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SANITIZER: THE ADVERSE REACTIONS IN THE COVID-19 ERA

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ABSTRACT:

Because of its contagious nature, the COVID-19 pandemic has become a major global public health problem, prompting widespread usage of hand disinfectants. As of May 7, 2020, there were 3.8 million documented cases globally, affecting over 200 nations. The Centres for Disease Control and Prevention advise routine hand washing with soap and water to stop the spread of viruses. As people in general and healthcare professionals emphasise using strict hand cleanliness. For COVID 19, alcohol-based hand sanitizers are advised as a significant infection prevention measure. Effective hand disinfection agents, which come in a variety of forms and types, including antimicrobial soaps, water- or alcohol-based hand sanitizers (the latter of which is frequently used in hospital settings), are the only thing that can ensure the efficacy of hand sanitization. Hand sanitizer sales have multiplied many times over. As a result, given how often hand sanitizers are used, it is crucial to do a thorough analysis and understanding of them. However, due to rising demands, public fear, and ignorance, improper use of disinfectants can become a major problem that has a detrimental impact on both the environment and human health. Although hand sanitizer has shown to be effective in eliminating germs, there may be adverse effects. Overuse of hand sanitizers can cause redness, discolouration, peeling, and dry, cracked skin. Therefore, using the data of adverse events submitted to the Food and Drug Administration Adverse Event Reporting System (FAERS) pharmacovigilance database, we sought to ascertain whether the outbreak was linked to an increase in reports of hand sanitizer-related adverse events. Reports on hand sanitizers, including those with and without alcohol, were examined in the FAERS Database.

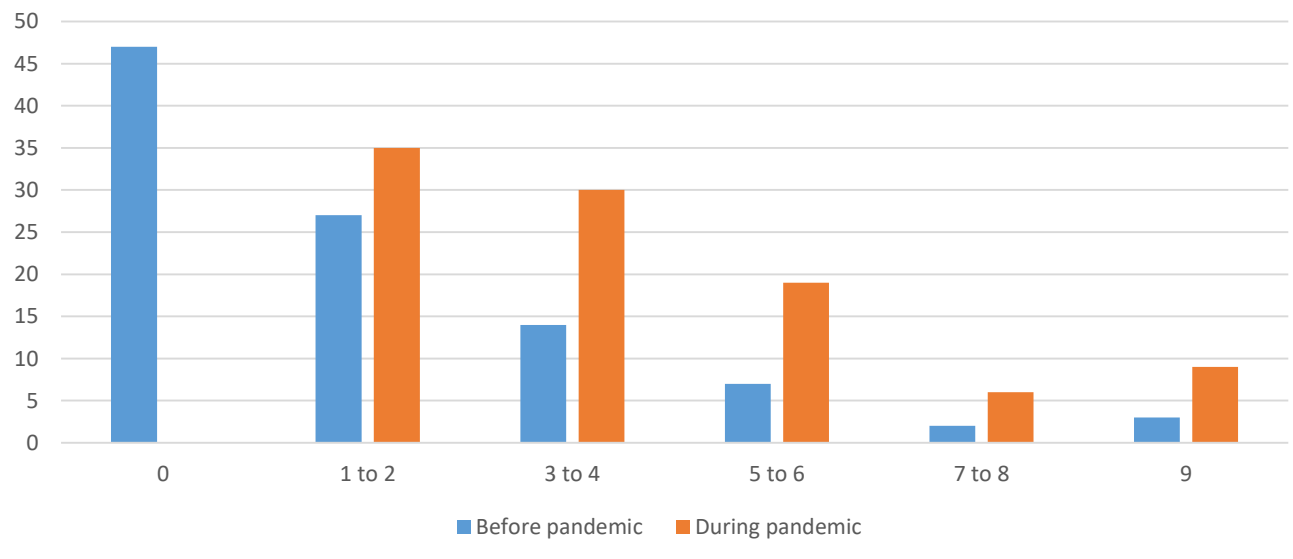
KEYWORDS– Covid19, hand sanitizer, pharmacovigilance, alcohol -based hand sanitizers.

INTRODUCTION:

During the COVID-19 epidemic, practising appropriate hand sanitization became crucial and one of the best preventative methods [1] (Fig 1). It is very important to stop the virus's chain of transmission by practising adequate hand sanitization during pandemic outbreaks. Contact isolation and stringent infection control measures, such as practising excellent hand hygiene in public and in medical settings, can help achieve it [2]. Incubation periods for human-to-human infections have been reported to range from two to ten days. This allows the virus to spread through droplets and contaminated hands or surfaces [3]. It's essential to break the chain of virus transmission by properly sanitising your hands. There are many different hand hygiene products on the market, but their effectiveness and safety vary [2]. There are many different types of hand hygiene solutions on the market, and although some of these formulations may be helpful against COVID-19, they

