

**Conference for Food Protection
2020 Issue Form**

Issue: 2020 III-036

Council Recommendation:	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
Delegate Action:	Accepted _____	Rejected _____	

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Issue History:

This is a brand new Issue.

Late Breaking Issue Title:

Amend Food Code – Define & outline DISINFECTION, modify SANITIZATION definition.

Late Breaking Issue you would like the Conference to consider:

Retail and foodservice workers are frequently tasked with sanitizing surfaces. Sanitizers, a type of antimicrobial pesticide, are delineated by the U.S. Environmental Protection Agency based on its intended use. For example, food-contact surface sanitizers are intended to control bacterial contamination on pre-cleaned surfaces. Because of this, sanitizer efficacy tests focus on their effect against pathogenic bacteria and not viruses and fungi, whereas disinfectant tests can evaluate a products efficacy all three categories.

The ongoing COVID-19 pandemic has highlighted the limitations of sanitizer usage in retail and foodservice establishments, given that SARS-CoV-2, the etiological agent for COVID-19, is a respiratory virus. Viruses are controlled using disinfectants not sanitizers. Because of COVID-19, disinfectant use has increased in retail and foodservice settings. Increased use of disinfectants by food handlers not familiar with their intended use can result in misuse. For example, using a disinfectant as a sanitizer on a food-contact surface, without the required subsequent rinsing, can result in unsafe levels of chemical compounds being introduced into food prepared on the disinfected surface. To complicate this matter, there are now no-rinse, food-contact surface disinfectants available. The retail/foodservice industry will need to begin training their workers on the difference between “no-rinse” versus “must rinse” disinfectants on food-contact surfaces. In addition, if a sanitizer is used as a disinfectant, viruses, such as noroviruses or SARS-CoV-2, might not be eliminated as sanitizer efficacy is only tested against pathogenic bacteria not viruses. These misuse scenarios illustrate the importance from a public health perspective of addressing both sanitizers and disinfectants in the Food Code.

COVID-19 has shed a light on the retail and foodservice industry’s misunderstanding of sanitization and disinfection. The 2017 Food Code does not define disinfection or outline disinfection requirements. In fact, the terms sanitization and disinfection are misused in Annex 3 5-304.11 System Flushing and Disinfection. In this section the Code requires users to flush and sanitize systems when the title indicates disinfection is required. It is unclear which act should be undertaken, disinfection or sanitization? Moreover, sanitization is defined in Chapter 1 and outlined in Section 4-7. However, the definition of sanitization needs to be modified as it states

“microorganisms” not “bacteria” creating confusion. As already stated, efficacy tests for sanitizers are only performed against pathogenic bacteria, not other microorganisms (e.g., viruses, fungi, and parasites). Furthermore, disinfection requirements are not addressed in the regulatory provisions (Chapters 1-8) but are mentioned in Annex 3 (2-501.11 -- vomit/diarrhea clean up; 5-101.12 and 5-304.11 -- system flushing and disinfection; and 4-204.110 -- filtering and disinfection of molluscan shellfish tanks).

To address these problems, we suggest four broad modifications to the Code: (1) modifying the definition of sanitization to reflect sanitizers are only efficacious against pathogenic bacteria; (2) defining disinfection in Chapter 1; (3) outlining disinfection requirements in Chapter 4. Addressing these in the regulatory provisions (i.e., Chapters 1-8) and not just in Annex 3 could minimize their misuse by shedding light on their important differences; (4) update Chapter 7 to reflect the addition of disinfectant and their criteria.

Public Health Significance:

The FDA Food Code sets standards for retail and foodservice establishments to prevent the transmission of etiologic agents that cause foodborne disease. These standards are not intended to prevent the spread of respiratory illnesses. In addition, the Code mainly focuses on control measures for the back-of-the-house (e.g., kitchen, storerooms, etc.) only broadly mentioning the front-of-the-house (e.g., dining rooms and bathrooms). For example, in 6-501, the Code states physical facilities (i.e., the structure and interior surfaces of the establishment) shall be cleaned as often as necessary to keep them clean with no mention of subsequent sanitizing or disinfection of the “cleaned” surface. It is well known that cleaning alone will not sufficiently remove, kill, or inactivate microorganisms. Moreover, the Code only requires food-contact surfaces be cleaned and sanitized; non-food contact surfaces only need to be cleaned. Implementation of current regulatory standards might not effectively prevent the spread of viruses, such as norovirus and SARS-CoV-2. Government guidance documents prepared in response to the COVID-19 pandemic address this problem by stating food handlers should frequently clean and “disinfect” high-touch surfaces. High-touch surfaces within retail and foodservice establishments are often nonfood-contact surfaces (e.g., door handles, dining tables/chairs, and touchscreen ordering devices) so per the Code only need to be cleaned. In addition, some high-touch surfaces are also food-contact surfaces so are typically sanitized not disinfected. The 2017 Food Code describes cleaning, including reference to the type of surface that needs to be cleaned and sanitized, but does not define or mention disinfection within the regulatory provisions (Chapters 1-8).

Preventing the introduction of human noroviruses continues to challenge retail and foodservice operations. Current regulatory standards focus on exclusion of infected food workers and hand hygiene compliance. However, noroviruses can also be present on surfaces under outbreak and non-outbreak conditions (Leone et al, 2018; Cheesborough et al, 2000). An FDA led quantitative risk assessment of norovirus transmission in food establishments suggests cleaning and disinfection within foodservice establishments should be part of a norovirus mitigation strategy (Duret et al, 2017) as disinfectants not sanitizers, are proven to eliminate viruses, such as human noroviruses.

COVID-19 has also highlighted the importance of proper cleaning, sanitizing, and disinfecting in retail and foodservice settings. While to date no evidence is available to suggest SARS-CoV-2 is transmitted by food, concern about its spread in retail and foodservice establishments has changed retail and foodservice sanitation protocols. As a result, misuse of sanitizers and disinfectants is possible. For example, there was a 20.4% increase in chemical poison control calls between January and March 2020 compared to the same time period in 2019 (Chang et al. 2020).

Sanitizers and disinfectants are both critical tools that can make food and food settings safer. But, there are risks associated with their use. These risks can be mitigated with education and messaging. Part of the education and messaging is informed by the FDA Food Code. The EPA has jurisdiction of antimicrobial pesticides but the retail and foodservice industry uses the Food Code for guidance and direction.

Recommended Solution: The Conference recommends...:

a letter be sent to FDA requesting that Section 1-2 of the most current edition of the Food Code be amended as follows (added language underlined and italicized):

"Disinfection" *means the application of cumulative heat, chemicals, or other means on a cleaned food contact surface or other hard, non-porous surfaces that, when evaluated for efficacy, destroys or irreversibly inactivates bacteria, fungi and viruses in accordance with EPA Product Performance Test Guidelines.*

"Poisonous or toxic materials" means substances that are not intended for ingestion and are included in 4 categories:

- (1) Cleaners ~~and~~ **SANITIZERS**, and DISINFECTANTS, which include cleaning and SANITIZING agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;
- (2) Pesticides, except **SANITIZERS** and DISINFECTANTS, which include substances such as insecticides and rodenticides;

"Sanitization" means the application of cumulative heat or chemicals on cleaned FOOD-CONTACT SURFACES that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease=~~microorganisms~~ causing bacteria of public health importance.

A letter be sent to FDA requesting that Section 4-7 of the most current edition of the Food Code be amended as follows (added language underlined and italicized):

4-7 SANITIZATION AND DISINFECTION OF EQUIPMENT AND UTENSILS

4-701.11 EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be disinfected, if necessary, to control non-bacterial pathogens.

4-702.11 UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT shall be SANITIZED before use after cleaning or after DISINFECTING except if the EPA approved use directions allows the disinfectant to be used under no rinse conditions.

4-703.11 Hot Water and Chemical SANITIZATION and DISINFECTION.

After being cleaned or DISINFECTED, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED in:

Insertion of:

4-703.12 DISINFECTION after Blood or Body Fluid Contamination or when inactivating viruses or fungi on hard non, porous surfaces

After being cleaned, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be disinfected prior to SANITIZATION by Applied according to the EPA-registered label use instructions.

Contact times shall be consistent with those on EPA-registered label use instructions
Rinsed in accordance with 4-603.16 prior to SANITIZATION
Those surface not considered a FOOD-CONTACT SURFACE do not require a rinse.

A letter be sent to FDA requesting that 7-1 of the most current edition of the Food Code be amended as follows (added language underlined and italicized):

7-102.11 Common Name

Working containers used for storing POISONOUS OR TOXIC MATERIALS such as cleaners and SANITIZERS, and DISINFECTANTS taken from bulk supplies shall be clearly and individually identified with the common name of the material.

Insertion of the following between 7-204.11 and 7-204.12

Disinfectant, Criteria

DISINFECTANTS shall:

(A) Meet the requirements to be listed on Environmental Protection Agency's List G: EPA's Registered Antimicrobial products Effective Against Norovirus.

(B) Meet the requirements to be listed on

Environmental Protection Agency's List C: EPA's Registered Antimicrobial products Effective Against Human HIV-1 virus.

Environmental Protection Agency's List E: EPA's Registered Antimicrobial products Effective Against Human HIV-1 and Hepatitis B virus.

Environmental Protection Agency's List F: EPA's Registered Antimicrobial products Effective Against Human Hepatitis C virus.

A letter be sent to FDA requesting that Annex 3, 2-501.11 Clean-up of Vomiting and Diarrheal Events of the most current edition of the Food Code be amended as follows (added language underlined and italicized):

Effective clean up of vomitus and fecal matter in a food establishment should be handled differently from routine cleaning procedures. It should involve a more stringent cleaning and ~~disinfecting~~ DISINFECTING process. Some compounds that are routinely used for sanitizing food-contact surfaces and other non-food contact surfaces ~~disinfecting countertops and floors, such as certain quaternary ammonium compounds,~~ may not be effective against Norovirus. It is therefore important that food establishments have procedures for the cleaning and disinfection of vomitus and/or diarrheal contamination events that address, among other items, the use of proper disinfectants at the proper concentration. Disinfectants should appear of the Environmental Protection Agency's List G: EPA's Registered Antimicrobial products Effective Against Norovirus.

Attachments:

Content Documents: (documents requiring Council review; approval or acknowledgement is requested in the recommended solution above)

n/a

Supporting Attachments: (documents submitted to provide background information to Council)

- Leone, Cortney M., et al. "Prevalence of human noroviruses in commercial food establishment bathrooms." *Journal of food protection* 81.5 (2018): 719-728.
- Cheesbrough, J. S., et al. "Widespread environmental contamination with Norwalk-like viruses (NLV) detected in a prolonged hotel outbreak of gastroenteritis." *Epidemiology & Infection* 125.1 (2000): 93-98.
- Duret, Steven, et al. "Quantitative risk assessment of norovirus transmission in food establishments: Evaluating the impact of intervention strategies and food employee

behavior on the risk associated with norovirus in foods." *Risk Analysis* 37.11 (2017): 2080-2106.

- Chang, Arthur, et al. "Cleaning and disinfectant chemical exposures and temporal associations with COVID-19—national poison data system, United States, January 1, 2020–March 31, 2020." *Morbidity and Mortality Weekly Report* 69.16 (2020): 496.
- Fraser, Angela M., et al. "Sanitizers and Disinfectants: A Retail Food and Foodservice Perspective." *Food Protection Trends* 41.3 (2021): 358-367.

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Research Paper

Prevalence of Human Noroviruses in Commercial Food Establishment Bathrooms

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ABSTRACT

Although transmission of human norovirus in food establishments is commonly attributed to consumption of contaminated food, transmission via contaminated environmental surfaces, such as those in bathrooms, may also play a role. Our aim was to determine the prevalence of human norovirus on bathroom surfaces in commercial food establishments in New Jersey, Ohio, and South Carolina under nonoutbreak conditions and to determine characteristics associated with the presence of human norovirus. Food establishments (751) were randomly selected from nine counties in each state. Four surfaces (underside of toilet seat, flush handle of toilet, inner door handle of stall or outer door, and sink faucet handle) were swabbed in male and female bathrooms using premoistened macrofoam swabs. A checklist was used to collect information about the characteristics, materials, and mechanisms of objects in bathrooms. In total, 61 (1.5%) of 4,163 swabs tested were presumptively positive for human norovirus, 9 of which were confirmed by sequencing. Some factors associated with the presence of human norovirus included being from South Carolina (odd ratio [OR], 2.4; 95% confidence interval [CI], 1.2 to 4.9; $P < 0.05$) or New Jersey (OR, 1.7; 95% CI, 0.9 to 3.3; $0.05 < P < 0.10$), being a chain establishment (OR, 1.9; 95% CI, 1.1 to 3.3; $P < 0.05$), being a unisex bathroom (versus male: OR, 2.0; 95% CI, 0.9 to 4.1; $0.05 < P < 0.10$; versus female: OR, 2.6; 95% CI, 1.2 to 5.7; $P < 0.05$), having a touchless outer door handle (OR, 3.3; 95% CI, 0.79 to 13.63; $0.05 < P < 0.10$), and having an automatic flush toilet (OR, 2.5, 95% CI, 1.1 to 5.3; $0.05 < P < 0.10$). Our findings confirm that the presence of human norovirus on bathroom surfaces in commercial food establishments under nonoutbreak conditions is a rare event. Therefore, routine environmental monitoring for human norovirus contamination during nonoutbreak periods is not an efficient method of monitoring norovirus infection risk.

