), hand sanitizers also contain added antiseptics like chlorhexidine, sporicides such as hydrogen peroxides, emollients, and gelling agents to reduce skin dryness and irritation, small amounts of sterile or distilled water, foaming agents, colorants or fragrances, etc., [21].

WHO has published a guide to producing large quantities of hand sanitizer from chemicals available in developing countries, where commercial hand sanitizer may not be readily available. Some WHO official alcohol-based formulations, volume, and active ingredients include ethanol 96%, glycerol 98%, hydrogen peroxide 3% and distilled water to 10000 mL; isopropyl alcohol 99.8%, glycerol 98%, hydrogen peroxide 3% and distilled water 1000 mL respectively [22].

Additionally, some commercial products are dangerous, either due to poor oversight and process control, or fraudulent motive. In June 2020, the FDA issued an advisory against the use of hand sanitizer products with excessive levels of methanol up to 81%. Methanol can be absorbed through the skin, is toxic in modest amounts, and in substantial exposure can result in "nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, and permanent damage to the nervous system or death [23]. Hence, we aimed to produce alcohol-based hand sanitizers following the WHO guidelines, subject them to different environmental conditions and quantify the potency and concentrations of alcohol in the products.

MATERIALS AND METHOD

The material used for the production includes ethanol, hydrogen peroxide, carbomer, glycerol, and sterile distilled water respectively. The area used in the production was ensured to be aseptic, and all glassware and equipment were thoroughly cleaned before the process.

The guidelines recommended by WHO for local production of hand sanitizer (rub) formulation were carefully followed [22]. The ethanol (96%) was diluted to 70% (since the desired percentage was 70%). The concentration was quantified with the aid of a pH meter. About 10 liters glass screw threaded stoppered tank was used to mix the required ingredients using the magnetic stirrer. 100 and 500ml measuring cylinders and analytical balance were used to measure the reagents. Carbomer was used as the thickening agent due to its skin-friendly nature. Valina and banana flavors were used as fragrances. After the production, a post-production analysis was conducted as a quality control measure to ascertain the concentration of ethanol. The pH of the final preparation (500ml) was between 7.0 – 7.5. The label was provided with adequate instructions. Twenty (20) products (250 mL each) selected at random were grouped into four categories – 10 bottles were subjected to Room Temperature (at 25-28°C); 5 samples with lids (unexposed) and 5 without lids (exposed),

respectively while the other 10 samples were stored in the car (at 28 - 38°C); 5 samples with lids (unexposed), and 5 samples without lids (exposed), respectively. The alcohol concentration was quantified respectively with the aid of the alcohol meter daily, up to a period of 30 days (one month), and was properly recorded.

RESULTS

Data generated from the daily quantification were analyzed using One-way ANOVA with GraphPad InStat version 3.00 for Windows 95, GraphPad Software, San Diego California USA. Results are presented in the table percentage, mean, standard deviation, and chart.

Table 1: Evaluation of ethanol concentration in 70% alcohol-based hand sanitizer at different temperatures