may also change the integrity and function of the skin barrier [4]. The greatest hand hygiene practise is emphasised for alcohol-based hand sanitizers, of which they are the main ingredient [1]. Which are mostly composed of various mixtures of hydrogen peroxide, ethanol, and isopropyl alcohols [5](fig 2).
The SARS-CoV-2 virus is efficiently rendered inactive by ethanol, according to recently published data. However, there is a dearth of information regarding hand sanitizer formulations that are currently in use in general and hospital settings in the United States. This study shows that SARS-CoV-2 in suspension can be effectively inactivated using foam and gel alcohol-based hand sanitizers that are sold commercially [6]. When utilised improperly, these mixes could be hazardous to both the environment and human health. When these substances evaporate, their known harmful and dangerous effects on the environment occur [5]. WHO recommended using two alcohol-based hand hygiene formulations in healthcare settings to increase hand sensitization and decrease coronavirus dissemination and infectivity (WHO, 2020). These suggestions are predicated on quick, potent, wide-spectrum antimicrobial activity along with convenient availability and careful consideration of safety [5]. Currently, the majority of efficacious hand sanitizer products are alcohol-based formulations that include 62%–95% alcohol due to their ability to denature microbial proteins and inactivate viruses [2]. Alcohol's capacity to penetrate viral membranes, denaturate and coagulate their proteins, disrupt their cellular metabolism, and ultimately analyse the components of the virus are all thought to contribute to its antiviral effect [2] (fig 3).
9504 instances of children under the age of 12 who were exposed to alcoholic hand sanitizer were reported to the American Association of Poison Control Centre. Alcohol poisoning in children can result from very small amounts of alcohol consumption, according to the centre. Symptoms include vomiting, drowsiness, and confusion; in extreme situations, respiratory arrest and death may occur [5]. Furthermore, ethanol application to skin that is still developing can cause responses and systemic toxicity, which manifests as ethanol intoxication as a result of percutaneous absorption, particularly in infants less than 33 months. Alcohol-free formulations, such as those based on benzalkonium chloride, are typically less effective than alcoholic-based hand sanitizers [1] (fig 3). Additionally, regular use of the aforementioned hand sanitizers has been linked to a higher risk of developing viral infections and antibiotic resistance [1].

Fig 1- Frequency of hand sanitizer use by adults before and during the pandamic.