Key words: Bathrooms; Environment; Fomites; Norovirus; Restaurants; Retail food

Human noroviruses are the leading cause of acute gastroenteritis and foodborne disease in the United States, sickening between 19 and 21 million people every year (24, 49). Although human norovirus is primarily spread from person to person (69% of infection cases) or via food (23%), an increasing body of epidemiological evidence suggests that environmental surfaces also play an important role in norovirus transmission (9, 15, 19, 24, 34, 64).

The most common setting for norovirus outbreaks is long-term care facilities (60%), and the second most common setting is food establishments (22%), such as restaurants, catering, and banquet facilities. The route of transmission of norovirus in food establishments is different from that in long-term care facilities; exposure is commonly attributed to the consumption of contaminated food (48%) rather than person-to-person (24). Food often becomes contaminated through contact by an infected food worker who handles ready-to-eat foods with bare hands. Another

underrecognized route of transmission may be environmental surfaces that become contaminated via contact with contaminated hands or with vomitus or feces either directly or through settling of aerosolized particles (15, 19, 64). Contaminated environmental surfaces in shared spaces, such as bathrooms, are especially likely to be a source of norovirus.

Bathrooms in most commercial food establishments are considered shared spaces because they may be used by both customers and employees. Shared bathroom surfaces could become contaminated with norovirus particles after use by an infected individual. These contaminated surfaces could then serve as a source to spread norovirus to others in the facility, leading to an outbreak. The presence of noroviruses on shared bathroom surfaces in food establishments under both outbreak and nonoutbreak conditions have been reported (10, 11, 61). In a systematic literature review, human noroviruses were found on bathroom surfaces under outbreak ($n = 11$) and nonoutbreak ($n = 5$) conditions (36). Swab samples from high-touch surfaces such as toilet seats, toilet flush handles, sink faucet handles, and bathroom door

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handles were most likely to be positive for norovirus. Some researchers further examined the relationship between select factors and the presence of human noroviruses. Boxman et al. (10) reported that population density had a borderline significant effect on the presence of human norovirus. Verhoef et al. (61) found that small commercial food establishments were more likely than large establishments to have human norovirus on surfaces, and Boxman et al. (10) reported that the number of employees did not have a significant effect on norovirus presence. In other studies, improper cleaning and disinfecting was linked to the prevalence of human norovirus on environmental surfaces (15, 19).

The aim of the present study was to determine the presence of human noroviruses on bathroom surfaces in commercial food establishments under nonoutbreak conditions in three U.S. states representing three geographic regions: New Jersey, Ohio, and South Carolina. Our objectives were to determine (i) the presence of human noroviruses on four types of surfaces commonly found in bathrooms and (ii) the characteristics associated with the presence of human noroviruses. To our knowledge, this is the first study to monitor human noroviruses on environmental bathroom surfaces in food establishments in multiple states using power calculations to determine sample size. Our results will help researchers fine-tune current risk models and highlight the importance of proper cleaning and disinfecting procedures for commercial food establishment bathrooms and the need for training food workers on how to properly clean and disinfect bathroom surfaces.

MATERIALS AND METHODS

Statistical power calculation of sample size. The sample size was calculated using the method presented by Naing et al. (41). Expected norovirus prevalence estimates of 1, 2, and 4% were used when calculating the sample size with a 95% confidence interval (CI) and a precision of 0.05, 0.01, and 0.02, respectively. Estimates of 1 and 4% were selected based on data reported by Boxman et al. (10). The authors used 1% as their expected norovirus prevalence but observed a 4% prevalence in commercial and institutional food establishments under nonoutbreak conditions (10). We used 2% as a middle value between 1 and 4%, resulting in a calculated necessary sample size of 750.

Sample distribution. The 750 sites included in this study were commercial food establishments distributed proportionately across three states in the United States—New Jersey, Ohio, and South Carolina—according to the number of food establishments per state. Commercial establishments were chosen because bathrooms in these types of facilities are generally spaces open to the public, and no special permission was required to gain access. Proportionality was determined using the number of food establishments in each state as reported by the National Restaurant Association in fall 2012 (<http://www.restaurant.org>). Of the 750 food service establishments, 38% (285) were in New Jersey, 46% (345) were in Ohio, and 16% (120) were in South Carolina.

Sample site selection. Nine counties in each state were selected to make visiting food establishments more efficient. All counties in each state were classified by population density into categories of high, medium, and low population density, and three

counties were randomly selected from each category using SAS 9.3 software (SAS Institute, Cary, NC). Because the size and populations of the three selected states differed greatly, the definition of counties with high, medium, and low population densities was allowed to differ by state. Percentiles (33 and 66) were used as an objective measure to break up population density without looking for natural breaks in the data. For New Jersey, low-density counties had an average of 0 to 535 residents per square mile, medium-density counties had 536 to 1,772, and high-density counties had 1,773 to 13,883. For Ohio, low-density counties had an average of 0 to 93 residents per square mile, medium-density counties had 94 to 166, and high-density counties had 167 to 2,779. For South Carolina, low-density counties had 0 to 56 residents per square mile, medium-density counties had 57 to 147, and high-density counties had 148 to 588 (55).

A list of all food establishments in each county was obtained from the appropriate regulatory agency or agencies in each state. All lists were reviewed, and any facilities that were not commercial food establishments (e.g., schools, long-term care facilities, and country clubs) were removed. Sampling sites were chosen randomly from the final lists using SAS 9.3 and distributed proportionally based on the number of food establishments in each of the three population density categories per state. In New Jersey, approximately 50% of establishments were located in high-density counties and 25% each were in medium- and low-density counties. In Ohio and South Carolina, about 75% of food establishments were located in high-density counties, 15% were in medium-density counties, and 10% were in low-density counties. We kept our sampling sites proportional to our source populations to ensure that our samples were as representative as possible. We also oversampled by 30% for each category in the event that we were unable to take samples from a selected site (e.g., the establishment was closed or did not have a public bathroom).

After sample sites were selected, they were randomly divided into two groups. One group contained swab samples collected from both types of bathrooms, i.e., those designated as male and those designated as female. Swab samples in the other group were collected from only one type of bathroom, i.e., bathrooms designated as male or bathrooms designated as female. This approach was necessary based on limited available resources. Bathroom designations for some sites were changed to unisex when such bathroom types were encountered during sampling.

Establishments also were categorized as chain or nonchain. A chain establishment was defined as any food establishment under a single brand name with central headquarters that was 1 of at least 10 units in two or more distinct geographical locations.

Environmental surface swabbing. Swab samples were collected from the selected food establishments during two winter seasons, February to March 2013 and December 2013 to March 2014. Macrofoam swabs (Puritan Medical Products, Guilford, ME) premoistened with a solution of phosphate-buffered saline and Tween 80 (0.02%) at pH 6.5 were used to collect samples from bathroom surfaces as described previously (46).

Four swab samples were collected from each bathroom: (i) the underside of the toilet seat where it connects to the toilet bowl, (ii) the flush handle of the toilet, (iii) the inner door handle of the stall door or, when there was no stall door, the inner door handle of the outer door, and (iv) the hot water knob of the sink faucet. For irregular surfaces (i.e., door handle, flush handle of toilet, and sink faucet handle), the entire surface was swabbed. For flat surfaces such as the toilet seat, an area ca. 10 by 10 cm was swabbed. Swabs were kept in a cooler at 4°C during overnight transport to Clemson University and stored at −80°C until analysis.

TABLE 1. *Oligonucleotide primers and probes used in this study (13)*

Name	Virus target	DNA sequence (5'–3')
Cog1F	GI	CGYTGGATGCGITTYCATGA
Cog1R	GI	CTTAGACGCCATCATCATTYAC
Ring 1E	GI	FAM-TGG ACA GGR GAY CGC-MGBNFQ ^a
Cog2F	GII	CARGARBCNATGTTYAGRTGGATGAG
Cog2R	GII	TCGACGCCATCTTCATTACACA
Ring 2	GII	Cy5-TGGGAGGGCGATCGCAATCT-BHQ
MS2F	MS2	TGGCACTACCCCTCTCCGTATTACAG
MS2R	MS2	GTACGGGCGACCCACGATGAC
MS2P	MS2	HEX-CACATCGATAGATCAAGGTGCCTACAAGC-BHQ2

^a MGBNFQ, minor groove binder and nonfluorescent quencher.

A checklist was used to collect information about the characteristics, materials, and mechanisms of objects in the bathroom, including the outer door handle, stall door handle, toilet flush handle, toilet seat, sink faucet, hand washing signage, soap type, hand drying devices, and cleaning schedule. Photographs of bathrooms were taken as a reference for any data missing from the checklist. All bathroom checklists were verified against their corresponding photographs when available.

Viral RNA extraction, concentration, and purification.

Swabs were thawed at room temperature approximately 20 to 30 min prior to RNA extraction. Viral RNA was extracted directly from macrofoam swabs, with bacteriophage MS2 (ATCC 15597-B1) as an internal process control (13). UNEX lysis buffer (Microbiologics, St. Cloud, MN) was combined with an MS2 working solution prepared from ATCC 15597-B1 using *Escherichia coli* (Migula) ATCC 15597 as the host at a ratio of 600:1 (v/v), and 3 mL of this buffer mixture was added to each swab. After mixing by vortexing, excess liquid was removed by pressing the swab against the tube wall, and the swabs were removed from their tubes and discarded. After 10 min at room temperature, 2 mL of absolute ethanol was added to each tube. All liquid (ca. 4.5 mL) was transferred to a HiBind RNA Midi column (Omega Bio-tek, Norcross, GA). The Midi columns were centrifuged at $5,000 \times g$ for 5 min, washed twice with 70% ethanol, and spun dry, and 250 μ L of prewarmed (70°C) TE buffer (10 mM Tris pH 8.0 and 1 mM EDTA pH 8.0) was used to elute RNA bound to the Midi column. Extracted nucleic acid was concentrated to 25 μ L with a Zymo-spin IC RNA Clean and Concentrator kit (Zymo Research, Irvine, CA) with slight modifications to the manufacturer's instructions, including use of TE buffer instead of water for the final elution.

Human norovirus TaqMan real-time RT-PCR. A previously reported multiplex reverse transcription TaqMan real-time PCR (RT-PCR) assay for the detection of genogroup I (GI) and genogroup II (GII) human norovirus (13) was carried out on a CFX96 Touch Real-Time PCR Detection System (BioRad, Hercules, CA) using the AgPath kit (Applied Biosystems, Carlsbad, CA). The assay included oligonucleotide primers and probes for the detection of GI, GII, and the internal extraction control MS2 (Table 1). Cycling conditions were reverse transcription for 10 min at 45°C, denaturation for 10 min at 95°C, and then 45 cycles of 15 s at 95°C and 1 min at 60°C. Samples with a threshold cycle (C_T) value of ≥ 30 for MS2 (expected value 28) were retested at 1:10 and 1:100 dilutions. A sample was presumed positive for norovirus when the amplification curve had typical S-shape and the C_T value was ≤ 40 .

Nested PCR and genotyping of norovirus. All samples positive for norovirus with the RT-PCR assay ($C_T \leq 40$) were tested by nested PCR targeting the 5'-region of the capsid gene (region C) (32), and negative samples were further tested by RT-PCR targeting a small region of the polymerase gene (region A) (60). PCR products of appropriate size (region C: 330 bp for GI and 344 bp for GII; region A: 327 bp) were visualized after separation on a 2% agarose gel (Seakem-ME, Lonza, Allendale, NJ) containing Gel Red (Biotium, Fremont, CA) and gel purification by ExoSAP-IT (Affymetrix, USB, Cleveland, OH) or by using the QIAquick PCR purification kit (Qiagen, Valencia, CA). Sanger sequencing was conducted (Eurofins MWG Operon, Louisville, KY), and norovirus genotypes were assigned after phylogenetic analysis using the unweighted pair group method with arithmetic means and reference sequences in CaliciNet (13, 59) for capsid genotyping.

Data analysis. Descriptive statistics, including odds ratios (ORs), were computed to compare norovirus prevalence by establishment and bathroom characteristics, such as whether an establishment was chain or nonchain and the gender type of the bathroom. A logistic regression model was used to examine the effects of state, population density, and the interaction between state (s) and population density (p) on norovirus prevalence in food establishments:

$$y_{ij} = \left[1 + e^{-(s_i + p_j + sp_{ij})} \right]^{-1}$$

where y_{ij} is the probability that norovirus is present at a food establishment in state i and population density j .

ORs were also used to compare the odds of norovirus prevalence in food establishments across states without adjusting for population density. This approach was used because of the lack of swab samples positive for norovirus for particular state–population density combinations (e.g., no swabs were positive for norovirus in medium-density counties in Ohio or in low-density counties in South Carolina). A chi-square test was used to examine the odds of norovirus between counties with different population densities. When expected value was less than 5 or the observed number was 0 in at least one cell of the resulting 2×2 contingency table, the P value for Fisher's exact test was computed and a small sample correction was applied before calculating confidence intervals (i.e., 0.5 was added to each cell of the contingency table). A significance level of 0.05 was used for all tests of significance.

