

ADDRESSING KNOWLEDGE GAPS AND DISPELLING MYTHS – RECENT RESEARCH UPDATES IN HAND AND SURFACE HYGIENE

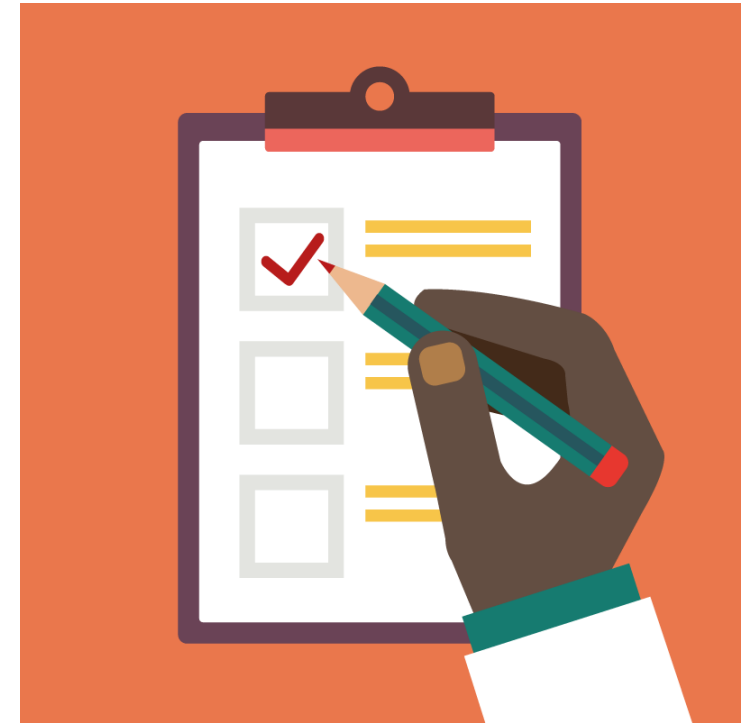
New Jersey Association for Food Protection

April 11, 2023

Clyde “Chip” Manuel, PhD - GOJO Industries

AGENDA

- Introduction to myself and GOJO – Who We Are
- Quick Norovirus Background Info
- Recent GOJO Research Updates and Learnings
- Key Takeaways and Closing Thoughts



INTRODUCTIONS

AN INTRODUCTION TO YOUR SPEAKER



Chip Manuel, Ph.D.

- Joined GOJO in 2019 as Food Safety Science Advisor
- Food Microbiology background with expertise in norovirus
- 7+ years industry experience, primarily in R&D microbiology roles



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GOJO HISTORY



- *Family Enterprise Founded in 1946 and Headquartered in Akron, Ohio*
- *Global Enterprise focused on the development and production of Hand and Surface Hygiene Solutions.*
- *Best know as the developers of PURELL® Instant Hand Sanitizer (1988)*

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GOJO IS A PURPOSE DRIVEN COMPANY



“Saving Lives and Making Lives Better through Well-Being Solutions”

"Everything I know, I learned from someone else."

- Jerry Lippman on the importance of lifelong learning



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GOJO VALUES



PEOPLE AT THE CORE:

- We uphold the essential dignity of all people.
- We care for ourselves and others.
- We see potential in every person and help each other grow.
- We celebrate our accomplishments.

BETTER TOGETHER:

- We embrace diverse perspectives and build upon each other's ideas.
- We combine our strengths as one GOJO team.
- We think whole-systems.
- We strive for win-wins.

UNCOMPROMISING INTEGRITY:

- We speak up and talk straight.
- We follow up and follow through.
- We take personal responsibility for our actions and inactions.
- We do what's right for the long haul.

ALWAYS LEARNING:

- We are learners, not knowers.
- We are hands-on. We try new things and keep what works.
- We seek insights from everyone and everywhere.
- We share our learnings.

BOLD LEADERSHIP:

- We innovate for a better world.
- We courageously take on challenges no one else will and inspire others.
- We imagine "how might we?"
- We play big, but don't act big.

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Effective

PURELL® products are formulated to be the most effective solution. We set the highest efficacy standards.



Safe

We use the safe and sustainable ingredients, and continually seek even better alternatives.



Good for you

PURELL® products help improve the health and well-being of people, facilities and institutions everywhere.

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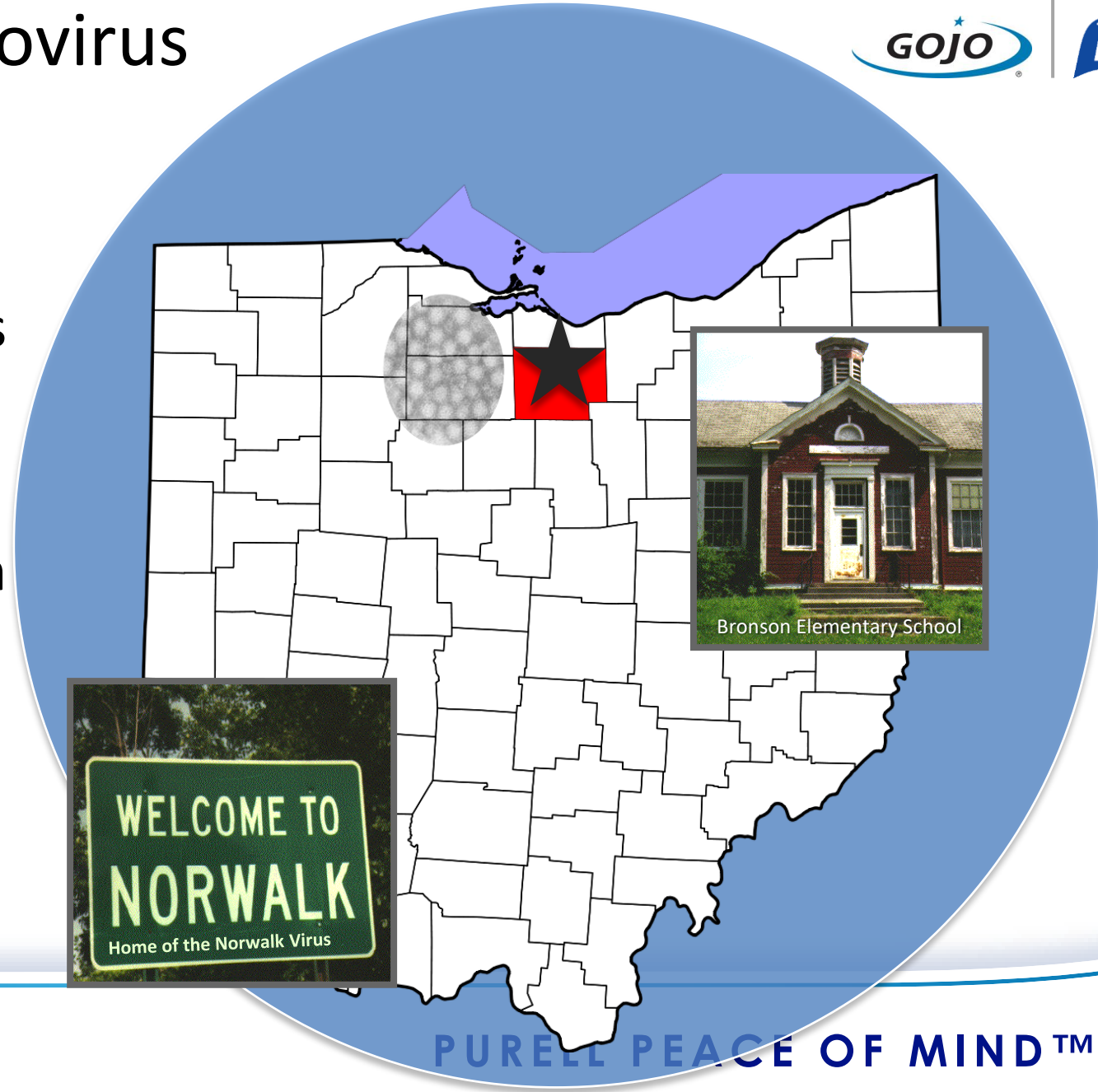
NOROVIRUS – BACKGROUND INFO

Ohio: Home of the Norovirus

“Norwalk virus” (NoV)

The first Norovirus identified as a cause of gastroenteritis following an outbreak of “winter vomiting disease” at an elementary school in Norwalk, Ohio in 1968.