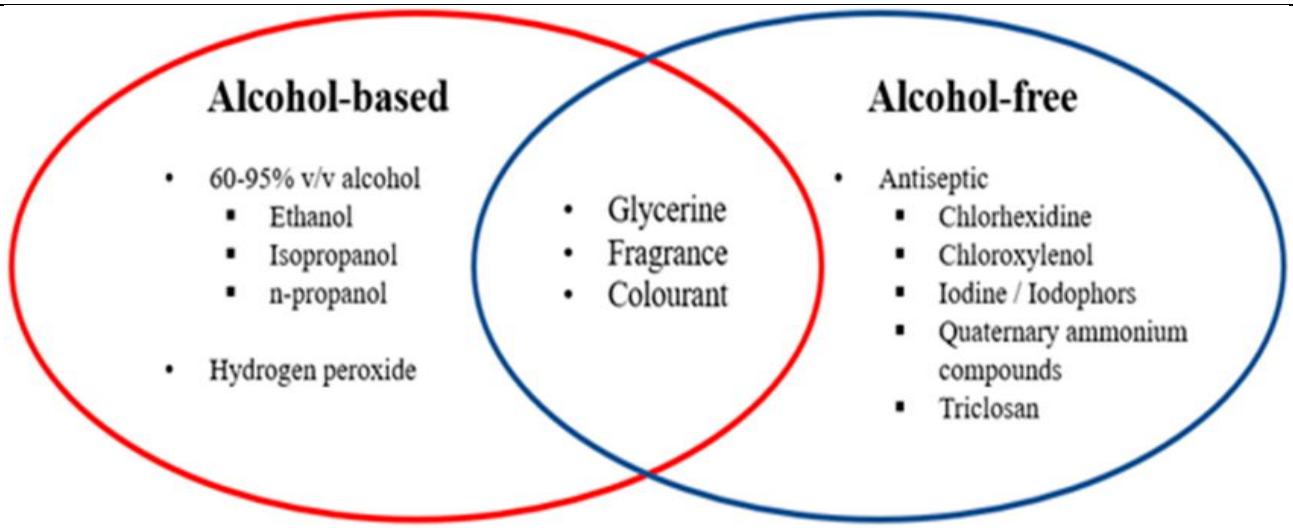


Figure 2- Composition of sanitizer

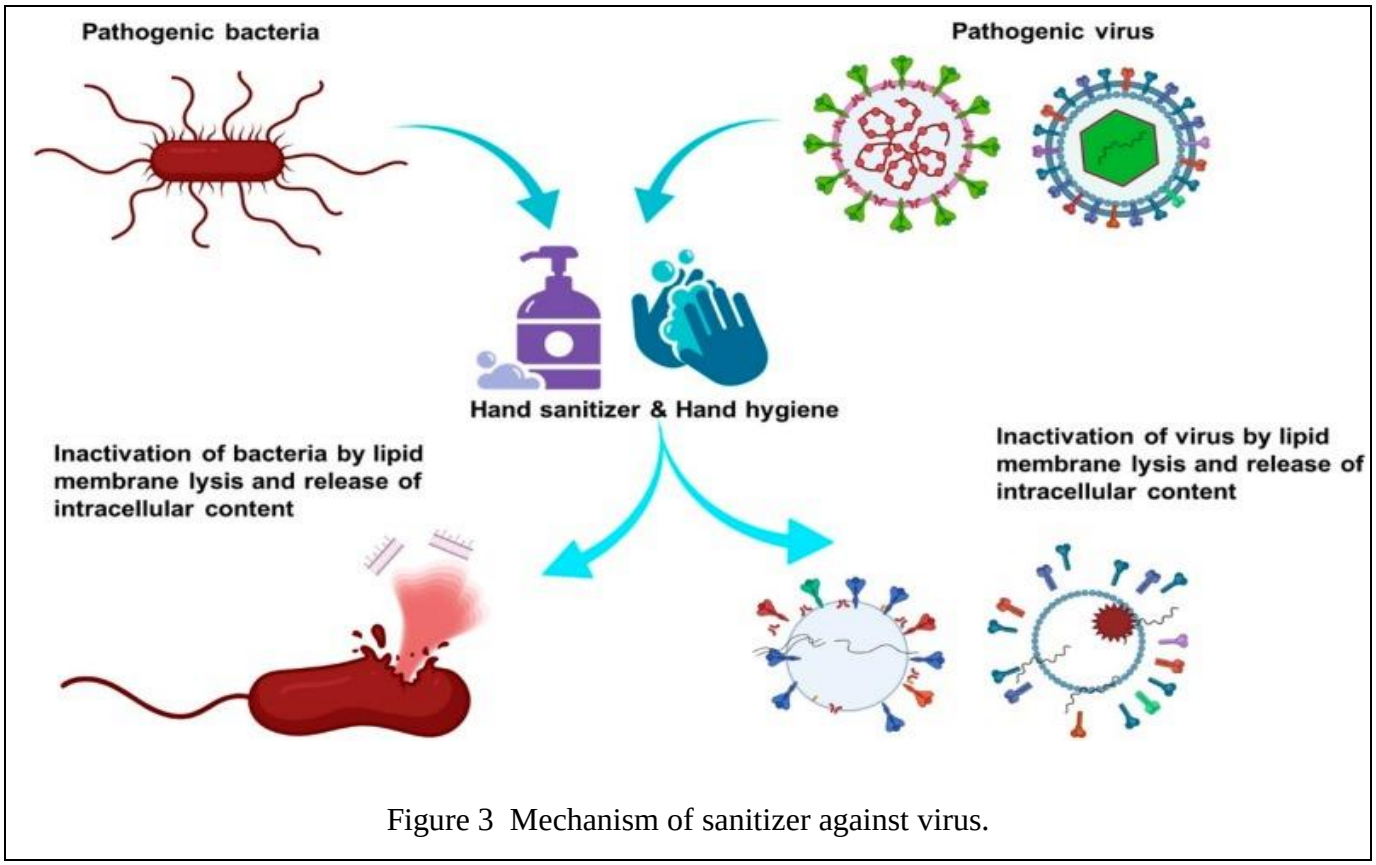


Figure 3 Mechanism of sanitizer against virus.

METHOD:

The FDA has improved data access and transparency and put in place systems that let the public and the pharmaceutical sector turn raw data into information that can be used. One of these technologies, the FDA Adverse Event Reporting System, or FAERS, Public Dashboard, was introduced by the FDA eight months ago [7]. The FDA introduced the FAERS Public Dashboard for COVID-19 emergency use authorization (EUA) items in reaction to the COVID-19 pandemic. Weekly updates of adverse event reports sent to FAERS for medications and therapeutic biological products used under EUA in COVID-19 are available via the COVID-19 EUA FAERS Public Dashboard [8]. The PRISMA guidelines were followed in the conduct of this investigation. Up until 2020, we thoroughly examined the material that was accessible through PubMed and

Google Scholar. Hand sanitizers, alcohol, treatment, hand washing, virucide, bactericide, and (cure OR failure OR fatality) are the search terms we utilised [2]. To find research on the potential negative effects of alcohol-based sanitizers as well as their ability to prevent the spread of COVID-19, a literature search of electronic databases including PubMed, Scopus, Research Gate, and Embase was carried out. The databases' creation dates were all the way up to August 2020 [9]. There are still restrictions on the data, even though the FAERS dashboard gives stakeholders a lot more options for finding and organising information on adverse events that have been reported to the FDA for several pharmaceutical and biologic products. For instance, just because a specific medication or biologic is mentioned in FAERS reports does not imply that the medication or biologic is to blame for the adverse event. Crucially, the FAERS findings do not, by itself, represent the drug's or biologic's safety profile [8].