TABLE 2. Number of samples collected by state and number of samples positive for human norovirus as determined by real-time RT-PCR

State	Sites visited	Bathrooms sampled	Surfaces sampled	No. of presumptive-positive samples ^a			% positive ^b
				GI	GII	Total	
New Jersey	286	377	1,505	14	13	27	1.8
Ohio	345	496	1,977	11	7	18	0.9
South Carolina	120	171	681	4	12	16	2.3
Total	751	1,044	4,163	29	32	61	1.5

^a Number of swab samples that were positive after analysis. GI, genogroup I noroviruses; GII, genogroup II noroviruses.

^b Number of positive swabs divided by the total number of swabs collected.

RESULTS

Swab sample results. Although our goal was to visit 750 commercial food establishments, we actually visited 751 establishments, in which 1,044 bathrooms and 4,163 surfaces were swabbed (Table 2). Of the 4,163 swabs collected, 61 (1.5%) were presumed positive for human norovirus (29 GI and 32 GII). Overall, 54 (7.2%) of the 751 food establishments had at least one swab that was positive for norovirus (Table 3). In most establishments with a positive result, only one of the four swabs was positive. However, one South Carolina establishment and three New

Jersey establishments had positive swabs from multiple surfaces. Only 9 of the 61 real-time presumed positive swabs were confirmed by sequencing.

Significant risk factors across the three states combined. The ORs for all states combined revealed that samples positive for norovirus were approximately 2.4 times more likely to be found in South Carolina establishments than in Ohio establishments (95% CI, 1.15 to 4.87; $P < 0.05$) and approximately 1.7 times more likely to be found in New Jersey establishments than in Ohio establishments (95% CI, 0.92 to 3.25; $0.05 < P < 0.10$) (Table 4). Based

TABLE 3. Results of swab sample analysis based upon state, establishment, and bathroom characteristics

Category	New Jersey		Ohio		South Carolina		Total	
	No. positive ^a /total	% positive	No. positive/total	% positive	No. positive/total	% positive	No. positive/total	% positive
Ownership^b								
Chain	6/70	8.6	14/181	7.7	10/58	17.2	30/309	9.7
Nonchain	16/216	7.4	4/161	2.5	4/62	6.5	24/439	5.5
Total	22/286	7.7	18/342 ^c	5.3	14/120	11.7	54/748 ^c	7.2
Service type^b								
Table service	10/141	7.1	5/128	3.9	3/43	7.0	18/312	5.8
Counter service	5/114	4.4	7/124	5.6	6/45	13.3	18/283	6.4
Self-service	4/25	16.0	5/73	6.8	3/25	12.0	12/123	9.8
Take-out	2/4	50.0	0/5	0.0	0/0	0.0	2/9	22.2
Multiple service	1/2	50.0	1/12	8.3	2/7	28.6	4/21	19.0
Total	22/286	7.7	18/342 ^c	5.2	14/120	11.7	54/748 ^c	7.2
Bathroom type^d								
Male	12/165	7.3	11/229	4.8	3/76	3.9	26/470	5.5
Female	8/146	5.5	5/240	2.1	11/83	13.3	24/469	5.1
Unisex	7/65	10.8	2/27	7.4	2/12	16.7	11/104	10.6
Total	27/376 ^e	7.2	18/496	3.6	16/171	9.4	61/1,043 ^e	5.8
Surfaces^f								
Toilet seat	14/377	3.7	10/495	2.0	6/171	3.5	30/1,043	2.9
Toilet flush handle	6/376	1.6	5/493	1.0	2/171	1.2	13/1,040	1.3
Inner door handle	5/377	1.3	1/496	0.2	5/169	3.0	11/1,042	1.1
Sink faucet handle	2/375	0.5	2/493	0.4	3/170	1.8	7/1,038	0.7
Total	27/1,505	1.8	18/1,977	0.9	16/681	2.3	61/4,163	1.5

^a Presumptive-positive results.

^b Characteristics at the establishment level (at least one positive swab in the entire establishment).

^c Ownership and service type could not be determined for three establishments.

^d Characteristics at the bathroom level (in each establishment, samples could be collected from one or two bathrooms).

^e Gender designation was not recorded for one bathroom.

^f Characteristics at the swab level (four surfaces swabbed in each bathroom).

TABLE 4. Significant and borderline significant factors for the presence of human norovirus in food establishments across New Jersey, Ohio, and South Carolina

Risk factor	Category comparison pair	No. with norovirus ^a	No. without norovirus	Odds ratio (95% CI)	P value
State	South Carolina vs	14	157	2.37 (1.15, 4.87)	0.0162 ^b
	Ohio	18	478		
	New Jersey vs	23	345	1.73 (0.92, 3.25)	0.0873 ^c
Chain	Ohio	18	478		
	Chain vs	30	279	1.86 (1.06, 3.25)	0.0273 ^b
	Nonchain	24	415		
Service type	Multiple vs	4	17	4.09 ^d (1.31, 12.77)	0.0405 ^b
	Table	18	294		
	Multiple vs	4	17	3.69 ^d (1.18, 11.52)	0.0542 ^c
	Counter	18	265		

^a Presumptive-positive results.^b Significant at $P < 0.05$.^c Borderline significant at $0.05 < P < 0.10$.^d When one observed frequency was 0 or at least one expected frequency was < 5 , a small sample correction was applied (0.5 added to each observed frequency), and the P value for Fisher's exact test is reported.

on the logistic regression analysis, none of the factors (state, population, or state by population interaction) were significant at predicting human norovirus prevalence in food establishments.

Of the 751 establishments visited, 309 were chain and 439 were nonchain (ownership could not be determined for 3 establishments) (Table 3). Positive swabs were approximately 1.9 times as likely to be found in chain establishments than in nonchain establishments (95% CI, 1.06 to 3.25; $P < 0.05$) when data from all states were combined (Table 4). Most establishments visited were classified as table service (312), followed by counter service (283), and then self-service (123) with very few take-out (9) or multiple service (21) establishments (service type could not be determined for 3 establishments) (Table 3). Positive swabs were more likely to be found in multiple service establishments than in establishments classified as table service (OR, 4.1; 95% CI, 1.31 to 12.77; $P < 0.05$) or counter service (OR, 3.7; 95% CI, 1.18 to 11.52; $0.05 < P < 0.10$) (Table 4).

Of the 1,043 bathrooms for which gender type was recorded, 470 were male, 469 were female, and 104 were unisex (Table 3). Positive swabs were approximately 1.9 times more likely to be found in unisex bathrooms than in bathrooms for males (95% CI, 0.89 to 4.10; $0.05 < P < 0.10$) and approximately 2.6 times as likely to be found in unisex bathrooms as in bathrooms for females (95% CI, 1.16 to 5.73; $P < 0.05$) for all states combined (Table 5). Almost half (30) of positive swabs were found on the underside of the toilet seat (Table 3). About 20% were found on the toilet flush handle (13) and the inner handle of the stall or outer door (11). Only 11% (7) of positive swabs were found on the sink faucet handle. The likelihood of a norovirus-positive sample from the underside of the toilet seat was significantly different from the likelihood of a positive sample from any other surface: toilet seat versus toilet flush handle (OR, 2.4; 95% CI, 1.2 to 4.6), toilet seat versus inner door handle (OR, 2.8; 95% CI, 1.4 to 5.6), and toilet seat versus sink faucet handle (OR, 4.4; 95% CI, 1.9 to 10.1) ($P < 0.05$).

Positive swabs were more likely to be found in bathrooms that had outer door handles that must be touched (e.g., knob or handle) than in bathrooms with outer door handles that could be touchless (e.g., flat plate) (OR, 3.3; 95% CI, 0.79 to 13.63; $0.05 < P < 0.10$) (Table 5). Bathrooms with automatic flush toilets were more likely to have positive swabs than were bathrooms with manual flush toilets (OR, 2.5; 95% CI, 1.14 to 5.33; $0.05 < P < 0.10$). Positive swabs also were more likely to be found in bathrooms with trash cans attached to the paper towel dispenser than in bathrooms with trash cans not attached to the paper towel dispenser (OR, 4.8; 95% CI, 2.28 to 10.02; $P < 0.05$).

Nucleotide sequencing of presumptive-positive samples. A total of 61 samples were presumed positive for human norovirus (29 GI and 32 GII) by RT-PCR ($C_T < 40$) (Table 2). Quality sequences were obtained for nine of these samples. Eight samples were identified to genotype using the nested region C assay (GI.3, $n = 3$; GII.3, $n = 1$; GII.7, $n = 1$; GII.13, $n = 1$; GII.14, $n = 1$), and one sample was typed as GII.Pe using the region A polymerase sequence. One nested PCR sample was positive for both GI.6 and GII.14. The majority of the samples positive by the real-time RT-PCR assay that could not be confirmed by sequencing had C_T values > 35 for GI and > 37 for GII viruses.

DISCUSSION

Our results support previous findings that human noroviruses are rarely present on bathroom surfaces in commercial food establishments under nonoutbreak conditions. Norovirus was present on 1.5% of bathroom surfaces sampled in this study, which is consistent with the 1.7 and 1.9% prevalence reported in The Netherlands in 2011 and 2015, respectively (10, 11). In a recent systematic review of seven articles published from 1980 to 2014 (36), only three included reports of norovirus-positive samples from bathroom surfaces in commercial and institutional settings under nonoutbreak conditions (10, 48, 61). One reason for the low

TABLE 5. Significant and borderline significant factors for the presence of human noroviruses in bathrooms of food service establishments across New Jersey, Ohio, and South Carolina

Risk factor	Category comparison pair	No. with norovirus ^a	No. without norovirus	Odds ratio (95% CI)	P value
Bathroom type	Unisex vs	10	91	1.91 (0.89, 4.10)	0.0916 ^b
	Male	26	452		
	Unisex vs	10	91	2.58 (1.16, 5.73)	0.0163 ^c
	Female	19	446		
Outer door handle type	Handle vs	15	182	4.37 (0.98, 19.47)	0.0359 ^c
	Flat plate	2	106		
	Touch vs	52	842	3.27 (0.79, 13.63)	0.0848 ^b
	Touchless	2	106		
Stall door handle latch type	Slide vs	19	227	3.12 (0.91, 10.78)	0.0584 ^b
	Turn	3	112		
Toilet flush mechanism	Automatic vs	8	65	2.46 ^d (1.14, 5.33)	0.0515 ^b
	Manual	47	901		
Soap type	Foam vs	23	317	1.66 (0.94, 2.93)	0.0780 ^b
	Liquid	28	640		
	Bar vs	2	1	37.45 ^d (4.78, 294.12)	0.0056 ^c
	Liquid	28	640		
	Bar vs	2	1	22.52 ^d (2.85, 178.57)	0.0147 ^c
	Foam	23	317		
Trash can type ^e	Attached vs	10	44	4.78 ^d (2.28, 10.02)	0.0004 ^c
	Not attached	42	861		

^a Presumptive-positive results.

^b Borderline significant at $0.05 < P < 0.10$.

^c Significant at $P < 0.05$.

^d When one observed frequency was 0 or at least one expected frequency was < 5 , a small sample correction was applied (0.5 added to each observed frequency), and the P value for Fisher's exact test is reported.

^e Trash can either attached or not attached to the paper towel dispenser.

prevalence in our study could be that human norovirus was present in such low numbers that they were below the limit of detection of our multiplex real-time RT-PCR (13) assay. The detection limit is approximately 20 copies per PCR for either GI or GII viruses (J.V., personal communication), and lower levels of contamination may not have been detected. A second reason could be that individuals experiencing gastroenteritis symptoms (e.g., vomiting and diarrhea) are less likely to leave the house, and the highest levels of virus are shed during the symptomatic phase of infection (2). The analytical methods, such as the recovery method and sensitivity of real-time PCR, also could affect results.

The low prevalence of norovirus found in this study also could be attributed to the frequency and effectiveness of bathroom cleaning. The U.S. Food and Drug Administration Food Code, which has been adopted (at least in part) by all 50 states and the District of Columbia (57), does not currently explicitly proscribe the frequency of bathroom cleanings but rather addresses the need to keep all physical facilities clean and properly maintained. However, food establishment guests see bathroom cleanliness as an indicator of kitchen cleanliness and thus the safety of the food (8). Many consumers have reported that they will not return to a food establishment that has bathrooms that appear dirty (1, 4, 33). Thus, many food establishments probably clean and disinfect their bathrooms frequently to ensure customer satisfaction. This frequency may account for the low prevalence of norovirus on bathroom surfaces and for the fact that norovirus-positive swabs were commonly found

on only one of the bathroom surfaces sampled instead of multiple surfaces in the same bathroom.

Our results showed a difference in the rate of norovirus detection in establishments across the three states included in our study, which may be attributable to population density. New Jersey has the highest population density of the three states (1,218.1 people per square mile) (43), and South Carolina has a relatively low population density (153.9 people per square mile) (54). Ohio falls in the middle, with a population density of 282.3 people per square mile (53). Most norovirus-positive swab samples came from New Jersey establishments and the fewest came from South Carolina establishments, suggesting that population density may have played a role in these results. However, because we set parameters for high, medium, and low population density by state rather than overall, we were unable to determine whether population density was a significant factor. Jarquin et al. (26) found that population density did not increase the risk of enteric infections transmitted via environmental surfaces, but Boxman et al. (10) found more norovirus-positive samples in regions with higher population densities ($0.05 < P < 0.10$). More studies are needed to clarify the contradictory findings related to population density as a risk factor for transmission of human noroviruses.