DAY	Exposed sanitizer (% Mean ±SD)	Unexposed sanitizer (% Mean ±SD)	Sanitizer stored in the car (% Mean ±SD)	Sanitizer exposed in the car (% Mean ±SD)
0.	70.0±0.00	70.0 ± 0.00	70.0± 0.00	70.0± 0.00
1.	68.2±0.84	70.0 ± 0.00	70.0± 0.00	68.2±0.45
2.	67.0±0.71	70.0 ± 0.00	70.0± 0.00	67.6±0.55
3.	65.0±0.71	70.0 ± 0.00	70.0± 0.00	63.2±0.84
4.	64.0±0.71	70.0 ± 0.00	69.0± 0.00	60.6±0.89
5.	62.0±0.71	70.0 ± 0.00	69.0± 0.00	58.4±0.55
6.	60.0±0.71	70.0 ± 0.00	69.0± 0.00	55.4±0.55
7.	58.2±0.45	70.0 ± 0.00	69.0± 0.00	52.4±0.55
8.	57.2±0.45	70.0 ± 0.00	69.0± 0.00	50.4±0.55
9.	56.2±0.45	70.0 ± 0.00	68.8±0.45	48.4±0.55
10.	56.2±0.71	70.0 ± 0.00	68.8±0.45	46.4±0.55
11.	55.8±0.45	70.0 ± 0.00	68.8±0.45	46.6±0.55
12.	55.4±0.45	70.0 ± 0.00	68.8±0.45	46.0± 0.00
13.	55.2±0.45	70.0 ± 0.00	68.8±0.45	46.0± 0.00
14.	54.8±0.45	70.0 ± 0.00	68.0± 0.00	45.4±0.55
15.	54.4±0.45	70.0 ± 0.00	68.0± 0.00	44.0± 0.00
16.	54.2±0.45	70.0 ± 0.00	68.0± 0.00	44.0± 0.00
17.	54.2±0.45	70.0 ± 0.00	68.0± 0.00	44.0± 0.00
18.	54.0± 0.00	70.0 ± 0.00	68.0± 0.00	43.0± 0.00
19.	54.0± 0.00	70.0 ± 0.00	67.8±0.45	43.0± 0.00
20.	53.6±0.55	70.0 ± 0.00	67.8±0.45	43.0± 0.00
21.	53.2±0.45	70.0 ± 0.00	67.8±0.45	43.0± 0.00
22.	53.2±0.45	70.0 ± 0.00	67.8±0.45	42.0± 0.00
23.	53.0± 0.00	70.0 ± 0.00	67.8±0.45	42.0± 0.00
24.	53.0± 0.00	70.0 ± 0.00	67.6±0.55	42.0± 0.00
25.	53.0± 0.00	70.0 ± 0.00	67.6±0.55	41.0± 0.00
26.	53.0± 0.00	70.0 ± 0.00	67.6±0.55	41.0± 0.00
27.	53.0± 0.00	70.0 ± 0.00	67.4±0.55	41.0± 0.00
28.	53.0± 0.00	70.0 ± 0.00	67.4±0.55	41.0± 0.00
29.	53.0± 0.00	70.0 ± 0.00	67.2±0.45	40.8±0.45
30.	53.0± 0.00	70.0 ± 0.00	67.2±0.45	40.8±0.45
P value	<0.0001	<0.0001	<0.0001	<0.0001

Statistical test was conducted at p-value ≤0.05. The P value from One-way Analysis of Variance (ANOVA) is < 0.0001, considered extremely significant. Variation among column means is significantly greater than expected by chance. Data presented as % Mean ± Standard Deviation (SD)