Search strategy and data analysis:

For a systematic review of the scientific literature, the research article on the issue of interest was looked for in Pubmed, Google Scholar, Sci-Hub, WHO, PubChem, and the American Association of Poison Control Centres (AAPCC). To make it easier to find pertinent information in the search engines and databases, different terminologies were employed. The most often used terms were COVID-19, Sar-Cov-2, disinfectants, alcoholism, sanitizers, impacts of disinfectants on humans and the environment, influence of disinfectants on wildlife, and a few more. To determine if a complete text report satisfied the inclusion requirements, it was examined. The majority of the articles were featured in the study that emphasised the dangerous consequences of COVID-19 on both people and wildlife. Since no relevant recent scientific work has been published on the subjects involved, the majority of the papers included in this study have recently been published, though some earlier publications have also been cited to clarify the essence of disinfectants and their effects on living things [10]. These reports were submitted to the FDA through obligatory drug manufacturer reports from several nations, or directly by consumers or healthcare professionals. The event report, sometimes called an individual case safety report (ICSR), includes information categorised as the case's identity document (ID), the suspected product name and active ingredients, the intended use, the outcome (serious or not), the nation, the kind of reporter, and the date of the incident. Demographic information such as the case's age and gender (male, female, or unknown) is also included in these adverse event reports [11].
This report's primary goal is to highlight the toxicity and major health hazards that come with using alcohol-based hand sanitizers and disinfectants on people. By identifying and characterising every exposure that was reported to the American Association of Poison Control Centres (AAPCC) between January 1, 2017, and May 30, 2021, instances were classified according to the source of toxicity, which included hand sanitizer, rubbing alcohol, disinfectant, and alcohol of unknown type. The regional Washington Poison Centre (WPC) served as the point of contact for acquiring national AAPCC data. We examined the cases in this analysis based on the substance, sex, patient age, site and purpose of exposure, therapies received, and results [11]. A history of alcohol-based hand sanitizer exposure (e.g., ingestion, dermal, ocular, inhalation, or injection) in any patient seeking medical attention in Arizona or New Mexico between May 1 and June 30, 2020, was considered a case of alcohol-based hand sanitizer–associated methanol poisoning. The CDC worked with the Arizona Department of Health Services, the Arizona Poison and Drug Information Centre System, the New Mexico Department of Health, and the New Mexico Poison and Drug Information Centre to identify and analyse poison centre call records in order to identify and characterise instances. Records meeting the case definition were subjected to the abstraction of clinical and demographic data. Age, sex, signs and symptoms at evaluation, blood test findings (including methanol levels), the existence of anion-gap acidosis, therapies received, and results were used to characterise the patients. Clinical and demographic information absent from the poison centre call records was examined in the medical records. A case vignette that serves as illustration is given. The activity was found to comply with 45 CFR 46.102's definition of public health surveillance [12].

RESULT:

Hundreds of calls to Poison Control are made each month regarding accidental hand sanitizer intake. Calls to Poison Control about hand sanitizer surged by 79% in March 2020 (during the COVID-19 outbreak) over March 2019. Most of these calls concerned inadvertent exposures to children under the age of five. As a result, it's critical to keep hand sanitizer out of children's reach and to watch over them while they use it [13]. The AAPCC noted that even a small amount of alcohol can cause alcoholism in children, which can result in poisoning, vomiting, and drowsiness. In the first five months of 2020, the AAPCC documented 9504 cases of

alcoholism cases of contact with hand sanitizer in children under the age of twelve. Severe instances may possibly result in respiratory arrest and even death [14] (Table 1).

A growing number of people are using alcohol-based hand sanitizers (ABHS) in the wake of the COVID-19 outbreak. By the end of January 2020, the first American case had been found. ABHS poses a safety risk and contains at least 60% ethanol or 70% isopropanol [15]. The number of notifications to the AAPCC about the increased usage of disinfectants and cleansers that may have been used improperly has suddenly increased after 2020. The likelihood of accidents and health issues can rise with the frequent and increased usage of disinfectants and hand sanitizers. The AAPCC data appears to have a clear transitory link with increased usage of these items, even while it does not reveal a strong correlation between the number of accidents and exposure to disinfectants and hand sanitizers as a result of the COVID-19 epidemic.Figure 4 illustrates the increase in cases between 2019 and 2020. The highest percentage increase (1080 instances, 176% increase) was attributed to hand sanitizers, followed by disinfectants (376 cases, 152% increase) and rubbing alcohol (336 cases, 111% increase) [11].

Cases of exposure to both hand sanitizers and disinfectants are reported to the AAPCC on a monthly basis. In comparison to case counts prior to the COVID-19 pandemic, a rapid 98% spike that starts in March 2020 and briefly declines in October 2020 has persisted to be high. When compared to the coronavirus infection case statistics reported by the CDC, the October 2020 temporary decline is consistent with the government of the United States' stay-at-home directive during that period [16] [figure 5]. There is no relationship between the number of cases and gender when it comes to hand sanitizer and disinfectant exposure. The increase in total cases from 2020 to May 2021 was observed across all age groups when the cases were broken down into different age groupings. Between May 2017 and May 2021, exposures among children under the age of ten accounted for a remarkably high percentage (48%) of all cases [11] [Table 2].