Other factors that could affect the distribution of norovirus-positive samples across states are temperature and humidity. Norovirus on hard surfaces survives longer at lower temperatures (4 to 9°C) than at higher temperatures (25 to 40°C) (17, 31, 35, 37, 39). However, findings on the

effect of humidity are conflicting. Colas de la Noue et al. (17) and Kim et al. (31) found that murine norovirus, a surrogate for human norovirus, survived longer at low relative humidity (10 to 30%) than at high relative humidity (70 to 100%). Conversely, Lamhoujeb et al. (35) found that human norovirus survived significantly longer at high relative humidity (86%) than at low relative humidity (30%). Although we did not gather data on specific weather during our sampling time, in general winters in Ohio and New Jersey tend to be colder and have more snow than winters in South Carolina, so more norovirus-positive samples might be expected from Ohio and New Jersey than from South Carolina (42, 44, 45, 50, 56). However, this assumption does not take into consideration indoor heating. More research is needed to determine the effect of temperature and humidity as a risk factor for human norovirus on surfaces under field conditions.

In our study, norovirus-positive samples were more likely to be found in chain food establishments than in nonchain food establishments. This finding differs from that of previous studies in which chain and nonchain food establishments were compared. In two studies, nonchain restaurants were cited for critical food safety violations more often than were chain restaurants (25, 40), and Jin and Leslie (28) found that hygiene at nonchain restaurants was poorer than that at chain restaurants. These findings most likely stem from the fact that chain establishments typically have their own food safety standards developed by the parent organization and potentially greater financial resources, allowing them to provide more food safety training and sanitary equipment (20, 47). In these studies, only visual indicators of cleanliness and hygiene were examined, whereas in our study we obtained microbiological results. Even when surfaces look clean, pathogens might still be present (18, 51), although visible moisture and food debris may be correlated with detectable bacteria (12). One factor that might explain the higher prevalence of norovirus in chain establishments is the number of customers. Chain establishments may have more patrons each day than nonchain establishments, which could result in more exposure of bathroom surfaces to human norovirus. However, we did not gather data on number of customers from the establishments we visited, so we were unable to test this hypothesis.

Risk factors for the presence of human norovirus were determined based on characteristics and equipment in establishment bathrooms. Norovirus-positive samples were more likely to be found in unisex bathrooms than in single-sex bathrooms, possibly because twice as many patrons use unisex bathrooms than use single-sex bathrooms. Additionally, unisex bathrooms tend to be single occupancy instead of multiple occupancy. Thus, more people may use a single unisex toilet than a toilet in a multiple occupancy bathroom. However, no significant difference was found between multiple occupancy bathrooms and single occupancy bathrooms (data not shown), suggesting the need for further research to understand the difference in findings between unisex and single-sex bathrooms.

Most norovirus-positive samples came from the underside of the toilet seat, followed by the toilet flush handle,

inner door handle, and the sink faucet. Leone et al. (36) found similar results in their literature review of the presence of human norovirus on bathroom surfaces. Norovirus-positive samples were found on toilet seats in five studies (9, 15, 19, 34, 64) and on sink faucet handles (15, 22, 23), toilet flush handles (48), and bathroom door handles (22, 34, 48) in fewer studies. These results suggest that areas further away from the toilet are less likely to harbor norovirus contamination; toilet surfaces (especially the underside of the seat) would be closest to vomiting and diarrheal events during which high numbers of norovirus particles could be shed (3). Flushing a toilet can reaerosolize virus particles, allowing them to be deposited onto bathroom surfaces, with the most droplets likely settling onto surfaces near the toilet (5). Surfaces not contaminated by aerosolized droplets (e.g., sink faucets or door handles) could become contaminated by contact with norovirus on users' hands (6, 52).

Our results also indicated that norovirus-positive samples were somewhat more likely to be found in bathrooms with automatic (touchless) flush toilets than in bathrooms with manual (touch) flush toilets ($P = 0.0515$). However, the opposite was true for the door handle mechanism; norovirus-positive samples were more likely in bathrooms with door handles that must be touched than in bathrooms with touchless door handles ($P = 0.0848$). Berry et al. (7) found that individuals perceived lower pathogen risk when using bathrooms with an automatic flush toilet than in bathrooms with manual flush toilets, which in turn decreased the likelihood that individuals would wash their hands. Lack of hand washing after using an automatic flush toilet could account for the higher presence of norovirus in those bathrooms due to the spread of pathogens to other bathroom surfaces via contact with contaminated hands. Contaminated hands may also explain the higher presence of norovirus in bathrooms with door handles that must be touched. Results of numerous studies have revealed that norovirus can be readily transferred from contaminated hands to hard surfaces (27, 29, 52), and Barker et al. (6) found that norovirus can be transferred to up to seven surfaces touched in sequence.

Most norovirus infection outbreaks in the United States are caused by GII noroviruses, specifically GII.4 viruses (13, 58) of which 16% of outbreaks have a foodborne etiology based on epidemiologic information. In our study, the prevalence of GI (43%) and GII (57%) noroviruses was very similar, and no GII.4 viruses were detected. In contrast, Boxman et al. (10) reported 2 GI-positive and 33 GII-positive surfaces in food establishments, and GII.4 was the most frequently detected genotype. Recent environmental surveillance studies revealed that human noroviruses in the environment are sometimes more genetically diverse than are outbreak strains, suggesting that the genotype distribution of noroviruses associated with sporadic or asymptomatic infections is higher. In sewage samples, the proportion of GI versus GII noroviruses is often similar (30, 62), which could also indicate different survival characteristics for GI and GII viruses.

Because we collected samples from only three geographical regions in the eastern United States, our findings may not be generalizable to the entire country. We visited

each establishment only once, so our findings represent only a snapshot in time of the prevalence of human noroviruses in each commercial food establishment during the winter months. Norovirus prevalence likely varies based upon season, patronage volume, effectiveness of sanitation procedures, and the chance that an infected individual would visit a given establishment. Because we chose to set population density parameters by state, we were unable to assess whether population density was a significant factor for norovirus presence.

Human noroviruses are found only rarely on surfaces in bathrooms in food establishments under nonoutbreak conditions. The factors of being a chain establishment, having a unisex bathroom, having automatic flush toilets, and having door handles that must be touched all increased the likelihood of norovirus contamination in food establishment bathrooms. Future research should consider how the layout of bathrooms can affect the presence and spread of microorganisms, e.g., testing the differences between single occupancy and multiple occupancy bathrooms and between high-touch and low-touch bathrooms. Our data suggest that routine environmental monitoring for norovirus during nonoutbreak periods is not a practical way to determine cleanliness. One alternative technique that is commonly used in food processing and health care settings is to assay for ATP bioluminescence (14, 16, 21, 38, 63). Although viruses do not contain ATP, bacteria and fecal matter do. Thus, ATP may be a good indicator of surface cleanliness because assays for this molecule are fast and may be more affordable than other methods.

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Widespread environmental contamination with Norwalk-like viruses (NLV) detected in a prolonged hotel outbreak of gastroenteritis

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SUMMARY

A protracted outbreak of Norwalk-like virus (NLV)-associated gastroenteritis occurred in a large hotel in North-West England between January and May 1996. We investigated the pattern of environmental contamination with NLV in the hotel during and after the outbreak. In the ninth week, 144 environmental swabs taken from around the hotel were tested for NLV by nested RT–PCR. The sites were categorized according to the likelihood of direct contamination with vomit/faeces. The highest proportion of positive samples were detected in directly contaminated carpets, but amplicons were detected in sites above 1·5 m which are unlikely to have been contaminated directly. The trend in positivity of different sites paralleled the diminishing likelihood of direct contamination. A second environmental investigation of the same sites 5 months after the outbreak had finished were all negative by RT–PCR. This study demonstrates for the first time the extent of environmental contamination that may occur during a large NLV outbreak.

INTRODUCTION

Norwalk-like viruses (NLVs, also known as SRSVs) are generally recognized to be the leading cause of outbreaks of diarrhoea and vomiting in the UK [1]. A typical case is characterized by sudden onset of nausea with projectile vomiting and watery diarrhoea, which resolves within 72 h. The combination of high viral load ($> 10^6$ particles/ml) in vomit and faeces, low infectious dose and lack of long-term immunity following previous infection accounts for the high secondary attack rate characteristic of NLV outbreaks. Contaminated food, aerosol and direct contact are believed to be the principal routes of transmission of NLV [2]. The role of fomites is less clear. While outbreaks in hotels and cruise ships in

which recurrent waves of infection occur in successive cohorts of guests suggest that environmental contamination may occur [3–5], direct evidence for this is lacking.

Several guidelines recommending measures to control outbreaks have been published and these include thorough environmental cleaning, changing curtains and steam cleaning carpets [6]. These recommendations are empirically based and the importance of contamination in particular environmental sites is unknown.

The development of a broadly reactive Reverse Transcriptase Polymerase Chain Reaction (RT–PCR) for NLV, capable of detecting minute quantities of viral RNA [7, 8], provides a method for environmental sampling of this uncultivable group of viruses [9] and the possibility of directly addressing this issue. In

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this study we have examined the scale of environmental contamination in a large hotel during an extended outbreak of NLV infection using RT-PCR.

METHODS

Description of outbreak

The outbreak occurred in a large hotel (500 beds) in North-West England between January–May 1996. Over the winter period, the hotel lets rooms for 3-day (Monday–Wednesday) or 4-day (Thursday–Sunday) ‘mini-breaks’. Guests who had arrived on 15 January 1996 became unwell while still resident in the hotel with typical NLV symptoms. Three of six faeces samples collected from guests were positive for NLV by electron microscopy. The subsequent course of the outbreak is shown in Figure 1. This epicurve is based on cases of diarrhoea and/or vomiting occurring among staff or guests which were reported to the hotel management between 15 January 1996 and 24 May 1996. Cases occurring among guests after their departure have not been included.

The majority of cases (77%) among the staff occurred during the first three mini-breaks. The number of cases among guests fluctuated widely over the next 12 weeks until 15 March 1996 when the hotel was closed for a deep clean. A total of 850 of 4291 guests staying at the hotel between 15 January 1996 and 15 March 1996 developed diarrhoea and/or vomiting. The attack rate among guests in different mini-breaks varied from 2.2 to 39.1% with a mean of 19.8%. Many guests were elderly and were sometimes unable to reach toilet facilities before vomiting.

Initial investigations failed to identify any high risk foods such as uncooked shell fish, and no associations with any particular meals or food items were noted on examination of menu based questionnaires administered to available guests with recent NLV symptoms in the first three mini-breaks. A formal case control study was not undertaken due to logistic problems. No serious lapses of hygiene were found on an inspection of the kitchens.

Initial control measures included procedures to avoid any contact between consecutive groups of guests in the foyer on change-over days, removal of non-cooked food items from the menu and the formation of a cleaning team who were rapidly mobilized following an episode of contamination in a public area. This had no measurable impact on the outbreak and the hotel was closed on the 15 March 1996. While closed, the hotel was thoroughly cleaned;

hard surfaces with warm water and detergents and carpets by shampooing followed by vacuum cleaning. Disinfectants were not employed due to concern that the carpets and soft furnishings would have been damaged. The hotel re-opened after 1 week on 22 March. Cases of NLV rapidly increased again peaking in a mini-break from the 29 March to 1 April in which 92 of 226 (40.7%) were affected. After this, the attack rate diminished with no further clinical cases after 28 June 1996.

Faecal samples

Faecal samples from four patients, two in the initial wave in January 1996 and two from cases occurring in mid-March were selected for testing by RT-PCR. These had previously been shown to contain NLV by electron microscopy and had been stored at 4 °C prior to PCR testing. Seventeen faecal samples collected from 13 outbreaks of gastroenteritis occurring at hospitals, nursing homes and at a school in Lancashire between January and March 1996 were also tested by RT-PCR/sequencing in order to compare strains circulating in the local community with that associated with the hotel outbreak.

Environmental samples

On 15 March 1996, prior to cleaning, environmental samples were collected by surface wiping an area of approximately 5 × 5 cm with a cotton tipped swab. The tip of the swab was moistened in virology transport medium prior to sampling. Swabs were sent to the Central Public Health Laboratory (CPHL) in sufficient transport medium to keep the swab moist during transit (approximately 100 µl).

A total of 144 swabs were collected from a range of sites within the hotel. These were ranked into eight categories (Table 1). The hotel management identified eight areas of carpet where guests had vomited within the 72 h prior to sampling (Category 1). These areas had all been cleaned with water and detergent followed by vacuuming and appeared clean at the time of sampling. Another 12 areas of carpet with no definite record of direct contamination with vomit were sampled (Category 2). Samples from within the toilet area, are divided into those likely to be directly contaminated by vomit or diarrhoea (Category 3) and those without direct contamination in which hand transfer is the likely route of contamination (Category 4).