Nor-OH-Virus

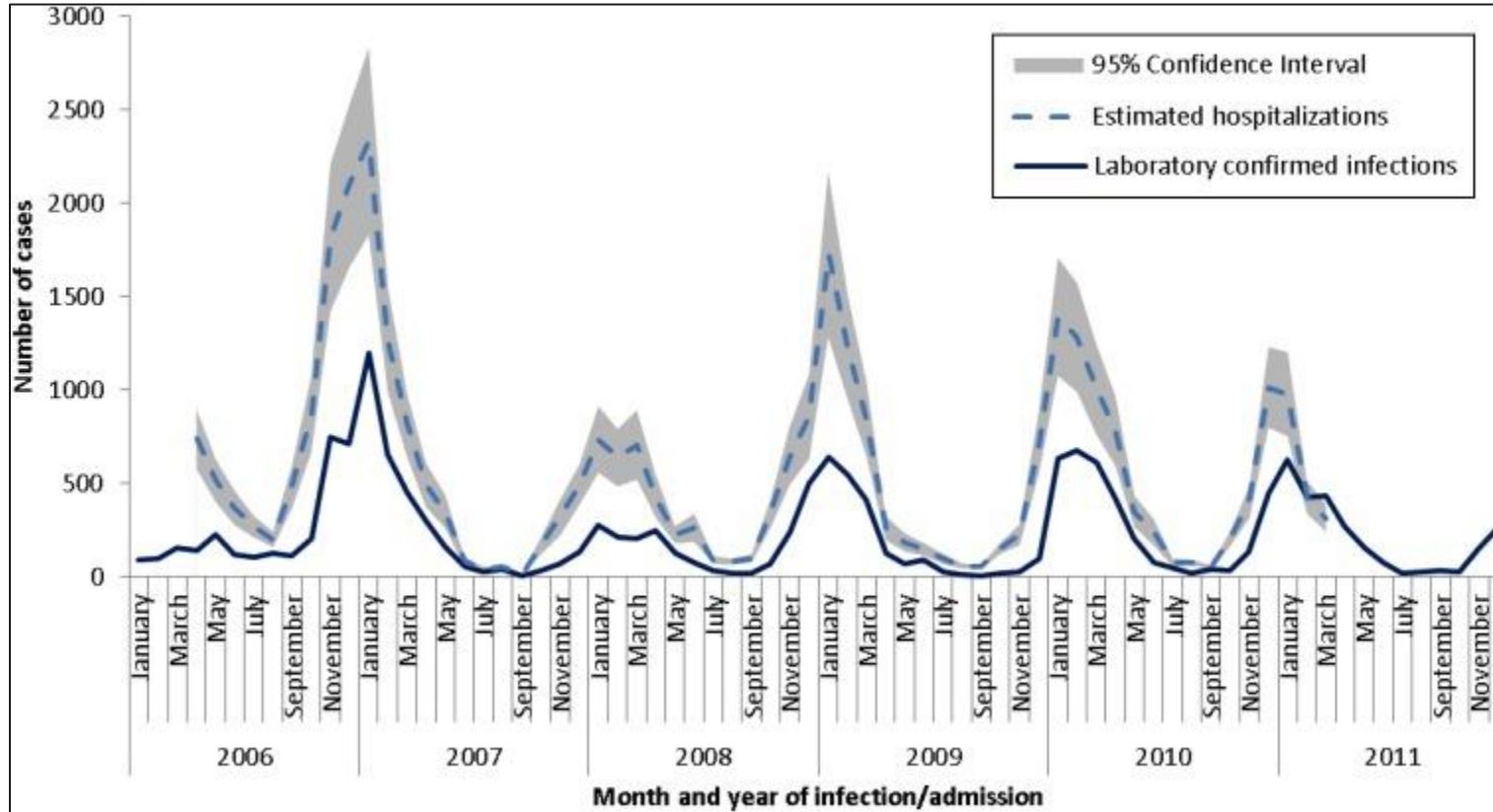


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HISTORY OF NOROVIRUS



- Before discovery, often called “winter vomiting disease” (coined in late 1920s)

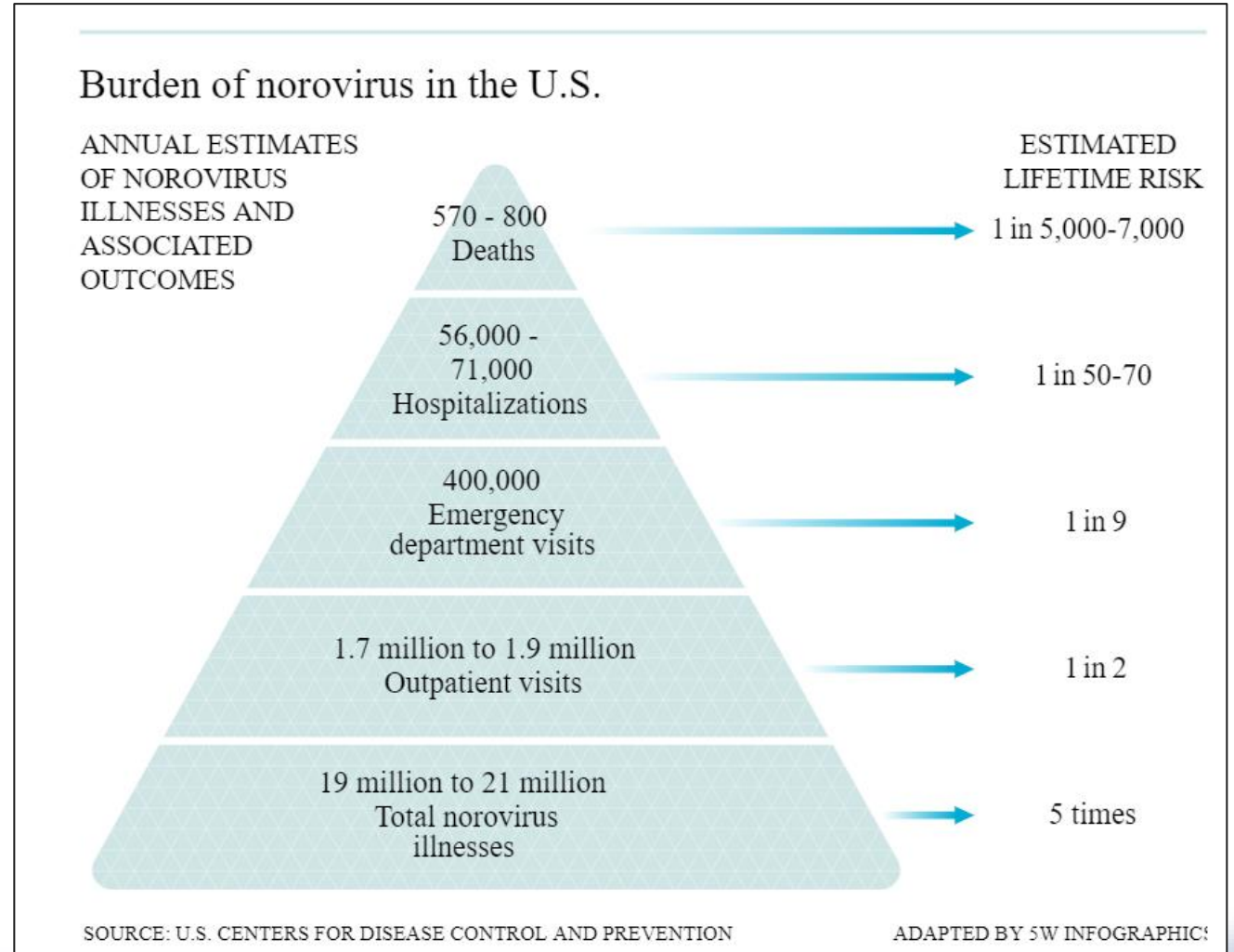


Epidemiol Infect. 2015 Dec; 143(16): 3528–3537.