The U.S. Centres for Disease Control and Prevention (CDC) said on August 5, 2020, that drinking hand sanitizer had resulted in four deaths and three patients experiencing visual impairments. In addition to cautioning against deceptive labels stating a hand sanitizer product is "FDA-approved," the FDA has recalled over 135 hand sanitizer goods for safety concerns. The FDA has not authorised any hand sanitizer products and never will [17].

The AAPCC has received reports of 8016 exposures to hand sanitizers and disinfectants since 2017. 3398 cases were documented in the three years leading up to the pandemic, from 2017 to 2019. Meanwhile, 4618 cases were reported during the 1.5 years from May 2020 to May 2021. More than 1000 additional cases in just half the time. Children ten years of age or less were exposed in about half of these cases. Inadvertent contact with hand sanitizers and disinfectants accounted for 96% of the cases among that age group. This could be the result of handling or placing the disinfection product incorrectly. The age group with the most purposeful exposures between 2017 and May 2021 was 10–19 years old. Own residence was the most frequent exposure venue in our investigation. There were considerably fewer major consequences—only 28 out of 8016—than there were minimal to no effects in almost 50% of the cases that were reported [15] [Figure 4]. A examination of calls to US poison control centres between January 1, 2018, and December 31, 2020 revealed 299 cases of harmful cutaneous and nasal/inhalation exposures to hand sanitizer products. During the COVID-19 pandemic that began in March 2020, there was a notable increase in these instances. Twelve percent of instances included children aged five or younger; the majority of cases involved adults and had little to no impact. Clinical symptoms from ethanol included vertigo/dizziness, headache, and nausea [18].

The FDA issued a warning on June 16, 2021, on the potential for symptoms like headache, nausea, and dizziness to arise following skin application of alcohol-based hand sanitizers. These symptoms were probably brought on by the hand sanitizer's fumes, either by being in enclosed areas or places with inadequate ventilation. Since the COVID-19 pandemic began, we have been inundated with more and more complaints of these adverse consequences. The majority of persons only had mild or negligible side effects; yet, in certain situations, medical attention was necessary [18]. A review of published instances' literature, a case report, and an inquiry into the National Poison Data System (NPDS).The purposeful consumption of alcohol-based hand sanitizers including ethanol, isopropanol, or mixes of isopropanol, 1-propanol, 2-propanol, and/or acetone was reported in 14 published case reports [19]. Nine men and four women, with one gender unspecified, made up the median age of 44.5 years (range: 27-81 years). Most were classified as having mental illness and abusing drugs or alcohol, and most ingestions happened in the ER or after being admitted to the hospital. Four acknowledged having attempted suicide. Out of the 14 patients, 13 had a full recovery, while 1 death was documented [20]. The CDC was notified by public health partners in Arizona and New Mexico on June 30, 2020, about cases of methanol poisoning linked to the consumption of alcohol-based hand sanitizers. The FDA released a consumer advisory on June 19, 2020, regarding certain hand sanitizers that contain methanol, which was followed by the case reports. Methanol poisoning can cause severe anion-gap metabolic acidosis,

seizures, and blindness, while ethanol poisoning can cause similar early clinical symptoms, such as headache, blurred vision, nausea, vomiting, abdominal pain, loss of coordination, and decreased level of consciousness. Methanol poisoning can be deadly if untreated [21] Poison Centres handled 13,526 exposure cases involving hand sanitizer in children aged 12 and under as of October 31, 2023 [14] (Figure 6).

Table 1: No. of exposure in children (12 years or younger) with hand sanitizer in 2020.
Note – Adapted from Hand Sanitizer by American Association of Poison Control Centre (AAPCC), 2020, retrieved from https://aapcc.org/track/hand.sanitizer

Month	No of exposure cases
January	1610
February	1674
March	2466
April	1882
May	1924
June	1833
July	2312
August	2248