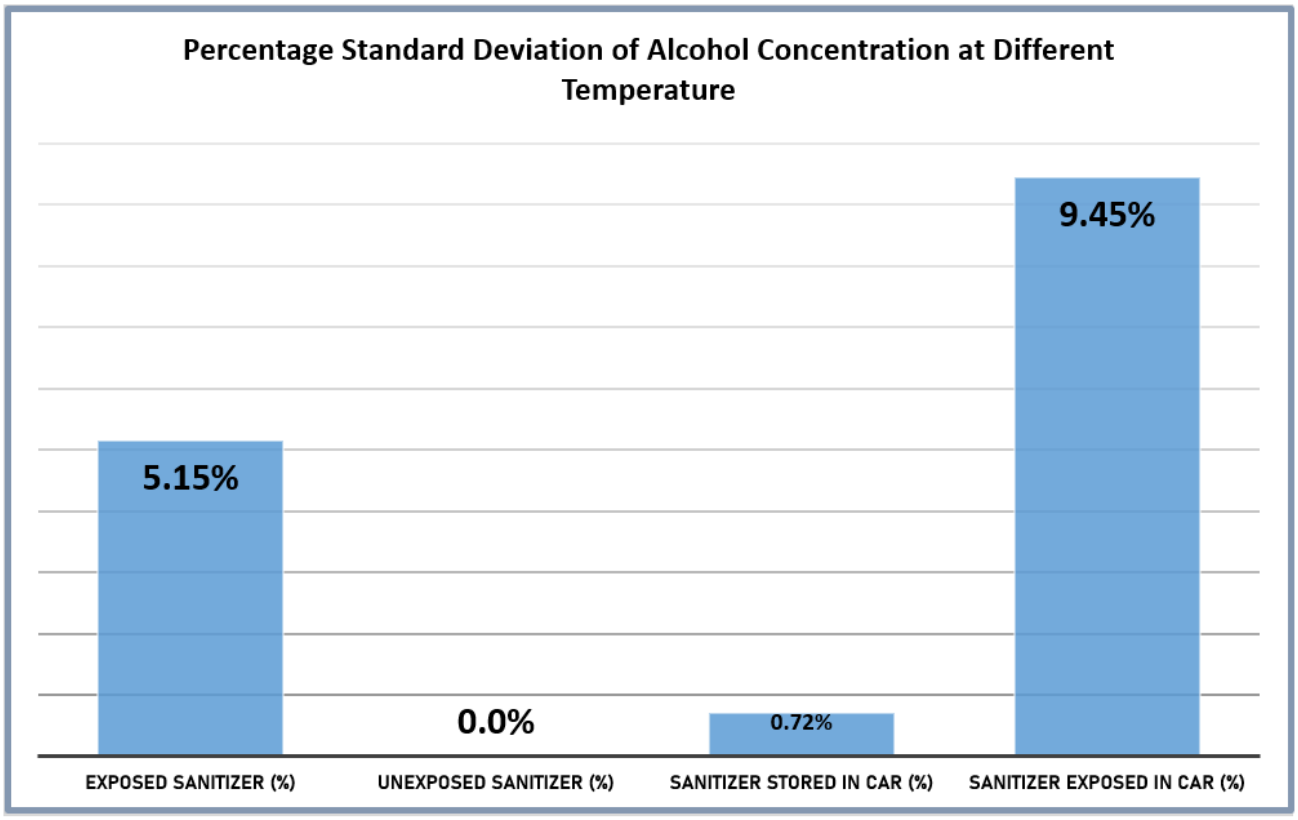

Figure 1: Percentage (%) standard deviation of alcohol concentration at different temperature

DISCUSSION

The prepared hand sanitizer (rub) was exposed to air, stored inside a car, and exposed in the car respectively at different temperatures. From the data analyzed, there was a significant statistical difference between the exposed hand sanitizer preparations compared to the standard at a p-value less than or at 0.05. There was a drastic reduction of the ethanol concentration from 70% to 53% of the exposed preparation. Also, of the ones stored in the car, one was exposed while the other product was corked intact. The ethanol concentration reduced from 70% to 68% of the well-closed product inside the car while there was an alcohol content reduction from 70% to 41% on other product that was exposed in the car at 28 - 38°C (Table 1).

No changes in alcohol concentrations were observed in the unexposed product, whose alcohol content remained at 70% throughout the 30 days of the quality control analysis, thus exposing it to high temperatures negatively affects its potency and efficacy (Figure 1). Hence, alcohol-based preparation shouldn't be exposed to air without adequate protection from sunlight or high temperature. These formulations were necessitated to meet the needs of the health facility, as well as the general public health during the COVID-19 global pandemic. Local production of hand sanitizers and other pharmaceutical products (including consumables) should be well encouraged and funded by government and Non-Governmental Organizations.

CONCLUSION

It is evident from the extensive analytical study that temperature directly affects the concentration of alcohol in hand sanitizer preparations. Since the bacteriostatic, fungistatic, and viriostatic or germicidal potency of any hand sanitizer preparation depends on the alcohol concentration, the higher the temperature, the lower the alcohol concentration. Also, these preparations should be to closely checked after use, and avoid storing them in vehicles, especially on sunny days, as this will reduce their potency and overall efficacy.

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