SYMPTOMS AND ILLNESS BURDEN

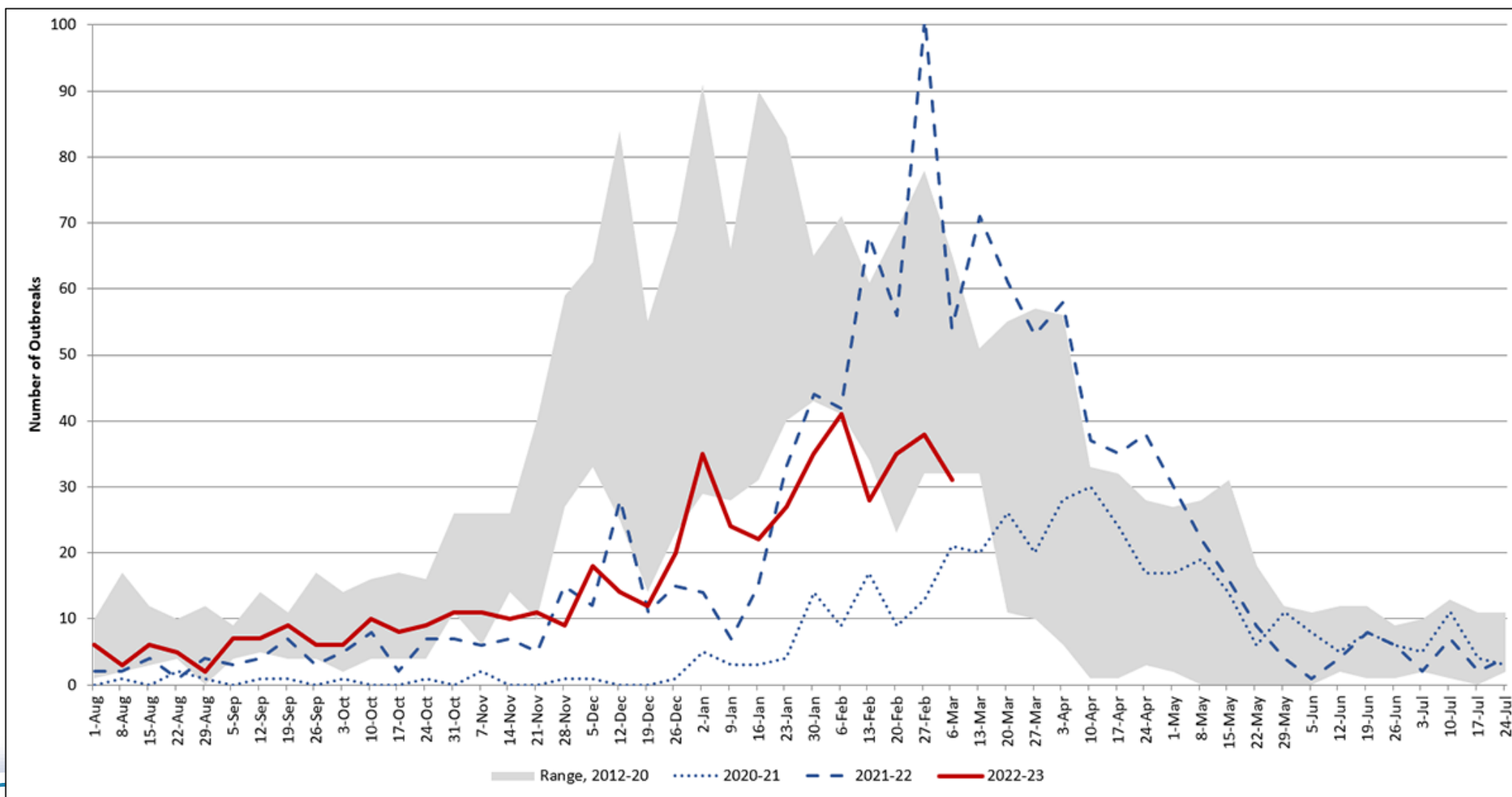


- Disease Characteristics
 - Causes vomiting (hallmark symptom), diarrhea, abdominal cramping, and nausea
 - Onset is 12-48h, duration 12-60h
 - Asymptomatic viral shedding is common
- Disease Burden
- Transmission Routes
 - Person to Person, fomites, contaminated food/water



1 Emerg Infect Dis. 2013 Aug; 19(8): 1198-1205.

Number of Suspected or Confirmed Norovirus Outbreaks Reported by NoroSTAT-Participating States Per Week, 2012-2023



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The Journal of Infectious Diseases

BRIEF REPORT

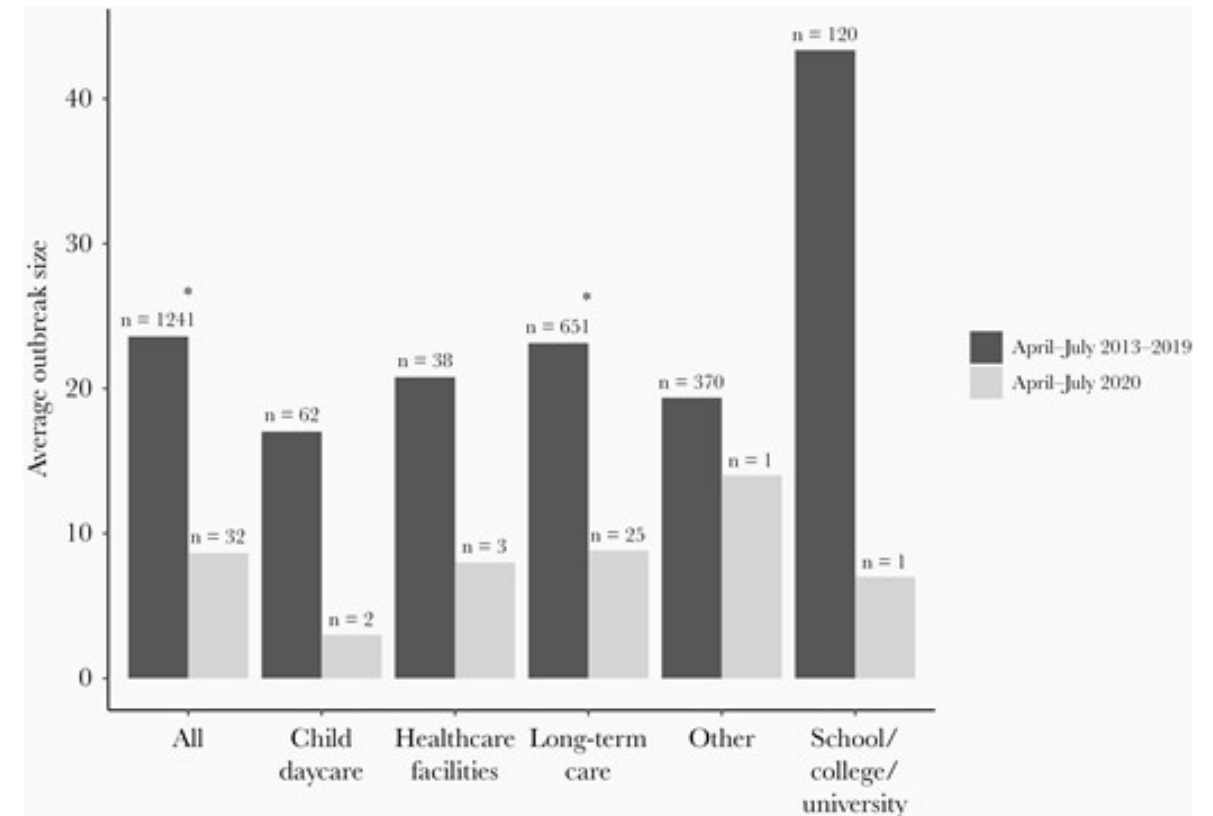
Impact of Nonpharmaceutical Interventions for Severe Acute Respiratory Syndrome Coronavirus 2 on Norovirus Outbreaks: An Analysis of Outbreaks Reported By 9 US States

Alicia N. M. Kraay,^{1,✉} Peichun Han,¹ Anita K. Kambhampati,² Mary E. Wikswo,² Sara A. Mirza,² and Benjamin A. Lopman¹

¹Epidemiology Department, Rollins School of Public Health, Emory University, Atlanta, Georgia, USA; and ²Division of Viral Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia, USA

The Journal of Infectious Diseases, Volume 224, Issue 1, 1 July 2021, Pages 9–13, <https://doi.org/10.1093/infdis/jiab093>

Figure 2.