Fig 4-No of exposures to alcohol based hand sanitizer 2017-2021

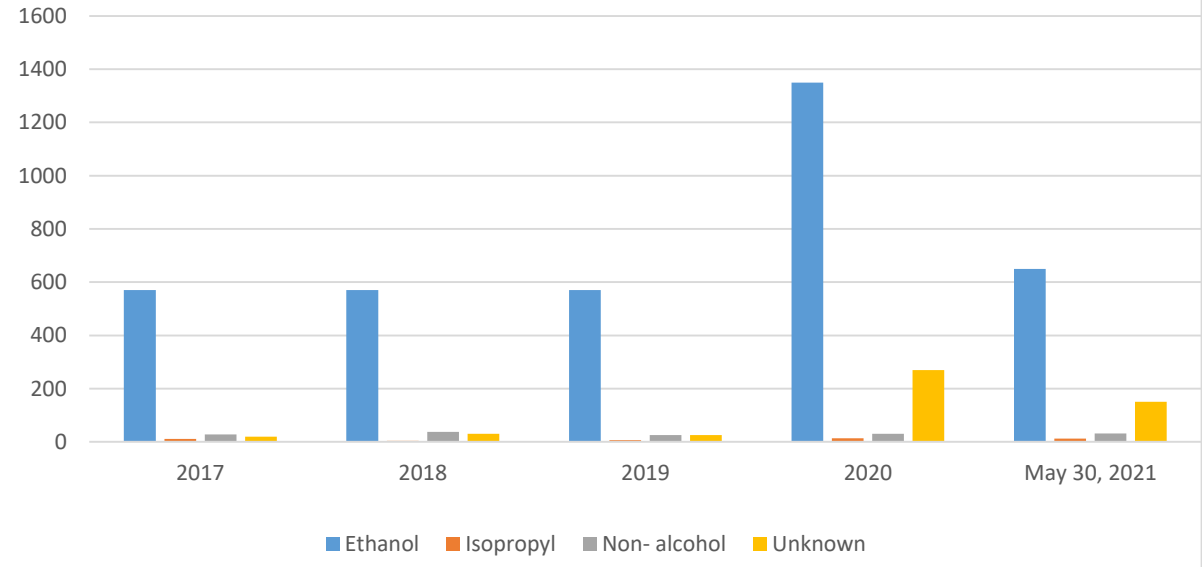


Fig 5 - No of monthly exposures to alcohol based hand sanitizer reported to AAPCC-US
July19 - May21

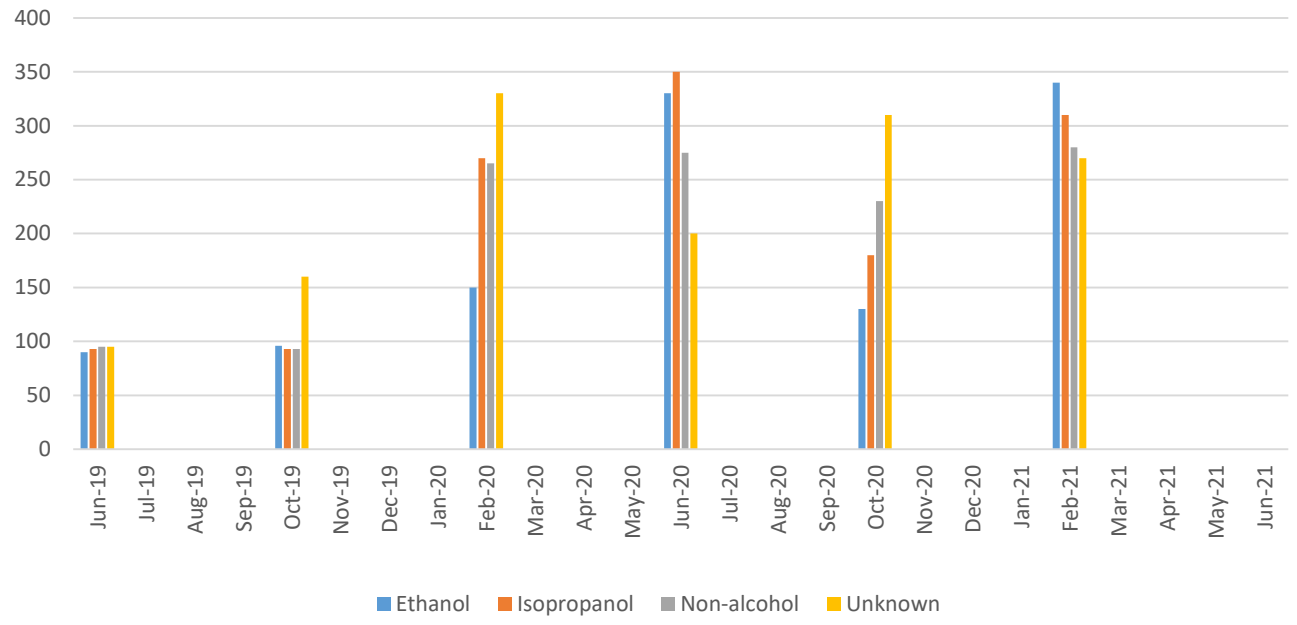


Table 2 – Yearly no of cases of exposures to hand sanitizers based on sex and age range.

		2017	2018	2019	2020	May2021
	Male	524	568	603	1412	714
Sex	Female	531	567	589	1630	834
	Unknown	3	6	7	22	6
	Total	1058	1141	1199	3064	1554
	Less than 10	545	560	565	1312	836
	10-19	85	102	104	207	127
	20-29	94	122	142	323	137
	30-39	88	89	107	360	105
Age(Years)	40-49	54	67	84	232	75
	50-59	51	47	69	193	87
	Over 60	71	90	86	292	123
	Unknown	70	64	42	145	64
	Total	1058	1141	1199	3064	1554