Outside the toilet areas, samples (other than those

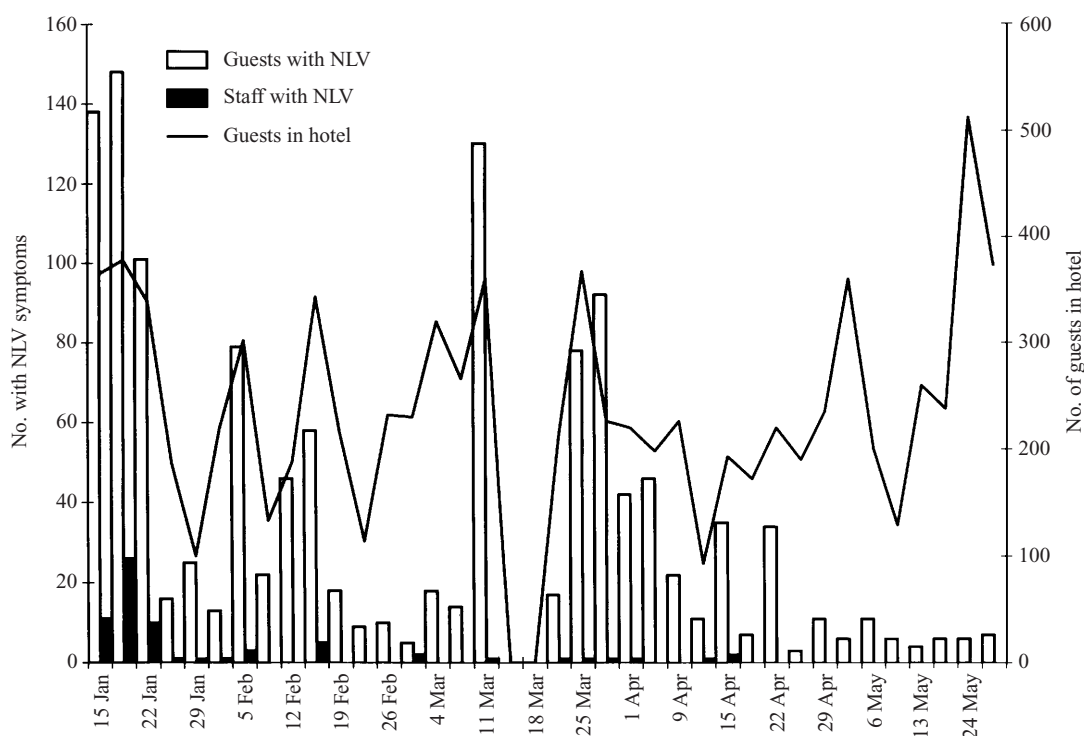


Fig. 1. Illness compatible with NLV among guests and hotel staff, January–May 1996. The number of guests on each mini-break, number falling ill while still in the hotel and the number of cases among hotel staff are recorded.

Table 1. *Results of RT–PCR on environmental swabs from the hotel by site of collection categories*

Category	Site category	RT–PCR results on environmental swabs	
		March 1996 Pos/total (%)	October 1996 Pos/total
1	Carpet (known recent vomit)	5/8 (62)	0/8
2	Carpet (no known recent vomit)	9/12 (75)	0/20
3	Toilet rims or seats	8/11 (73)	0/11
4	Toilet handles, taps, basins and surfaces	13/33 (39)	0/33
5	Horizontal surfaces (outside toilet) below 1.5 m, e.g. tables, ledges	11/29 (37)	0/29
6	Horizontal surfaces (outside toilet) above 1.5 m, e.g. mantle piece, light fittings	6/12 (50)	0/12
7	Frequently handled objects, phones, door handles, etc.	7/29 (24)	0/29
8	Soft furnishings, cushions, curtains, etc.	2/10 (20)	0/10
	Total	61/144 (42)	0/144

from carpets) were collected from a wide range of sites, including table and counter tops, dado rails, mantelpieces, tops of wardrobes, light fittings, switches, telephones and soft furnishings. These have been categorized into; hard horizontal surfaces below 1.5 m which may have been directly handled (Category 5); hard horizontal surfaces above 1.5 m of which direct handling is unlikely (Category 6); objects likely to be handled frequently such as door knobs, telephones, TV remote controls (Category 7) and soft

furnishing such as cushions or curtains (Category 8). Repeat samples from all sites were collected in October 1996, 5 months after the end of the outbreak.

RT–PCR

RNA extraction from faecal samples and environmental swabs

RNA was extracted from 100 µl faecal extract using a modification of the ‘Boom’ method as previously

described [7]. The environmental swabs were processed similarly except that 900 μ l guanidinium isothiocyanate lysis buffer were added directly to the swab container. After thorough mixing, the swab was carefully removed from the container and discarded. The lysis buffer was removed from the swab container to an Eppendorf tube, spun in a microfuge for 1 min and 10 μ l silica particle suspension added. Adsorption of the RNA to the silica and subsequent washing and elution stages were as for the faecal samples. Complementary DNA (cDNA) was generated from the extracted RNA using random hexamers and MuMLV reverse transcriptase. This cDNA was used as template for each two PCRs; (i) Direct single-round amplification with the Ni/E3 primer pair [7], (ii) Nested RT-PCR with first round amplification with primers G1/G11/31 [8]. After 30 cycles, 1 μ l first-round mix was transferred for PCR with the nested primer pair Ni/E3 [8].

The amplicons from both the direct Ni/E3 PCR and the nested Ni/E3 PCR were analysed by electrophoresis in agarose gels. Amplicons of the correct size (113 bp) were confirmed to be NLV by Southern blot hybridisation with NLV-specific probes [7].

The nested RT-PCR was demonstrated to be 100-fold more sensitive than the single-round RT-PCR for the NLV strain associated with this outbreak (data not shown).

NLV strain characterization

PCR amplicons were separated from unincorporated nucleotides and primers using Chromaspin 100-TE spin columns and were sequenced using an ABI Taq FS cycle sequencing kit and an ABI automated sequencer. Sequence data were analysed using SeqED and DNASTar analysis packages.

RESULTS

Faecal samples

Four faecal samples collected from the hotel outbreak were positive for NLV by RT-PCR. Nucleotide sequences from all amplicons were identical, which showed that a single strain had been the cause of both the January and March incidents. Phylogenetic analysis showed that this strain was most closely related to Grimsby virus [10] with 97.5% nucleotide sequence identity within the intra-primer region. Faecal samples

from 10 of 13 contemporaneous outbreaks in the North West of England were positive by RT-PCR. Amplicons obtained from eight samples were suitable for sequencing, of which six were shown to be closely related (> 95% nucleotide identity within the 76 bp intra-primer region) to the strain associated with the hotel outbreak. This indicates that this strain was circulating widely in the community at the time of the hotel outbreak.

Environmental swabs

The results are expressed as first-round RT-PCR positive and nested RT-PCR positives. Six environmental swab samples were positive by direct first round RT-PCR, five of which were taken from carpets, and one from a toilet rim. By nested PCR, 61 (42%) of the 144 swabs were positive for NLV RNA. Table 1 shows a trend of diminishing frequency of RT-PCR positivity across the categories, which broadly correlates with the likelihood of direct contamination. Sites in all categories yielded RT-PCR positive swabs.

None of the 144 samples collected in October was positive for NLV RNA by nested RT-PCR.

DISCUSSION

Prolonged NLV outbreaks of this type have been recorded in other large institutions and cruise ships [5, 11] and this is the largest documented hotel outbreak. The ascertainment of the epidemiological data is imperfect, since it is reliant on self reporting by guests to the hotel reception desk. No attempt was made to exclude cases of diarrhoea or vomiting due to other causes nor cases presenting within the incubation period (15 h) of arriving at the hotel. While these factors may result in over reporting, it is more likely that substantial underreporting has occurred by not including any cases presenting within 36 h after leaving the hotel. While many such cases were reported to the hotel management they would not have contributed to the environmental contamination within the hotel.

Factors that may have contributed to the size of the outbreak include: the very rapid turnover of guests; the high level of occupancy; the advanced age and often some degree of disability among guests. The reliance on natural (open window) ventilation in most of the hotel and the problem this poses for maintaining

a comfortable temperature during the winter season may be an additional factor. The most remarkable features of this outbreak are its long duration and wide variation in attack rate between successive cohorts of guests.

The possible routes of transmission between successive cohorts of guests include a continuously contaminated food or water, direct contact or droplet spread between successive cohorts of guests, spread from hotel staff with long-term carriage of NLV, successive re-introduction of NLV by new guests or contact with contaminated fomites within the hotel environment.

These routes are clearly not mutually exclusive and it is likely that each may have played a role at some point in the outbreak. However, some estimate of the relative importance of each route can be deduced from epidemiological investigations and the pattern of the outbreak. Each will be considered in turn.

The possibility of contaminated food was investigated by examining kitchen hygiene and food histories of affected guests in the first two waves of the outbreak. No deficiencies in food handling practices were identified nor was there any clear association found with the consumption of any particular food. There were no reports of illness among catering staff while at work. High-risk foods such as raw shellfish were not served in the hotel and salads and cooked shellfish were withdrawn from the menu after the first wave of infection.

Measures to reduce direct contact between successive cohorts of guests by minimizing any mingling of departing and arriving guests were instigated after the third affected mini-break. This had no measurable impact on the course of the outbreak. Staff were affected during the first 2 weeks of the outbreak and cases were infrequent thereafter. Staff turnover was low and it is likely that the majority of staff would have developed immunity to this strain within the first month of the outbreak. While prolonged asymptomatic excretion among staff with subsequent spread to guests is a theoretical possibility, it is not supported by current knowledge of the duration of NLV excretion in humans.

The possibility of successive reintroduction of NLV into the hotel by guests incubating the illness on arrival cannot be completely discounted. During the first 3 months of 1996, numerous outbreaks of NLV were reported from hospitals, schools and nursing homes in North West England. However, the incubation period for NLV is short (12–60 h) and only

three other outbreaks of diarrhoea and vomiting suggestive of NLV were reported among the many hotels in the area. Moreover, the study outbreak persisted into May by which time reports of general community outbreaks of NLV had fallen to the average background level.

The final route, contact with contaminated fomites, appears to have played an important role in maintaining this outbreak. While transmission from fomites is likely to be inefficient compared with highly infectious aerosols generated by vomiting, it would explain the link between successive cohorts of guests. While infection from fomites directly may result in only a few cases, these cases may then cause a large number of secondary cases amongst other guests, resulting in a large wave of infection. A critical factor is likely to be the time and location at which these initial fomite derived cases become unwell: vomiting in a bedroom has a much lower risk of causing multiple secondary cases than in a busy public area. This pattern of a continuing background of cases in each mini-break with superimposed peaks fits well with that observed in this outbreak.

The rapid recrudescence of the outbreak when the hotel was re-opened after cleaning in late March could be explained by the immediate re-introduction by a guest incubating NLV at the time of arrival at the hotel. However the re-infection of guests from the environment with subsequent amplification by cross-infection between clinically affected guests seems more plausible.

While environmental contamination has been suggested as an important factor in outbreaks on epidemiological grounds, this is the first utilization of a nested RT-PCR to demonstrate the extent of environmental contamination with NLVs that can occur during such outbreaks. The uniformly negative results on the repeat sample survey confirm the specificity of these findings.

All the samples yielding a positive result on first round PCR were collected from sites likely to have been directly contaminated such as carpets or toilet rims. Positive carpet swabs were obtained after cleaning and in all cases were collected from carpets that appeared clean at the time of sample collection, indicating that standard carpet cleaning with detergent followed by daily vacuuming will not remove all virus. Samples positive on second round PCR were obtained from a wide variety of sites and were just as likely to be positive if collected from a high horizontal surface, very unlikely to have been touched, as they

were from items likely to be handled such as telephones, light switches or door knobs. This suggests that airborne dissemination occurs and virus persists in areas unlikely to be cleaned with any frequency.

An important question that cannot be answered with certainty is the extent to which a positive signal represents RNA not associated with viable virus. While it is possible that some of the positive PCR results represent non-infectious virus, NLVs have an ssRNA genome which is susceptible to RNAses found widely in the environment and it is likely therefore that positive signals are associated with virus particles.

Some previously reported prolonged outbreaks have only been successfully curtailed with extensive control measures including thorough environmental cleaning [3, 12]. We have not been able to establish the relative importance of contamination at different sites. The wide variety of sites yielding positive results offers infection control teams little assistance in targeting key areas for decontamination but the relatively high levels of RT-PCR signal found in carpets suggests that these should be a priority. The capacity of carpets to harbour viable virus for up to 12 days has been recently been suggested [13]. Steam cleaning of carpets, which cannot tolerate hypochlorite, has been recommended as the most appropriate means of decontamination [14]. While formal evidence that this is superior to wet shampooing, steam cleaners were not used during the closure and this may, at least in part, explain the continuation of the outbreak after re-opening. This study suggests that the nested RT-PCR assay for NLVs, in addition to demonstrating the extent of environmental contamination, may provide a means to formally evaluate cleaning and decontamination methods including steam-cleaning and thus to develop procedures to limit the time course of NLV outbreaks in semi-closed institutions.

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Quantitative Risk Assessment of Norovirus Transmission in Food Establishments: Evaluating the Impact of Intervention Strategies and Food Employee Behavior on the Risk Associated with Norovirus in Foods

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We developed a quantitative risk assessment model using a discrete event framework to quantify and study the risk associated with norovirus transmission to consumers through food contaminated by infected food employees in a retail food setting. This study focused on the impact of ill food workers experiencing symptoms of diarrhea and vomiting and potential control measures for the transmission of norovirus to foods. The model examined the behavior of food employees regarding exclusion from work while ill and after symptom resolution and preventive measures limiting food contamination during preparation. The mean numbers of infected customers estimated for 21 scenarios were compared to the estimate for a baseline scenario representing current practices. Results show that prevention strategies examined could not prevent norovirus transmission to food when a symptomatic employee was present in the food establishment. Compliance with exclusion from work of symptomatic food employees is thus critical, with an estimated range of 75–226% of the baseline mean for full to no compliance, respectively. Results also suggest that efficient handwashing, handwashing frequency associated with gloving compliance, and elimination of contact between hands, faucets, and door handles in restrooms reduced the mean number of infected customers to 58%, 62%, and 75% of the baseline, respectively. This study provides quantitative data to evaluate the relative efficacy of policy and practices at retail to reduce norovirus illnesses and provides new insights into the interactions and interplay of prevention strategies and compliance in reducing transmission of foodborne norovirus.