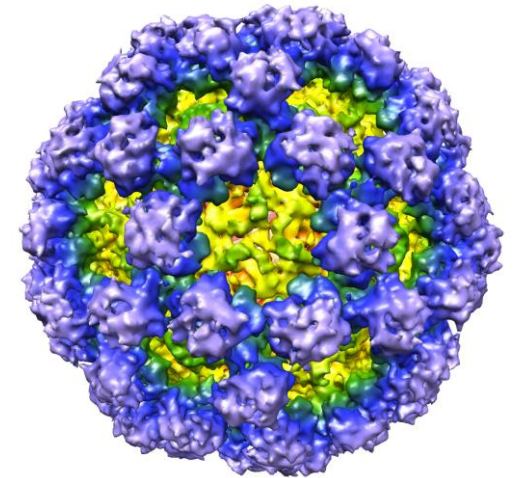
Control measures associated with COVID-19 control impacted norovirus outbreak size during the pandemic

Noroviruses: The Perfect Human Pathogens?



Aron J. Hall Division of Viral Diseases, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia

- Low infectious dose (18 – 1,000 particles)
- Rapid and prolific shed in vomitus and feces
- Prolonged shedding of asymptomatic individuals
- Viral evolution
- Short term immunity
- Resistance to physical stressors and persistence on surfaces/objects

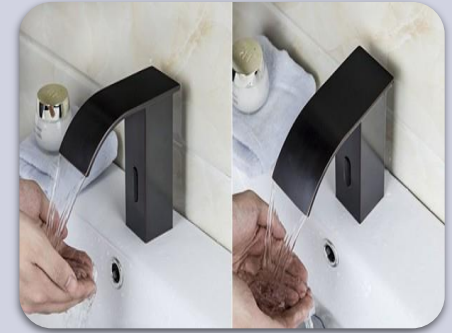


Aron J. Hall

J Infect Dis (2012) 205 (11): 1622-1624

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REDUCING NOROVIRUS IN RESTAURANTS



Exclusion from work of symptomatic food employee

Full Compliance: 75% reduction
No Exclusion: 226% increase

Efficient Hand Washing
58% reduction

Handwashing frequency associated with gloving compliance
62% reduction

Elimination of contact between hands, faucets, doors handles
75% reduction

[Risk Analysis](#). 2017 Nov;37(11):2080-2106

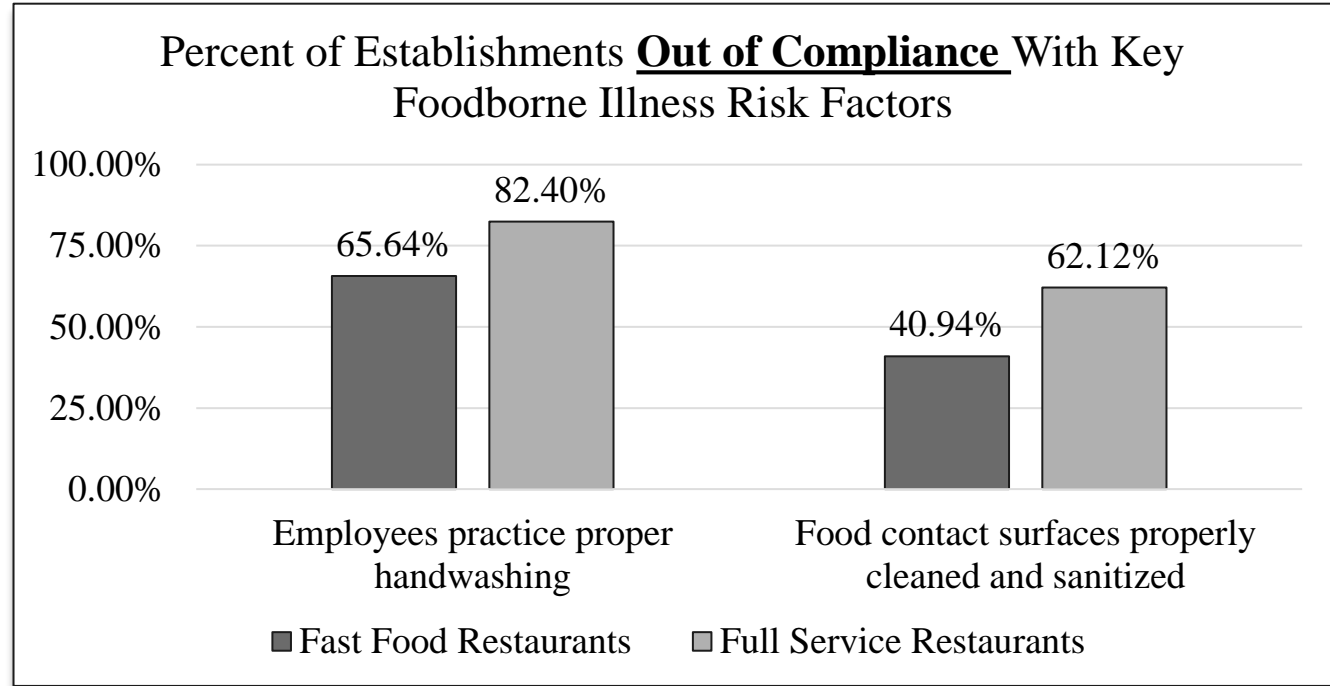
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FOODBORNE ILLNESS RISK FACTORS



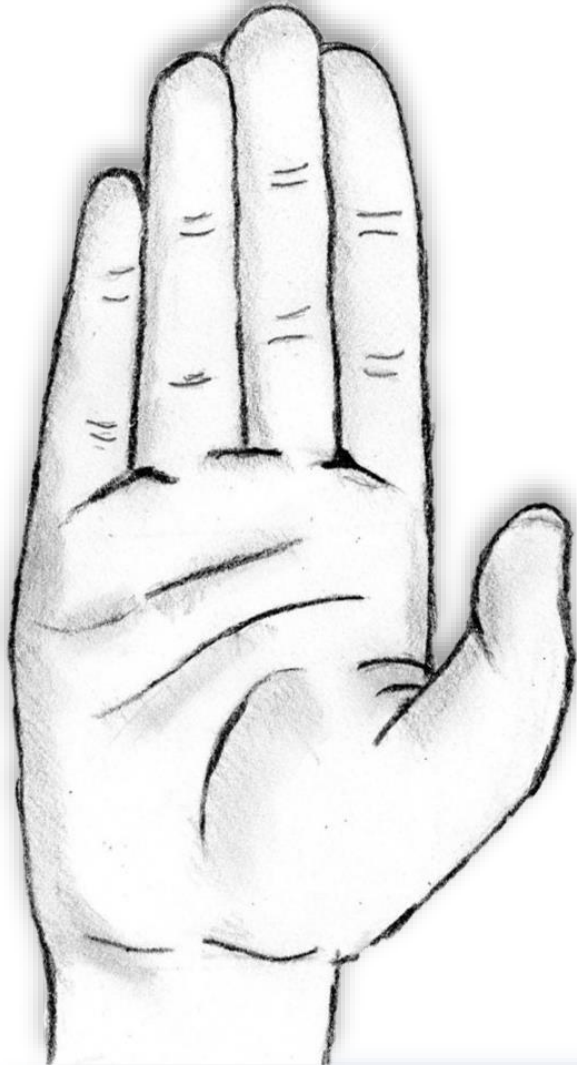
- The CDC identifies 5 major risk factors contributing to foodborne illness outbreaks:

- Poor personal hygiene
- Food from unsafe sources
- Improper cooking
- Improper holding (time/temperature)
- Contaminated equipment



Most recent (2013-2014) results from FDA's 10-year risk factor study, representing 425 Fast Food Restaurants and 396 Full-Service Restaurants. Available at <https://www.fda.gov/media/117509/download>

PATHOGENS SURVIVE ON SKIN



| Pathogen | Duration of Persistence |
|------------------------------|-------------------------|
| <i>Norovirus</i> | Up to 2 hours |
| <i>Hepatitis A</i> | 5.50 to 7.70 hours |
| <i>Influenza A</i> | 1/2 hour to 1 hour |
| <i>Escherichia coli</i> | Up to 1 ½ hour |
| <i>Klebsiella pneumoniae</i> | Up to 1 ½ hour |
| <i>Shigella</i> | Up to 3 hours |
| <i>Serratia marcescens</i> | Up to 1 ½ hour |
| <i>Staphylococcus aureus</i> | Up to 1 ½ hour |