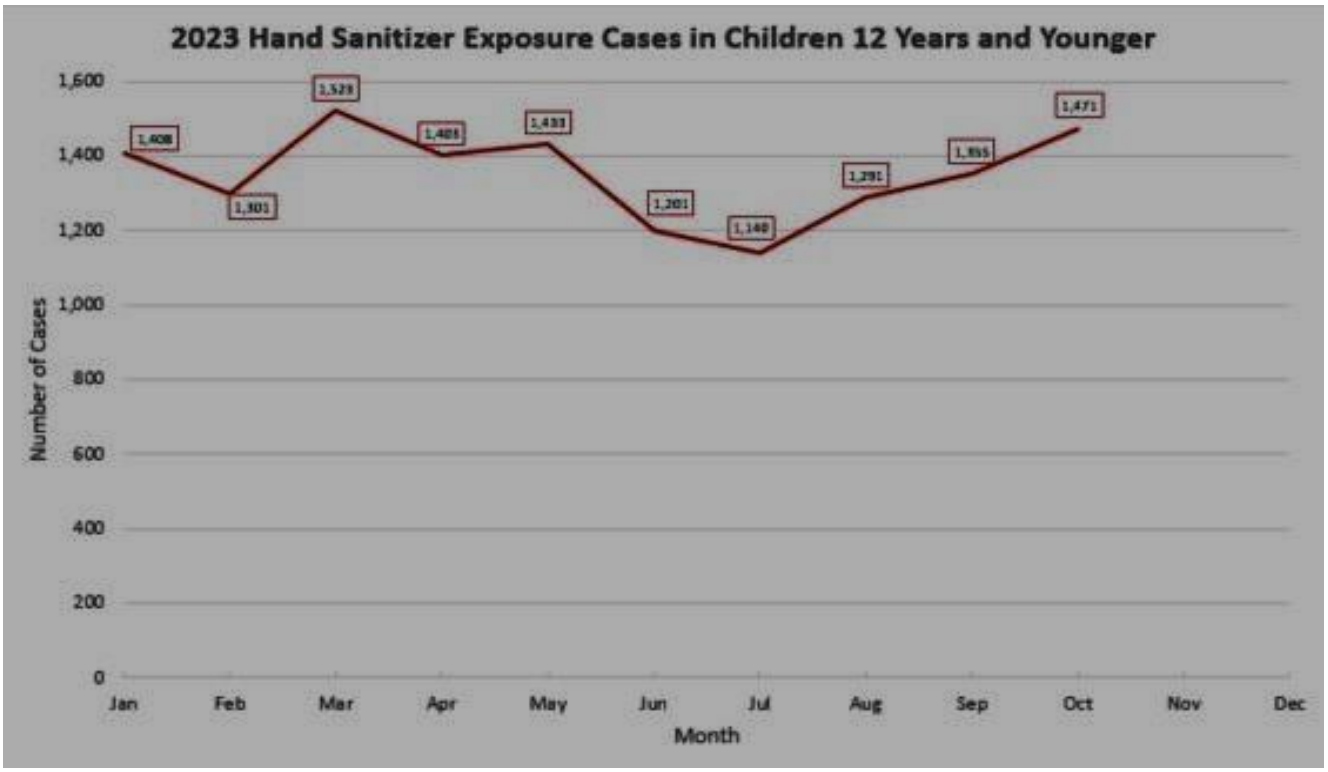


Fig 6- Hand sanitizer exposure cases in children 12 years and younger in 2023

DISCUSSION:

The product is dehydrating your skin when you use hand sanitizer on your hands several times a day. Skin that is dry, flaky, and sensitive to the touch may arise from this. According to the American Academy of Dermatology Association, having dry skin might actually increase your risk of contracting germs in addition to being uncomfortable [22].

When the items are applied to the skin, they may result in allergic reactions (contact allergy), which can manifest as rapid reactions (contact urticaria) or less frequently as delayed type reactions (allergic contact dermatitis).Preservatives and scents are the most frequent causes of contact allergy, emulsifiers less so.Hand hygiene products affect the stratum corneum by denaturing its proteins, altering intercellular lipids, reducing corneocyte cohesiveness, and reducing the stratum corneum's ability to bind water. Skin damage also alters the ecology of the skin, making staphylococci and gram-negative bacteria more likely to colonise the skin. Regular alcohol exposure causes the skin's lipid barrier to be depleted because the substance alters the flora on the skin and penetrates deeper into the skin's layers. Acute gastroenteritis cases have been linked to the hand sanitizers that healthcare workers use for regular hand cleaning [23].

The two most common skin reactions to alcohol-based hand sanitizers that are recorded are allergic and irritant contact dermatitis. ICD symptoms, which include dryness, pruritus, erythema, and bleeding, can range in severity from minor to weakening. The most severe signs and symptoms of ACD are respiratory failure or other anaphylactic symptoms. After ACD, symptoms can range from mild and localised to severe and widespread [24]. The development of germs resistant to antibiotics is caused by the active ingredient in hand sanitizers, triclosan. Thus, in a sense, employing hand sanitizers to prevent infections could have unintended consequences. It can eradicate beneficial microorganisms that aid in the fight against illness. Lower resistance to illnesses and infections results from this [9].