KEY WORDS: Discrete event model; microbial risk assessment; norovirus; retail food establishment

1. INTRODUCTION

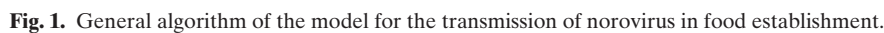
Noroviruses are often spread through person-to-person contact; however, foodborne transmission can cause widespread exposures and presents important prevention opportunities.⁽¹⁾ Norovirus is the leading

cause of foodborne illness globally and within the United States.^(2–4) Restaurants are the most common setting (64%) of food preparation reported in outbreaks in the United States.⁽¹⁾ Most foodborne norovirus outbreaks linked to food establishments are traced to contamination of food that is not cooked or otherwise treated before consumption (“ready-to-eat” [RTE] food).^(4–7)

The disease is characterized by a sudden onset of vomiting, diarrhea, and abdominal cramps, with a duration of one to three days before reaching a full resolution of symptoms.⁽⁸⁾ Large numbers of virus are

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The lack of availability of a single effective prevention strategy for controlling norovirus has led to the adoption of a combination of prevention strategies used by many jurisdictions.^(7,13,14) The U.S. Food and Drug Administration (FDA) has included a combination of prevention strategies focused on reducing viral contamination of food and surfaces from infected food employees in the FDA Food Code⁽¹⁴⁾ and the FDA Employee Health and Personal

Hygiene Handbook.⁽¹⁵⁾ Current prevention strategies involve the restriction or exclusion of infectious food employees from work, proper hand hygiene, food contact surface (FCS) sanitation, and eliminating barehand contact with RTE food.⁽¹⁴⁾

While individual prevention strategies have been studied, the relative impact of each of these strategies, their level of compliance, and the interplay of combinations of these strategies on norovirus transmission in food establishments have not been well studied. This study was conducted specifically to evaluate these impacts on the mean number of contaminated food servings and infected customers. Additional prevention strategies such as increasing the current efficacy of handwashing or preventing hand contact with faucets and doors in the restrooms were also tested to identify effective ways to reduce the risk associated with norovirus in a food establishment.

2. BACKGROUND AND METHODS

2.1. Food Establishment Setting

The model was developed to study the spread of norovirus in a food establishment. A discrete event model was selected as the most suitable model framework to describe the series of consecutive tasks undertaken by food employees. A main advantage of the discrete event model framework is its flexibility, which allows for the inclusion of additional events or the modification of event sequences. This flexibility facilitates comparison of different situations or scenarios such as the impact of new regulations or a change in level of compliance in the quantitative risk assessment.⁽¹⁶⁾

The conceptual model developed is presented in Fig. 1. The shift (work period) of a food employee was represented as a chronological sequence of events occurring at discrete instants in time. The main tasks (events) of the food employees are: (i) prepare food (sequence of five minutes), (ii) assemble food (sequence of five minutes), (iii) wash and sanitize FCS, (iv) use the restrooms, or (v) do nothing (idle). At any time (t), food employees executed one of the five different main events (tasks—dashed rectangle), each task including sequences of actions (e.g., wash hands, change gloves, touch an FCS, etc.) described with function/action, decision/loop, objects, and object states. Solid and dashed arrows represent

action transition and norovirus transfer between the objects, respectively.

Three employees, referred as FE-1, FE-2, and FE-3, working together during one eight-hour shift per day for five consecutive days, were considered. FE-1 and FE-2 prepared food and touched FCS and nonfood contact surfaces (NFCS), while FE-3 did not prepare food but sporadically touched NFCS. One type of food, consisting of a three-item sandwich (e.g., bacon, lettuce, and tomato sandwich), was served to the customers. The two employees FE-1 and FE-2 both prepare a total of 200 sandwiches per shift. It is assumed that the food ingredients are initially free of norovirus. The food establishment included two different areas: a food preparation and sandwich assembly area and the restrooms. The food preparation and assembly area included three generic FCS (e.g., knife, cutting board, stainless work surface, etc.) and three generic NFCS (e.g., refrigerator door handle, microwave handle, etc.) (Fig. 1). The restrooms, the FCS, and NFCS were washed and sanitized before the beginning of each shift. The FCS were additionally washed and sanitized every four hours, as recommended by the Food Code.⁽¹⁴⁾

2.1.1. Restrooms

The restrooms included three potentially contaminated objects: the door handle, the faucet, and the air environment. The number of visits in the restroom for each employee was related to their health status (symptomatic or not) (Table I) and will be further discussed (Section 2.2). The visits to the restrooms were randomly distributed within the shift. The level of compliance with required handwashing after using the restroom was assumed to be 100% after emesis and 65% and 90% after urination and defecation, respectively.⁽¹⁷⁾ Table I describes other parameters regarding the norovirus concentration in feces and vomit, as extracted from the literature.

2.1.2. Food Preparation/Sandwich Assemblage

Food preparation and sandwich assemblage sequences were adapted from Mokhtari *et al.*⁽¹⁸⁾ and Stals *et al.*⁽¹⁹⁾ The food preparation and sandwich assemblage were considered to be two distinct events. We assumed that the food ingredients (e.g., lettuce, tomato, and bacon) were first prepared (e.g., sliced) by batch, and later assembled to make sandwiches. The objects and actions initiated during the

Table 1. Model Parameter Distributions and Sources

Input	Definition [Unit]	Distribution	Mean [0.025; 0.5; 0.975 Quantiles]	Reference
Inputs Associated with Food Employees in the Restrooms				
V_{Rest}	Volume of the restrooms [m ³]	$cste(12.1)$	–	27
n_D	Number of defecations per shift on day 0 of sickness, divided by 2 each day while sick	$Poisson(4.5)$	4.5 [1; 4; 9]	24
P_{vomit}	Probability that the sick food employee vomits	$cste(0.72)$	–	10
n_V	Number of vomit events per shift minus 1 each day while sick	$cste(3)$	–	57
n_U	Number of restroom visits to urinate per shift	$cste(2)$	–	Assumed
m_H	Mass of feces on hands after defecation [log ₁₀ g]	$BetaPert(min=-8, mode=-3, max=-1)$	–3.5 [–6.17; –3.38; –1.44]	58, 59
S_H	Hand surface [m ²]	$cste(0.01)$	–	19
V_H	Volume of vomit on hands after vomiting events [mL]	$cste(10)$	–	Assuming 1 mm of vomit on all hand surface S_H
NoV_v	Norovirus concentration in vomit [log ₁₀ GEC NoV/mL]	$BetaPert(3; 4.5; 7)$	4.67 [3.37; 4.62; 6.16]	43
NoV_{sh}	Shedding level of food employee [log ₁₀ GEC NoV/g]	$BetaPert(4; 8; 10)$	7.67 [5.40; 7.74; 9.52]	9, 60, 61
D_{sh}	Time to 1 log ₁₀ reduction of NoVs in shedding food employees [minutes] (eq. one log ₁₀ decrease per week)	$cste(10,080)$	–	9, 60, 61
$T_{Env, d}$	Aerosol contamination during diarrhea events [NoV/m ³]	$lognormal(7.6820; 0.468)$	2,420 [867; 2,168; 5,425]	27
$T_{Env, V}$	Aerosol contamination during vomit events [GEC Nov/m ³]	$lognormal(7.6820; 0.468) + 1,100$	3,520 [1,967; 3,268; 6,525]	27, 28
d_s	Symptom duration [minutes]	$gamma(scale=1.508; rate=0.000513)$	2,940 [218; 2,321; 9,140] (eq. 49 [4, 39, 152] hours)	24
$P_{Wash, H; Rest}$	Probability of washing hands in the restrooms (vomit, defecate, urinate)	$cste(1; 0.9; 0.65)$	–	17
Inputs Associated with Food Employees Characteristics and Behavior				
$n_{Hwash; NFH}$	Number of handwashings per shift for nonfood handling employees	$cste(4)$	–	Assumed
$P_{Shedders}$	Probability of asymptomatic shedders	$cste(0.15)$	–	23
$P_{wear\ gloves}$	Probability of wearing gloves during food preparation (0; .5; .9; 1 of the time)	(0.336; 0.14; 0.12; 0.40)	–	20
P_{change_gloves}	Probability of changing gloves when engaging in food preparation	$cste(0.37)$	–	22
$P_{wash, H}$	Probability of washing hands when engaging in food preparation	$cste(0.41)$	–	22
$P_{wash, H}$	Probability of washing hands while changing gloves	$cste(0.30)$	–	22

(Continued)

Table 1 (Continued)

Input	Definition [Unit]	Distribution	Mean [0.025; 0.5; 0.975 Quantiles]	Reference
Inputs Associated with Transfer of Norovirus from Surface 1 to Surface 2 ($Tr_{1,2}$)				
$Tr_{H,S}$	Norovirus transferred from hand to surface	inv.logit(normal(−3.82, ResTrans))	0.02 [4.61×10^{-4} ; 0.02; 0.51]	Meta-analysis: 51,52,62–69
$Tr_{S,H}$	Norovirus transferred from surface to hand	inv.logit(normal(0.11, ResTrans))	0.53 [2.30×10^{-2} ; 0.53; 0.98]	
$Tr_{G,S}$	Norovirus transferred from glove to surface	inv.logit(normal(−2.14, ResTrans))	0.11 [2.47×10^{-3} ; 0.11; 0.85]	
$Tr_{S,G}$	Norovirus transferred from surface to glove	inv.logit(normal(−1.34, ResTrans))	0.21 [5.48×10^{-3} ; 0.21; 0.93]	
$Tr_{F,H}$	Norovirus transferred from food (nonmeat) to hand	inv.logit(normal(−3.86, ResTrans))	0.02 [4.43×10^{-4} ; 0.02; 0.50]	
$Tr_{H,F}$	Norovirus transferred from hand to food (nonmeat)	inv.logit(normal(−2.95, ResTrans))	0.05 [1.10×10^{-3} ; 0.05; 0.71]	
$Tr_{Fm,H}$	Norovirus transferred from food (meat) to hand	inv.logit(normal(−2.62, ResTrans))	0.07 [1.53×10^{-3} ; 0.07; 0.78]	
$Tr_{H,Fm}$	Norovirus transferred from hand to food (meat)	inv.logit(normal(−0.034, ResTrans))	0.49 [0.02; 0.49; 0.98]	
$Tr_{F,G}$	Norovirus transferred from food (nonmeat) to glove	inv.logit(normal(0.90, ResTrans))	0.71 [0.05; 0.71; 0.99]	
$Tr_{G,F}$	Norovirus transferred from glove to food (nonmeat)	inv.logit(normal(−0.82, ResTrans))	0.31 [0.01; 0.31; 0.95]	
$Tr_{Fm,G}$	Norovirus transferred from food (meat) to glove	inv.logit(normal(−0.13, ResTrans))	0.47 [0.02; 0.47; 0.98]	
$Tr_{G,Fm}$	Norovirus transferred from glove to food (meat)	inv.logit(normal(−0.29, ResTrans))	0.43 [0.02; 0.43; 0.97]	
$Tr_{F,S}$	Norovirus transferred from food (nonmeat) to surface	inv.logit(normal(−2.82, ResTrans))	0.06 [1.25×10^{-3} ; 0.06; 0.74]	
$Tr_{S,F}$	Norovirus transferred from surface to food (nonmeat)	inv.logit(normal(0.87, ResTrans))	0.70 [0.05; 0.70; 0.99]	
$Tr_{Fm,S}$	Norovirus transferred from food (meat) to surface	inv.logit(normal(−0.94, ResTrans))	0.28 [0.01; 0.28; 0.95]	
$Tr_{S,Fm}$	Norovirus transferred from surface to food (meat)	inv.logit(normal(4.45, ResTrans))	0.99 [0.64; 0.99; 1.00]	
$Tr_{H,G}$	Norovirus transferred from hand to glove	inv.logit(normal(−2.78, ResTrans))	0.06 [1.30×10^{-3} ; 0.06; 0.75]	
ResTrans	Residuals of the meta-analysis for transfer	cste(1.97)	–	
D_{WH}	Handwashing efficiency [\log_{10} NoV]	$BetaPert(0.17; 0.45; 6; \text{shape}=4)$	1.33 [0.23; 1.13; 3.47]	Meta-analysis: 55,56,58,62,70–81
Inputs Associated with Survival of Norovirus on Surfaces				
D_H	Time to 1 log reduction of GEC NoV on hands [minutes]	$lognormal(6.50; \text{ResSurv})$	1,154 [85; 665; 5,208] (eq.: 19 [1, 11, 87] hours)	Meta-analysis: 63,64,82–95
D_S	Time to 1 log reduction of GEC NoV on hard surface [minutes]	$lognormal(10.17; \text{ResSurv})$	45,309 [3,334; 26,108; 204,426] (eq.: 755 [56, 435,3407] hours)	