PATHOGENS SURVIVE ON SURFACES

| Type of Pathogen | Duration of Persistence |
|--|-------------------------|
| <i>Escherichia coli</i> | 1.5 hours - 16 months |
| Norovirus | 4 - 6 weeks |
| <i>Hepatitis A</i> | 3 weeks |
| <i>Listeria spp.</i> | 1 day - months |
| <i>Salmonella typhi</i> | 6 hours - 4 weeks |
| <i>Staphylococcus aureus, incl. MRSA</i> | 7 days - 7 months |
| <i>Shigella</i> | 2 - 28 days |
| <i>Campylobacter</i> | 1- 4 hours |



NOROVIRUS SURROGATES



Slide courtesy of Lee-Ann Jaykus

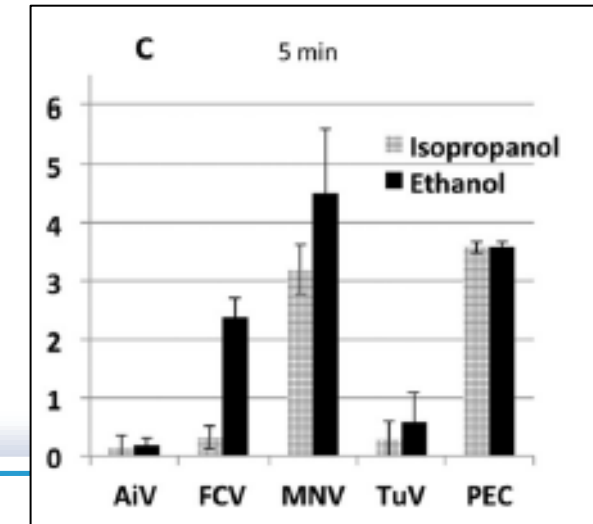
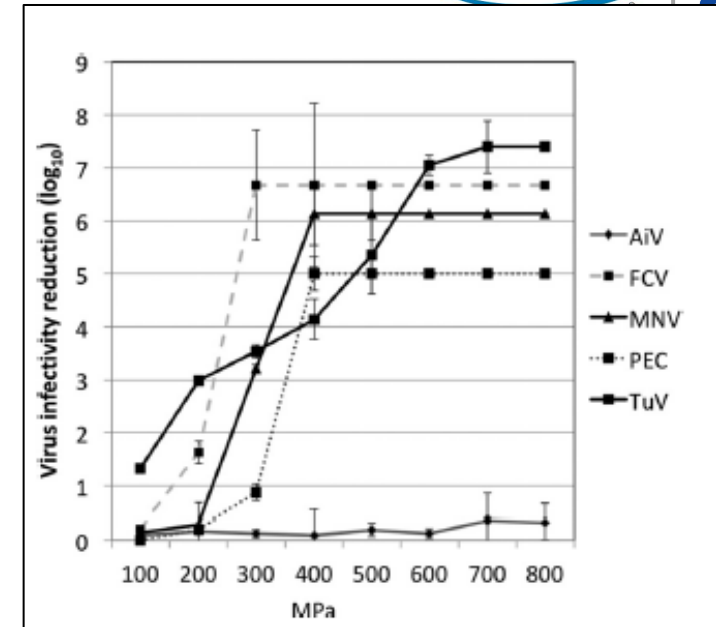
- Historically, Norovirus has been difficult / impossible to culture, making research difficult
- PCR methods and surrogate viruses used to approximate infectivity, but have limitations
- Takeaway:** Data on human norovirus is ideal as surrogate viruses behave differently

TABLE 1 Chlorine treatment of surrogate viruses dried on stainless steel discs

| Chlorine concn (ppm) | Log ₁₀ reduction in infectivity ^a for: | | | | |
|----------------------|--|-----------|-----------|-----------|-----------|
| | AiV | FCV | MNV | PEC | TuV |
| 200 | 0.9 ± 0.2 | 0.2 ± 0.7 | 0.1 ± 0.7 | 0.4 ± 0.1 | 0.3 ± 0.1 |
| 1,000 | 1.3 ± 0.9 | 5.3 ± 0.7 | 1.4 ± 0.4 | 1.2 ± 0.5 | 1.2 ± 0.2 |

^a Values are means for 4 or more replicates from 2 separate experiments ± standard deviations.

From: Cromeans et al., *App. Environ. Microbiol.*, 2014.

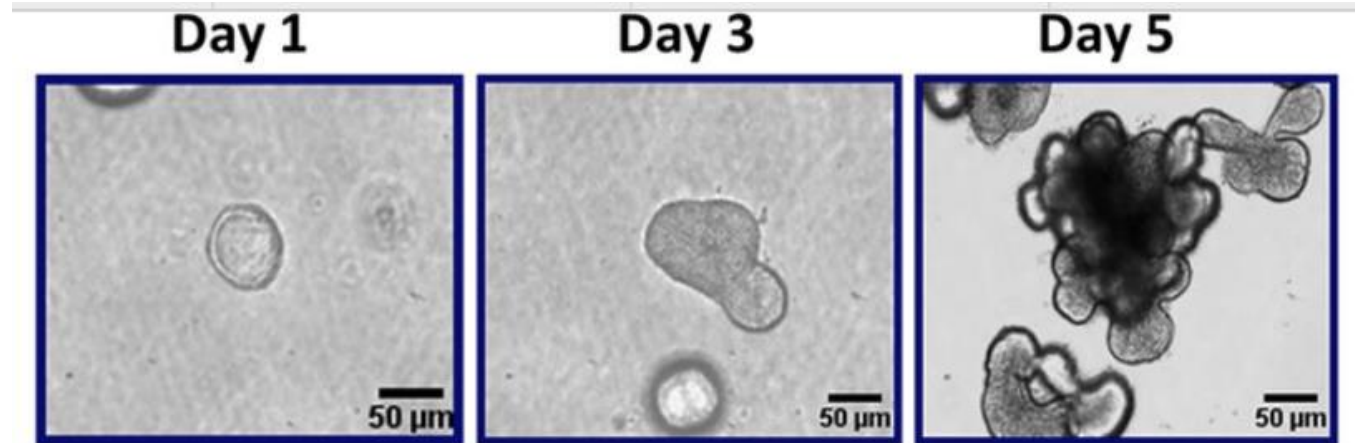


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NOROVIRUS CULTURE SYSTEM

- Culture system developed in 2016
- Fold-change in viral RNA measured over time by RT-qPCR
- Difficult to use, but a significant step forward to help our understanding of this virus



J. Virol. January 2016 vol. 90 no. 1 43-56

GOJO RESEARCH UPDATES

Recent Research Efforts at GOJO



Myth 1: All Hand Sanitizers Are the Same

As long as the hand sanitizer has 60% alcohol, it will be effective



The brand of hand sanitizer I use isn't really important, is it?



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NEWS OUTLETS HAVE HIGHLIGHTED QUALITY AND SAFETY CONCERNS WITH HAND SANITIZERS



valisure
 March 24, 2021
 Division of Dockets Management
 Food and Drug Administration
 5630 Fishers Lane, Room 1061
 Rockville, MD 20852

Re: Valisure Citizen Petition on Hand Sanitizer Products Containing Benzene Contamination and Other Significant Issues

Dear Sir or Madam:

The undersigned, on behalf of Valisure LLC ("Valisure" or "Petitioner"), submits this Citizen Petition ("Petition") pursuant to Sections 301(21 U.S.C. § 331), 501 (21 U.S.C. § 351), 502 (21 U.S.C. § 352), 505 (21 U.S.C. § 355), 702 (21 U.S.C. § 372), 704 (21 U.S.C. § 374), and 705 (21 U.S.C. § 375) of the Federal Food, Drug and Cosmetic Act (the "FDCA"), in accordance with 21 C.F.R. 10.20 and 10.30, to request the Commissioner of Food and Drugs ("Commissioner") to issue a regulation, request recalls, revise industry guidance, and take such other actions set forth below.