Anything that is used frequently, even hand sanitizer, can lead to long-term skin damage and discomfort. Your body's natural defences against illnesses and pathogens are the good bacteria that reside there. Excessive use also eliminates good bacteria from the digestive tract and the skin. When the good bacteria in the digestive system are killed, an imbalance between the good and bad bacteria occurs. This imbalance can lead to a variety of diseases, including cancer, obesity, diabetes, liver disease, chronic heart disease, and inflammatory bowel disease, as well as intestinal symptoms like diarrhoea and abdominal pain. Moreover, overuse of alcohol-based skin sanitizers causes natural mutations in microbes and exacerbates the toxicity and harmful effects on skin. This can exacerbate the problem of antimicrobial resistance, which is already a serious threat to developing nations and continents like Bangladesh, India, Pakistan, and Africa [21].

A significant number of serious problems, including respiratory distress and respiratory arrest, cardiac problems such as cardiac dysrhythmias, ketoacidosis, hypotension, hypokalaemia, acute liver damage, hypomagnesaemia, myoglobinuria, hypocalcemia, and hypophosphatemia, have been linked to excessive inhalation or ingestion of ethanol [25]. Nausea, eye discomfort, mouth irritation, ocular irritation, stomach pain, and coughing are a few typical side effects. Acidosis, headache, respiratory distress, blindness, glycemia, epilepsy, and even coma or death are among the infrequent side effects of utilising ABHS and NABHS [26]. According to the current research, fewer than 8% of individuals self-reported experiencing neurological side effects from using sanitizers and disinfectants, such as headache, nausea, and dizziness. Following the use of formaldehyde (the least amount) and alcohol (the most), respectively, a total of 7114 and 419 subjects reported headache, vertigo, and vomiting, respectively. The findings showed that the use of analysis was associated with a statistically significant association between potential neurological issues [27]. It has been noted that using alcohol-based hand sanitizers excessively can result in drug resistance, which could strain already overworked medical personnel. Recurring exposure of germs to disinfectants, antibiotics, or other genotoxic compounds can lead to natural mutations that make the microbes resistant to hand sanitizer use [28].

The safety range of methanol is significantly smaller than that of ethanol and isopropanol. Elevated methanol concentrations can result in fatalities and irreversible blindness due to drastic alterations in body chemistry during its metabolism. Make sure your hand sanitizer is not one of the contaminated goods by checking here, even if the label states it contains alcohol, ethanol, isopropyl alcohol, or benzalkonium chloride. The label won't make reference to methanol [29]. Hand sanitizers with alcohol content have a negligible but detectable risk of burns and flames. When using alcohol-based hand sanitizers, caution must be exercised as alcohol fumes are extremely combustible, increasing the danger of burns and fires. Employees using alcohol-based hand sanitizers should stay a safe distance away from areas that are open to fire because there is a chance they could burn their skin. Hand sanitizer is probably filled with hazardous chemicals if it smells at all. Phthalates, which are hormone-mimicking endocrine disruptors that may modify genital development, are present in synthetic scents. Research has indicated that ethanol sanitizers have an impact on the amount of ethyl glucuronide in pee [30].

Because alcohol-based hand sanitizers are ineffective against bacterium spores, protozoa, and non-lipophilic viruses, people who are unaware of this might assume they are safe to handle non-lipophilic viruses after using alcohol-based hand sanitizers [31]. Occasionally, triclosan is a chemical found in hand sanitizer. Triclosan, which has been used in body wash and toothpaste, is supposed to fight microorganisms, according to the FDATrusted Source. Additionally, according to the FDA, some research suggests that prolonged exposure to triclosan may interfere with normal hormone cycles and could affect fertility. Although more investigation is required to completely comprehend the effects of triclosan on humans, the component has already been outlawed from a number of product categories [17].

CONCLUSION:

The CDC and WHO have advised frequent hand washing with soap and water for at least 20 seconds during the COVID-19 pandemic, particularly after being in public, blowing your nose, coughing, or sneezing. The CDC advises using an alcohol-based hand sanitizer using ethyl or isopropyl alcohol if soap and water are unavailable. On the other side, severe poisoning can result from using disinfectants and hand sanitizers incorrectly and too frequently. Suicide attempts, unintentional ingestion, and skin-contact absorption may be to blame for this. Long-term exposure to genotoxic chemicals and antibiotics tends to generate natural changes in microorganisms that render them resistant to the repeated use of hand sanitizers. Notwithstanding the paucity of current studies, the ability of ethanol to cause skin cancer through skin absorption and carcinogenicity is still being debated and researched in science. Standard hand sanitizers have also been connected to low system toxicity. Poisoning is more likely to occur in children. Hand sanitizers are most commonly applied to skin. Hand dermatitis and hand eczema are probably caused by frequent usage of hand sanitizers.

Additionally, by revising chemical usage guidelines and, if feasible, substituting low-risk, low-dose, high-impact chemicals in the production process, the current results can assist safety and health organisations that regulate the manufacture of chemicals.

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