(Continued)

Table I (Continued)

Input	Definition [Unit]	Distribution	Mean [0.025; 0.5; 0.975 Quantiles]	Reference
D_G	Time to 1 log reduction of GEC NoV on gloves [minutes]	$lognormal(11.02; ResSurv)$	106,006 [7,801; 61,083; 478,285] (eq.: 1,766 [130, 1,018, 7,971] hours)	
D_F	Time to 1 log reduction of GEC NoV on food [minutes]	$lognormal(9.57; ResSurv)$	24,866 [1,829; 14,328; 112,191] (eq.: 414 [30, 238, 1,870] hours)	
ResSurv	Residuals of the meta-analysis for survival	$cste(1.05)$	–	
Inputs Associated with Disinfection				
P_{dis}	Probability of using a type of disinfectant in store (quaternary ammonium; chlorine)	$(0.6; 0.4)$	–	
$D_{iss,QUAT}$	GEC NoV reduction due to disinfection of hard surfaces with quaternary ammonium	$log_{10}(inv.logit(norm(-3.44, ResDis)))$	–1.51 [–4.55; –1.51; –0.01]	Meta-analysis: 75–79, 85, 93, 94, 96–105
$D_{iss,QUAT}$	GEC NoV reduction due to disinfection of hard surfaces with chlorine	$log_{10}(inv.logit(norm(-6.02, ResDis)))$	–2.61 [–5.67; –2.61; –0.13]	
$D_{iss,QUAT}$	GEC NoV reduction due to disinfection of hands with quaternary ammonium	$log_{10}(inv.logit(norm(-6.16, ResDis)))$	–2.67 [–5.73; –2.67; –0.15]	
$D_{iss,QUAT}$	GEC NoV reduction due to disinfection of hands with chlorine	$log_{10}(inv.logit(norm(-8.74, ResDis)))$	–3.80 [–6.85; –3.80; –0.81]	
ResDis	Residuals of the meta-analysis for disinfection	$cste(3.59)$		

Cste: constant; BetaPert: betapert distribution with shape parameter 4⁽³⁰⁾, $X \sim lognormal(a, b)$ if $\ln(X) \sim normal(mean=a, SD=b)$; $inv.logit(x) = \exp(x)/(1+\exp(x))$.

assemblage and preparation events were similar (Fig. 1). First, an FCS for food preparation/assembly was randomly assigned to the employee. Then for each ingredient, contacts between FCS, gloves/hands, or food occurred twice in a random sequence. Contact with NFCS occurred once during each random sequence. Food employees prepared 20 pieces of one ingredient per minute (e.g., sliced 20 tomato slices). An additional cooking step was included for one of the ingredients (e.g., bacon), eliminating any norovirus present on this ingredient at the time. A pace of one sandwich assembled per minute was considered. If at least one type of food ingredient was not available, a sandwich could not be assembled; the food employee would instead prepare this type of ingredient and then return to sandwich preparation.

2.1.3. Food Employee Practices

The behavior of food employees was included in the model using data from surveys.^(17,20–22) Frequency of handwashing when engaging in food preparation was based on data from CDC,⁽²²⁾ which reported that food employees washed their hands in 27% of activities in which they should have. Regarding glove-use frequency when touching RTE food (Table I), food employees reported that they never (33%), sometimes (6%), almost always (14%), or always (40%) wore gloves. Food employees changed gloves 37% of the time when engaging in food preparation, based on a CDC report.⁽²¹⁾ We note that use of food contact utensils such as spatulas or tongs instead of gloves were not modeled because of limitations in data on the frequency of use and efficiency of transfer to and from these objects.

Some individuals infected with norovirus will develop asymptomatic infection, while others will develop symptoms of vomiting and diarrhea. In the model, two food employees (FE-2 and FE-3) were not sick but had an independent probability to be asymptomatic shedders of 15%.⁽²³⁾ Only one employee (FE-1) was assumed to be symptomatic. The duration of the symptoms was modeled using a gamma distribution so that the mean duration was 49 hours with a standard deviation of 40 hours.⁽²⁴⁾ We assumed that a symptomatic food employee (FE-1) always experienced diarrhea. The number of defecations per day was assumed to be 4.5 on average per shift at the onset of the symptoms,⁽²⁴⁾ and this average was reduced by two each day until the end of the symptomatic illness. Seventy-two percent of symp-

tomatic cases experienced vomiting,⁽¹⁰⁾ with three vomiting events on the first day, two vomiting events on the second day, and one vomiting event on the third day, if still sick. Other parameters regarding the concentration of norovirus in feces and vomit are described in Table I.

In order to protect consumers from symptomatic food employees that may have an undiagnosed norovirus infection (which represent the majority of norovirus cases since most will not be specifically diagnosed), the FDA Food Code recommends an exclusion period of food employees from work when they are experiencing vomiting and/or diarrhea symptoms and for at least 24 hours after the symptoms resolve in the absence of confirmation of the norovirus infection.⁽¹⁴⁾ However, food employees do not always comply with this exclusion period. Surveys have shown that, for various reasons, some food employees have worked while ill.⁽²⁵⁾ A survey by Sumner *et al.*⁽²⁶⁾ reported that 20% of food employees declared having experienced vomiting or diarrhea while working during the year preceding the interview. We included a rate of compliance P_c in the model to account for ill employees (FE-1) who reported illness and complied with the exclusion period and food employees who did not report or did not comply with the exclusion period and may have worked while ill. We considered that FE-1 was ill and could belong to four categories (“compliant,” “noncompliant 1,” “noncompliant 2,” and “noncompliant 3”) to accurately represent compliance with the exclusion guidance, as presented in Fig. 2:

- Compliant ill food employee: Reported illness symptoms, stayed away from work and reported symptom resolution after end of symptoms, stayed away from work during an additional postsymptomatic exclusion period (24/48 hours depending on the scenario) (i.e., did not work while ill).
- Noncompliant ill food employee; type 1 (“noncompliant 1”): Reported illness symptoms, stayed away from work at the beginning of the symptomatic period but reported symptom resolution prematurely, stayed away from work during an additional exclusion period (24/48 hours depending on the scenario) and came back after symptom resolution (i.e., did not work while ill).
- Noncompliant ill food employee; type 2 (“noncompliant 2”): Reported illness symptoms, stayed away from work at the beginning of

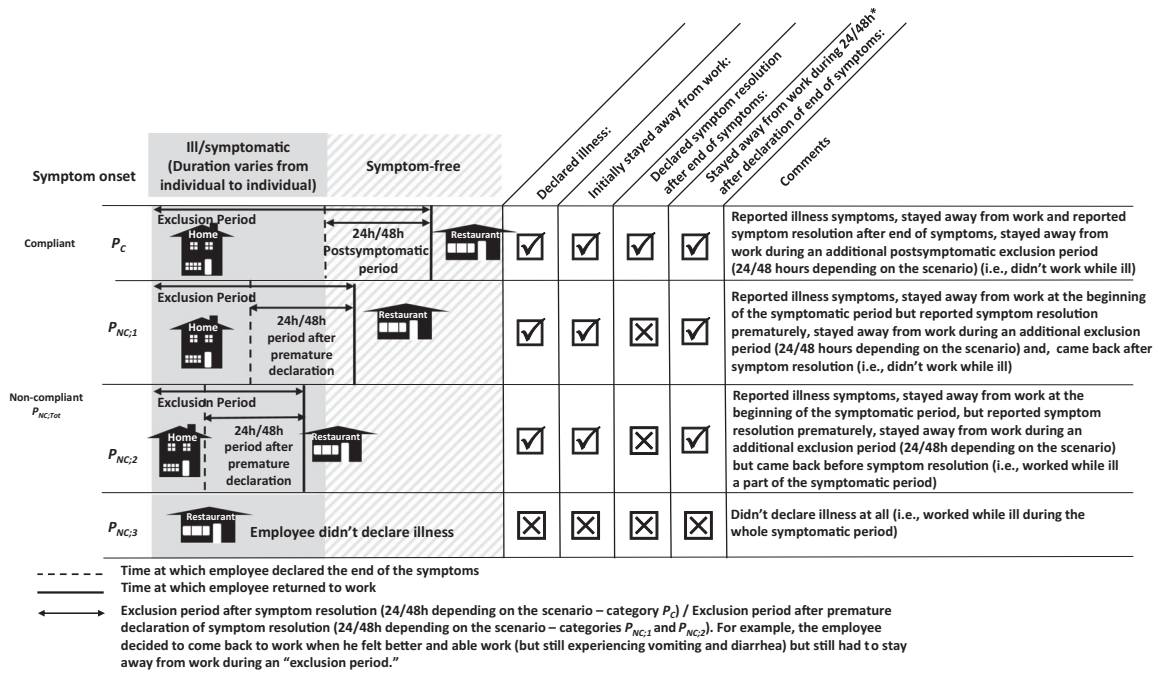


Fig. 2. Graphical illustration of food employee behavior regarding declaration of illness/symptom resolution and compliance with the exclusion period. Note that the duration of the sickness (from symptom onset to symptom resolution) varies from one simulation to the other in the model.

the symptomatic period, but reported symptom resolution prematurely, stayed away from work during an additional exclusion period (24/48 hours depending on the scenario) but came back before symptom resolution (i.e., worked while ill a part of the symptomatic period).

- Noncompliant ill food employee; type 3 (“non-compliant 3”): Did not declare illness at all (i.e., worked while ill during the whole symptomatic period).

Each category is represented by a proportion with:

$$P_{NC} = 1 - P_C = P_{NC1} + P_{NC2} + P_{NC3}, \quad (1)$$

where P_{NC} is the proportion of noncompliant food employees, P_C is the proportion of compliant food employees, and $P_{NC,i}$ is the proportion of noncompliant food employees of type i . We assumed that the category “noncompliant 3” represented 50% of the proportion of total noncompliant:

$$P_{NC3} = 0.5 \times P_{NC} = P_{NC1} + P_{NC2}. \quad (2)$$

Food employees of categories “noncompliant 1” and “noncompliant 2” declared premature symptom resolution within 24 hours after symptom

onset, according to a uniform distribution $\text{Uniform}(0;24)(\text{hours})$, with an average of 12 hours. The values of P_{NC2} and P_{NC3} are determined from the exclusion period time and the cumulative function of the gamma distribution of symptom duration. For an exclusion period of 24 hours, food employees will come back to work at time $12 + 24 = 36$ hours on average. According to the gamma distribution used to model the duration of symptoms, the symptoms are resolved for 46% of food employees at 36 hours. Then:

$$P_{NC1} = p_{\text{asympt};36h} \times 0.5 \times P_{NC}, \quad (3)$$

where $p_{\text{asympt};36h} = 0.46$ is the proportion of asymptomatic food employees at $t \geq 36$ hours according to the considered gamma distribution and

$$P_{NC2} = (1 - p_{\text{asympt};36h}) \times 0.5 \times P_{NC}. \quad (4)$$

This dynamic of symptomatic illness leads to a reduction of symptoms (diarrhea, vomiting) with time, and thus as a function of the exclusion period. As an example, for an extended exclusion period of 48 hours, food employees will come back to work at time $12 + 48 = 60$ hours on average and $p_{\text{asympt};60h} = 70\%$.

2.2. Norovirus Transfer in the Retail Environment

2.2.1. Sources of Contamination

Initial transfer of norovirus from infected food employees to the retail environment takes place in the restrooms via defecation (symptomatic and asymptomatic food employees) and vomiting events (symptomatic food employees). Hand contamination during defecation was considered for symptomatic and asymptomatic food employees. The level of norovirus on hands NoV_H after defecation and vomit were calculated using:

$$NoV_H = NoV_{Sh} \times m_H \quad [\text{GECNoV}], \quad (5)$$

$$NoV_H = NoV_V \times V_H \quad [\text{GECNoV}], \quad (6)$$

where NoV_{Sh} is the level of norovirus shed by the food employee at that time, m_H is the mass of feces on hands, NoV_V is the level of norovirus in vomit, and V_H the volume of vomit on hands after vomit.

In addition, for symptomatic employees, norovirus aerosolization within restrooms, and subsequent contamination of the environment ($NoV_{Env,t=0}$) within the restrooms, was considered for toilet flushing of diarrheal events and during vomiting, using data extracted from Barker *et al.*⁽²⁷⁾ and Tung-Tompson *et al.*,⁽²⁸⁾ respectively.

$$NoV_{Env,t=0} = V_R \times Tr_{Env,d} \quad [\text{GECNoV}], \quad (7)$$

$$NoV_{Env,t=0} = V_R \times Tr_{Env,V} \quad [\text{GECNoV}], \quad (8)$$

where V_R is the restroom volume and $Tr_{Env,d}$ and $Tr_{Env,V}$ are the transfer rate of norovirus to the restroom environment during diarrheal and vomiting events, respectively. The aerosol contaminated the door handle and the faucet handle through sedimentation of suspended norovirus on those surfaces. A sedimentation rate of $1 \log_{10}$ of norovirus per $D_{sed} = 30$ minutes is used in the model.⁽²⁷⁾ The total amount of norovirus during a sedimentation time Δt (minutes) was simulated with:

$$NoV_{sed} \sim \text{binomial} \left(NoV_{Env,t=0}, 1 - 10^{-\frac{\Delta t}{D_{sed}}} \right) \quad [\text{GECNoV}]. \quad (9)$$

The amount of norovirus on the faucet handle NoV_f was calculated using a binomial distribution:

$$NoV_f \sim \text{binomial} \left(NoV_{sed}, \frac{S_f}{S_R} \right) [\text{GECNoV}], \quad (10)$$

where S_f is the surface of the faucet handle (assumed equal to the hand surface S_H) and S_R is the surface of the restrooms. The same methodology was used for the contamination of the door handle. Self-contamination of hands and transfer between hands, faucet, and door handle were also considered (Table I).