A. Action Requested

Hand sanitizers are considered drugs that are regulated by the U.S. Food and Drug Administration ("FDA"). Valisure has tested and detected high levels of benzene and other contaminants in specific batches of hand sanitizer products containing active pharmaceutical ingredients of ethanol and isopropanol. The Centers for Disease Control and Prevention ("CDC") states that the Department of Health and Human Services has determined that benzene causes cancer in humans.¹ The World Health Organization ("WHO") and the International Agency for

Menu Search **Bloomberg**

Prognosis
Carcinogen Found in Hand Sanitizers That Plugged Covid Gap

CBS NEWS | March 29, 2021, 7:34 AM

Study finds carcinogen above FDA limit in several hand sanitizer brands

USA TODAY

Carcinogen found in 44 hand sanitizer brands introduced during pandemic

MONEY

FDA issues alert about methanol-contaminated hand sanitizer imported from Mexico

Nathan Bomey USA TODAY
 Published 3:11 p.m. ET Jan. 26, 2021

BECKER'S

HOSPITAL REVIEW

CONSUMER

FDA places alert on hand sanitizers over 'toxic ingredients' – see list of sanitizers to avoid

f t w i e +



THE HILL

Dangerous hand sanitizers need immediate FDA attention

BY STEVE POCIASK AND KRISZTINA PUSOK, OPINION CONTRIBUTORS — 07/08/21 10:00 AM EDT
 THE VIEWS EXPRESSED BY CONTRIBUTORS ARE THEIR OWN AND NOT THE VIEW OF THE HILL

295 SHARES

f SHARE t TWEET

Just In...

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QUESTIONABLE PRACTICES EMERGE – REFILLABLE HAND SANITIZER

- While struggling to find refills from trusted brands like PURELL®, many end users begin to refill existing dispensers and bottles with off-brand products
- According to a recent GOJO survey, this practice became widespread during the pandemic:
 - 61% of end users report refilling bulk dispensers
 - 81% of end users report refilling bottles

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Use of bulk ABHS dispensers in US community settings has major risks



Unknown Product

- **70%** lacked compliant labeling including Drug Facts, Manufacturer, Lot, Expiry Date
- **15%** contained visible impurities

Exposure to Potentially Dangerous Impurities

- **30%** contained Acetal and Acetaldehyde in excess of FDA guidelines
- **6%** contained Methanol in excess of FDA guidelines

Compromised Efficacy

- **9%** of samples from community settings contained < 60% alcohol

Bulk dispenser design itself and/or its misuse (including failure to seal the reservoir) may lead to alcohol evaporation

PLOS ONE

OPEN ACCESS PEER-REVIEWED

RESEARCH ARTICLE

Presence of unsafe chemical impurities, accelerated evaporation of alcohol, and lack of key labeling requirements are risks and concerns for some alcohol-based hand sanitizers and dispenser practices during the COVID-19 pandemic

Clyde S. Manuel, Dawn J. Yeomans, Jessica A. Williams, Christopher Fricker, Kaury Kucera, David Light, James W. Arbogast

Published: March 18, 2022 • <https://doi.org/10.1371/journal.pone.0265519>



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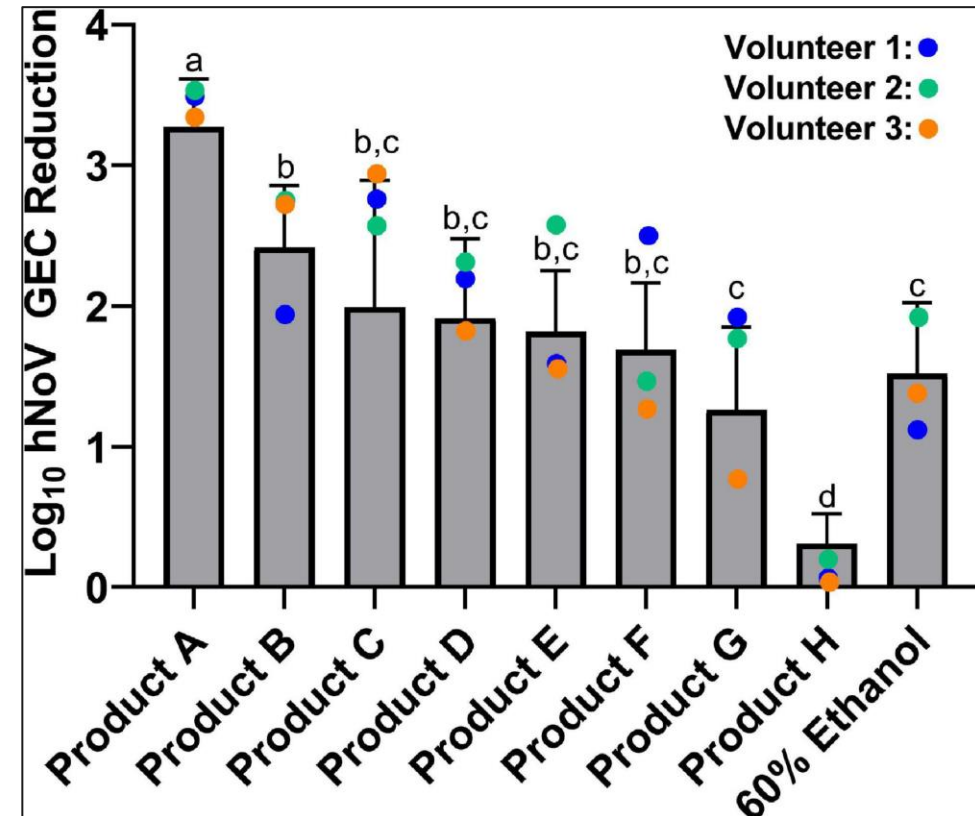
EFFICACY VARIES BY PRODUCT FORMULATION

Comparative Assessment of the Efficacy of Commercial Hand Sanitizers Against Human Norovirus Evaluated by an *in vivo* Fingerpad Method

Blanca I. Escudero-Abarca¹, Rebecca M. Goulter^{1*}, Clyde S. Manuel², Rachel A. Leslie², Kristen Green², James W. Arbogast² and Lee-Ann Jaykus¹

¹ Department of Food, Bioprocessing and Nutrition Sciences, North Carolina State University, Raleigh, NC, United States, ² GOJO Industries, Inc., Akron, OH, United States

Front. Microbiol., 07 April 2022 | <https://doi.org/10.3389/fmicb.2022.869087>



Recent Research Efforts at GOJO



Myth 2: Alcohol doesn't work against norovirus

I should probably use chlorine if I want to inactivate norovirus



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[BY-NC](#)

EFFICACY VARIES BY PRODUCT FORMULATION

ORIGINAL ARTICLE Journal of Applied Microbiology **sam**

Efficacy of an alcohol-based surface disinfectant formulation against human norovirus

Blanca I. Escudero-Abarca¹ | Rebecca M. Goulter¹ | Justin Bradshaw^{1,2} | Jeremy Faircloth¹ | Rachel A. Leslie³ | Clyde S. Manuel³ | James W. Arbogast³ | Lee-Ann Jaykus¹

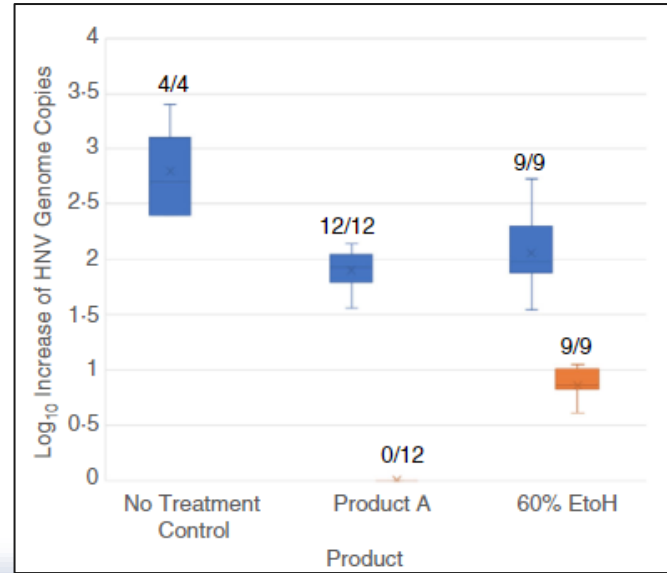
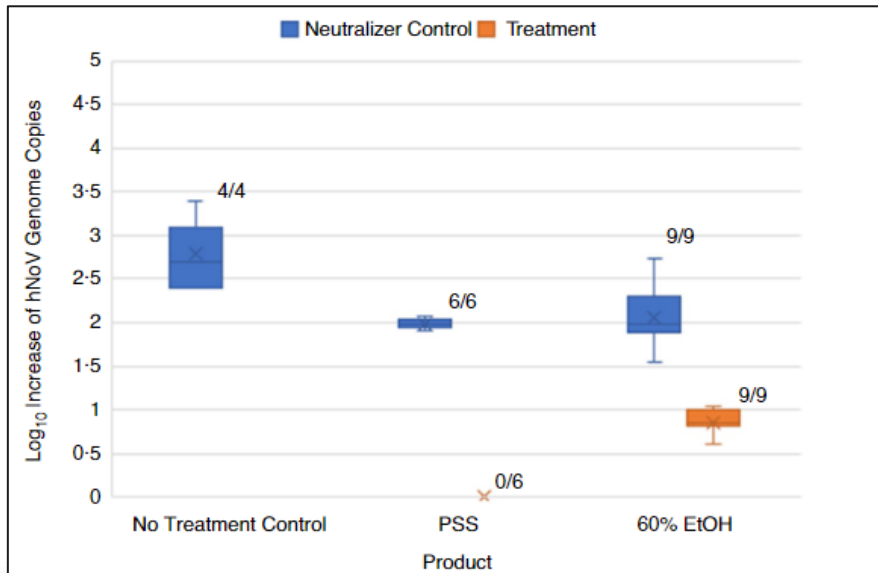
Letters in Applied Microbiology **sam**
Letters in Applied Microbiology ISSN 0266-8254

ORIGINAL ARTICLE

Efficacy of alcohol-based hand sanitizers against human norovirus using RNase-RT-qPCR with validation by human intestinal enteroid replication

B.I. Escudero-Abarca¹, R.M. Goulter¹, J.W. Arbogast², R.A. Leslie², K. Green² and L.-A. Jaykus¹

¹ Department of Food Bioprocessing and Nutrition Sciences, North Carolina State University, Raleigh, NC, USA
² GOJO Industries Inc, Akron, OH, USA



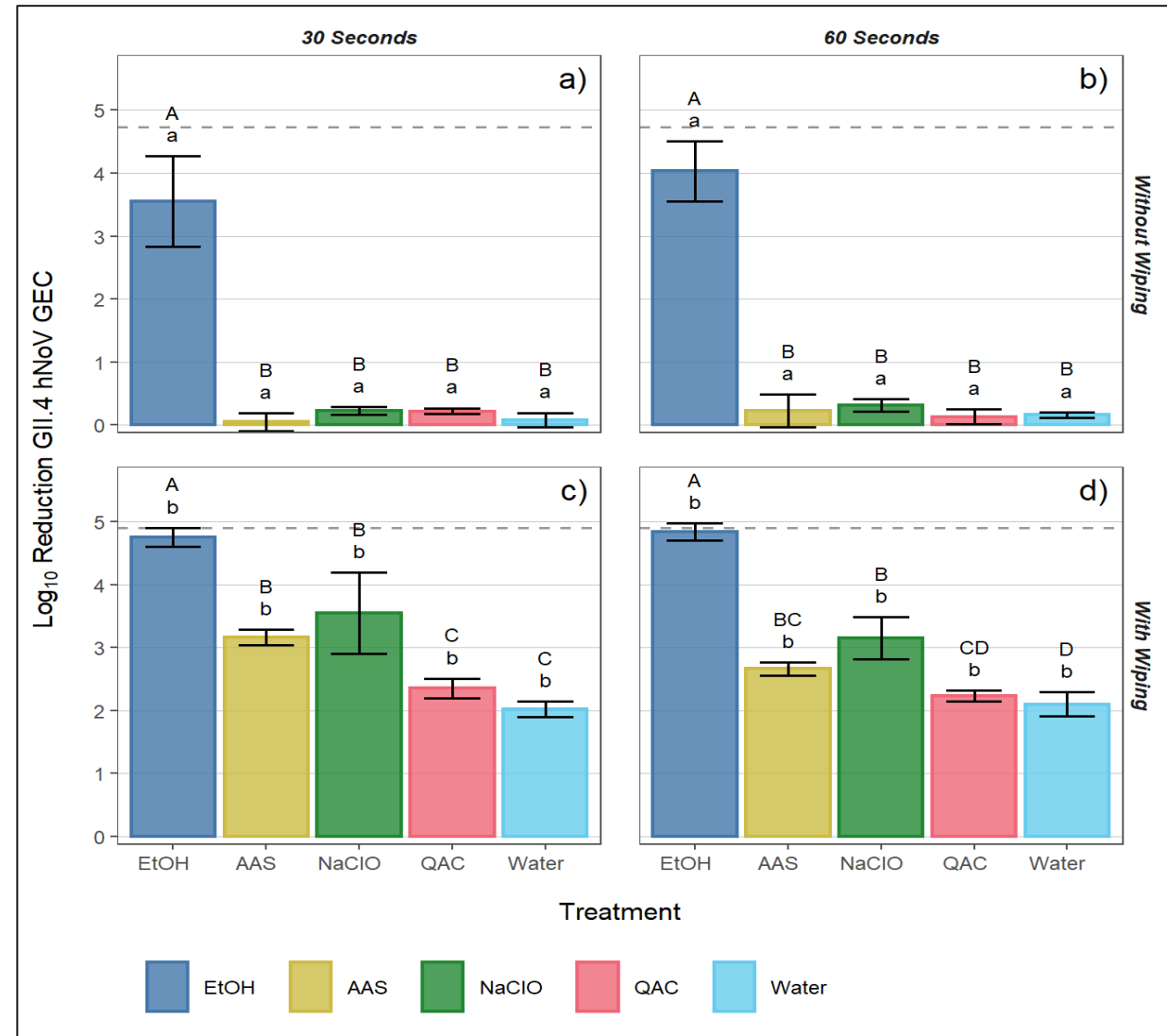
J Appl Microbiol 2022 Feb 8. doi: 10.1111/jam.15479.

Lett Appl Microbiol 2020 Dec;71(6):605-610. doi: 10.1111/lam.13393

EFFICACY VARIES BY PRODUCT FORMULATION

- Recent research shows not all surface sanitizers are created equal
- Wiping has an additional impact on product efficacy (~2 log increase via removal)

Efficacy of Disinfectants Against Human Norovirus on Food Contact Surfaces. Presented at IAFP 2021, Phoenix AZ.



Recent Research Efforts at GOJO



Myth 3: Handwashing with soap and water is better than hand sanitizer

Is handwashing with soap and water better at removing germs from hands than using hand sanitizer?



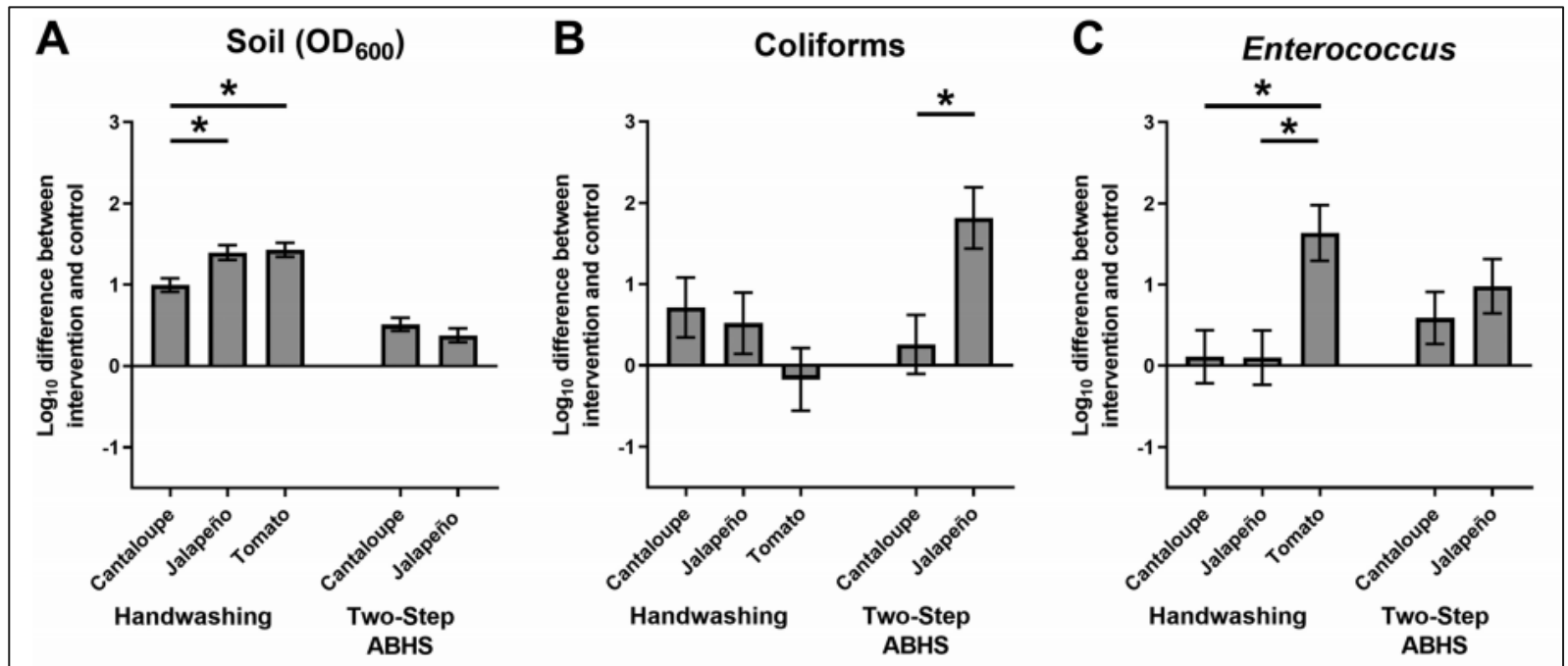
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Both Handwashing and an Alcohol-Based Hand Sanitizer Intervention Reduce Soil and Microbial Contamination on Farmworker Hands during Harvest, but Produce Type Matters

Jessica L. Prince-Guerra,^a Molly E. Nace,^b Robert H. Lyles,^c Anna M. Fabiszewski de Aceituno,^a Faith E. Bartz,^{a*} James W. Arbogast,^d Jennifer Gentry-Shields,^{e*} Lee-Ann Jaykus,^e Norma Heredia,^f Santos García,^f Juan S. Leon^{a,b}



Photos from a previous study, but illustrative of hand conditions after produce harvesting
Journal of Food Protection, Vol. 78, No. 11, 2015, Pages 2024–2032



[Appl Environ Microbiol.](#) 2020 Sep; 86(18): e00780-20.

Recent Research Efforts at GOJO

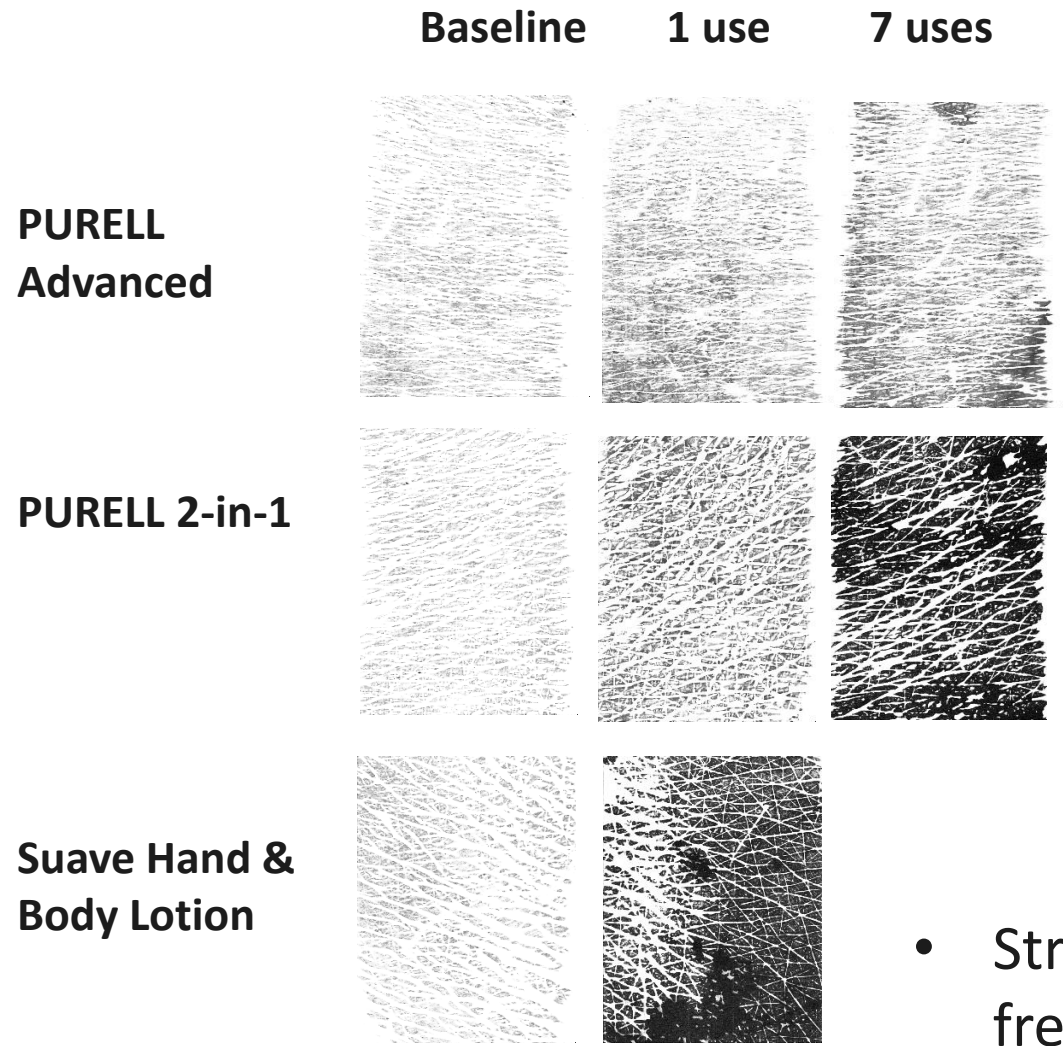


Myth 4: Hand sanitizer
dries out hands more
than soap and water

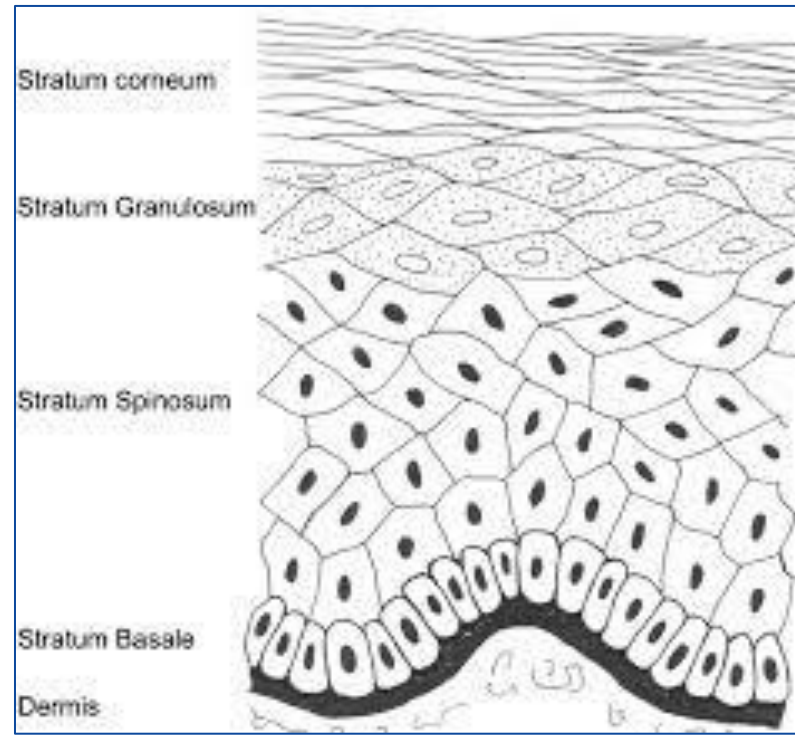
Alcohol just dries out
hands, right?



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Darker = More hydrated



- Stratum corneum layer can be stripped away with frequent handwash
- Well formulated hand sanitizer use can prevent this
- Caveat* - not all hand sanitizers are the same!

CLOSING THOUGHTS AND KEY TAKEAWAYS

KEY TAKEAWAYS AND CLOSING THOUGHTS



- Hand and surface hygiene remain critical for public health – especially for foodborne illnesses like norovirus
- Product formulation matters for both hand and surface products – efficacy and aesthetics can differ widely, which impacts performance and compliance.
- Creating a culture that emphasizes and understands the importance of food safety is crucial for success and has been shown to reduce foodborne illness risk.

THANK YOU FOR YOUR TIME

PLEASE E-MAIL ME WITH ANY
QUESTIONS OR COMMENTS!

Contact Information:

- ManuelC@GOJO.com



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