2.2.2. Norovirus Transfer and Survival

For each physical contact between two objects/surfaces, the quantities of norovirus transferred from surface S1 to surface S2, $NoV_{S1;S2}$, and from surface S2 to surface S1, $NoV_{S2;S1}$, were calculated using a binomial distribution:

$$NoV_{S1;S2} \sim \text{binomial} (NoV_{S1;t}, Tr_{S1;S2}) \quad [\text{GECNoV}], \quad (11)$$

$$NoV_{S2;S1} \sim \text{binomial} (NoV_{S2;t}, Tr_{S2;S1}) \quad [\text{GECNoV}], \quad (12)$$

where $NoV_{S1;t}$ and $NoV_{S2;t}$ are the respective levels of norovirus on surface S1 and S2 at the time t of the contact and $Tr_{S1;S2}$ is the transfer probability of norovirus. The levels of norovirus $NoV_{S1;t+1}$ and $NoV_{S2;t+1}$ on surfaces S1 and S2 after the contact were calculated with:

$$NoV_{S1;t+1} = NoV_{S1;t} - NoV_{S1;S2} + NoV_{S2;S1} \quad [\text{GECNoV}], \quad (13)$$

$$NoV_{S2;t+1} = NoV_{S2;t} - NoV_{S2;S1} + NoV_{S1;S2} \quad [\text{GECNoV}]. \quad (14)$$

The survival on surfaces during a time step was calculated using a log linear reduction model:

$$NoV_{S1;t+1} \sim \text{binomial} \left(NoV_{S1;t}, 1 - 10^{-\frac{\Delta t}{D_{S1}}} \right) \quad [\text{GECNoV}], \quad (15)$$

where Δt (minutes) is the time step and D_{S1} is the time (minutes) for a $1 \log_{10}$ reduction of norovirus on the surface S1.

The level of norovirus $NoV_{S1;t+1}$ after disinfection of the surface S1 was calculated with:

$$NoV_{S1;t+1} \sim \text{binomial} (NoV_{S1;t}, 1 - 10^{-Dis}) \quad [\text{GECNoV}], \quad (16)$$

where Dis is the norovirus reduction due to disinfection. Removal of norovirus from hands by handwashing is defined similarly with:

$$NoV_{S1;t+1} \sim NoV_{S1;t} - binomial(NoV_{S1;t}, 1 - 10^{-D_{WH}}) [GECNoV]. \quad (17)$$

2.3. Data Sources

A meta-analysis was conducted to collect data from peer-reviewed articles for survival, transfer, handwashing, and disinfection through the online libraries PubMed and Web of Science in field tags “titles and abstracts” and using the Boolean logic {(norovirus OR norovirus surrogates) AND (inactivation OR persistence OR survival OR disinfection OR transfer OR wash)}. A total of 846 abstracts were studied, and 330 articles were screened according to the relevance of the abstract. Articles were selected for transfer from surface to surface (10 articles), persistence on surfaces (16 articles), handwashing (16 articles), and disinfection (18 articles) based on the quality of the data, the validity of the surrogates, and the methodology.

The inclusion criteria included a variety of surrogate viruses. These surrogates have been extensively described in the literature as having similar properties with norovirus as far as some of their morphological, cultural, genetic, and structural characteristics. In addition to norovirus genogroup I (GI) and genogroup II (GII), the surrogates used were the feline calicivirus (FCV F9 or KS20), murine norovirus (MNV-1 or MNV99), and the most recently discovered Tulane virus (TV). Additionally, nontraditional surrogates outside the calicivirus family, such as rotavirus, poliovirus, hepatitis A virus, or even nonanimal viruses like F-specific RNA coliphage MS2, were also included for certain studies. Particularly, the transfer and handwashing analysis data were supplemented with those from other viruses as these events are mainly physical and assumed independent of the physiology of each particular virus.

Detection through reverse transcriptase-polymerase chain reaction (RT-PCR) is currently the only method to quantify norovirus titer, which is expressed in terms of genomic copies, or genome equivalents (RNA copies or transcripts if they were generated by real-time system or just RT-PCR amplifiable units for conventional platforms). Data for both norovirus genogroups GI and GII were extracted, where available, but not reported separately.

For all the surrogate viruses, as they are all culturable, data generated by both RT-PCR detection and infectivity assays (plaque assay and TCID50) were extracted. All data were expressed as genomic copy equivalents of norovirus (GCE NoV) as, currently, there are no infectivity data available for norovirus. Publications that did not adequately describe methodologies and did not include controls to justify any heterogeneity among the test viruses were excluded. Regarding disinfection, only disinfectants typically used in food service (i.e., quaternary ammonium and sodium hypochlorite) were included.

Additional information on the data collected for the meta-analysis and fitted models is presented in Table II. Models were fitted using fixed and mixed effects linear models. The specific study from which a set of data was collected was used as a random effect in mixed models. Models were compared using the F -test (95% confidence interval) or likelihood ratio test when nested. When two models were not nested, the Akaike information criterion (AIC)⁽²⁹⁾ was used to select the preferred one. Besides handwashing, for which a $BetaPert$ distribution⁽³⁰⁾ was fitted, mixed effect models were preferred to fixed effect models because of the nonnegligible impact of the study effect (results not shown). Moreover, mixed effect models allow generalizing the results to a population of studies that were not included in the analysis.⁽³¹⁾ The factors resulting from the meta-analysis and used in the model to predict transfer, disinfection, handwashing, and survival of norovirus are shown in Table I.

2.4. Customer Probability of Infection

A dose-response model was used to evaluate the number of infected customers and the number of illnesses resulting from the consumption of prepared sandwiches in the population. Teunis *et al.*⁽³²⁾ developed a dose-response model for norovirus from experimental infection data. For a discrete number of norovirus, as considered in the model, this dose-response model can be written:⁽³³⁾

$$\text{Prob}\{\text{infection}|NoV_i, \alpha, \beta\} = 1 - \frac{\Gamma(\alpha + \beta) \Gamma(\beta + NoV_i)}{\Gamma(NoV_i) \Gamma(\alpha + \beta + NoV_i)},$$

where $\Gamma(x)$ is the gamma function, NoV_i is the number of ingested norovirus, $\alpha = 0.040$, and $\beta = 0.055$. These parameters were estimated for a susceptible (positive secretor, Se^+) population. The probability of illness given infection for an Se^+ individual at random ingesting NoV_i norovirus is:

$$\text{Prob}\{\text{illness}|\text{infection}, NoV_i, \eta, r\} = 1 - (1 + \eta NoV_i)^{-r},$$

Table II. Details of the Meta-Analyses

Meta-Analysis (Number of Selected Articles/ Observations)	Dependent Variable ^a	Virus and Surrogates	Considered Independent Variables					Model	Model Normalization
			Method	Type of Surface	Surface Characteristic	Temperature	Disinfectant		
Transfer (10/420 data points)	$Tr_{SI, S2}$	Norovirus (GI, GII), FCV, MNV1, MS2, Tulane, HAV	Plaque assay Real-time RT-PCR	Hard surface, hand, glove, nonmeat food, meat	Wet, dry	NA	NA	Mixed effect	for GEC NoV at: Wet, real-time RT-PCR, NoV
Persistence (16/138 curves)	D_S	Norovirus (GI, GII), FCV, MNV1, MS2, Tulane, MS2	Plaque assay Real-time RT-PCR	Hard surface, hand, gloves, nonmeat food, meat	NA	Refrigerated, room	NA	Mixed effect	for GEC NoV at: Room temperature and real-time RT-PCR
Disinfection (18/249 data points)	Dis	Norovirus (GI, GII), FCV, MNV1, MNV99, MS2, Tulane	Plaque assay Real-time RT-PCR TCID50	Hard surface food, meat	Wet, dry	NA	Quaternary ammo- nium, chlorine	Mixed effect	for GEC NoV at: Wet, real-time RT-PCR, NoV
Handwashing (16/50 data points)	D_{WH}	Norovirus (GI, GII), FCV, MNV1, MNV99, MS2, Tulane, HAV, Rotavirus, Poliovirus	Plaque assay Real-time RT-PCR TCID50	Hand	NA	NA	NA	<i>BetaPert</i> (0.17; 0.45; 6; shape=4)	NA

^aSee Table I. FCV: Feline calicivirus, MNV: murine norovirus, MS2: F-specific RNA coliphage MS2, Tulane: Tulane virus, HAV: hepatitis A virus, NA: nonavailable.

where $r = 2.55 \times 10^{-3}$ and $\eta = 0.086$ from Teunis *et al.*⁽³²⁾ We considered that 80% of the population was Se^+ and that the remaining population was fully resistant to the infection.⁽³⁴⁾

As an alternative to the estimate of number of infected and sick customers, we provide the proportion of servings including more than 0, 100, and 1,000 GEC NoV as an indicator of the potential of norovirus infection from consumption of sandwiches by a susceptible population prepared in the setting.

2.5. Baseline and Scenarios

A total of 22 scenarios describing specific prevention strategies (Table III) and presented in Table IV were compared to evaluate the impact of model parameters on the risk of illness associated with norovirus contamination of foods served in this setting.

Scenario 1 is the baseline of this study in the sense that it represents existing knowledge of current practices and food employee behavior in food establishments. FE-1 was ill and belonged to categories “compliant,” “noncompliant 1,” “noncompliant 2,” and “noncompliant 3” in 74%, 6.0%, 7.0%, and 13% of simulated stores, respectively. FE-2 and FE-3 were asymptomatic shedders in 15% of the stores. Restrooms, NFCS, and FCS were washed every morning before the beginning of the shift. FCS were washed every four hours. Current practices based on existing knowledge were used to describe the frequency of handwashing in restrooms, and the frequency of handwashing, wearing, and changing of gloves when engaging in food preparation (Table I).

A scenario in which FE-1 was not ill (but could be asymptomatic shedder as FE-2 and FE-3; scenario 2—lower baseline) and a scenario in which FE-1 systematically worked while ill during the whole symptomatic period (scenario 3—upper baseline) were included.

The 19 other scenarios were variations around the baseline to test the impact of different parameters of the model corresponding to specific prevention strategies and their compliance to reduce norovirus transmission (Tables III and IV). The impacts of extending the exclusion period after symptom resolution from 24 to 48 hours and associated compliance with this exclusion period was studied in scenarios 4–9. The impacts of the frequency of handwashing in restrooms (scenario 10), no barehand contact (scenario 11), compliance with handwashing and glove use when engaging in food preparation according to

the Food Code recommendation (scenario 18), and handwashing efficacy were also studied (scenarios 18 and 19). The impact of food employee restriction was also evaluated (scenarios 14–17).

2.6. Implementation of the Model

This model was written in the open-source language R version 3.2.4 (R Core Team).⁽³⁵⁾ In view of the numerous scenarios and the discrete event framework of the model, the code was written to be launched on parallelized processors using high-performance computing tools (Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, FDA, Silver Spring, MD, USA). Nonetheless, the code can be run on a desktop. For each tested scenario, 1,000 stores in which the actions of the employees are different were simulated. The model was vectorized to simulate 1,000 independent teams of three food employees for each of the 1,000 stores, each team doing the same events at the same time, but, for example, with different transfer coefficients or handwashing efficacy, for each of the 1,000 stores, resulting in a total of 1,000,000 simulated stores. Variability in (asymptomatic) infection of FE-2 and FE-3, in different transfer coefficients sampled at each contact, as well as the probability to wear gloves and wash hands was considered for each food establishment team. A thousand stores serving 400 sandwiches per day during five days were studied. The total number of servings for each of the 22 scenarios is 2×10^9 . The convergence of all output was checked graphically.

The code is available on request to the corresponding author.

3. RESULTS

The proportion of contaminated servings (prevalence), the proportion of highly contaminated servings (>100 and $>1,000$ GEC NoV), and the mean number of infected and ill customers (according to the Teunis *et al.*⁽³²⁾ dose response model) for each of the 22 scenarios are presented in Table V. The estimated mean number of infected customers and the proportion of highly contaminated servings ($>1,000$ GEC NoV) for each scenario were normalized to the scenario 1 (baseline of this study), to provide a relative measure. In addition to the mean, the 90% variability interval, i.e., the 5th and 95th percentiles of the distribution of the number of infected and sick customers over 1,000,000 stores, is presented in

Table III. Overview of the Prevention Strategies and Factors Studied

Preventive Strategy	Factors	Scenarios ^a
Exclusion period from work (time to stay away from work while symptomatic and after declaration of symptom resolution)	Duration (symptomatic period + 24 hours after symptom resolution, symptomatic period + 48 hours after symptom resolution) and compliance	1, 3, 4, 5, 6, 7, 8, 9, 15, 17
Restroom cleaning	Frequency	10
No hand contact with faucet and door in restrooms	–	13
Restriction from food preparation area, no contact with food	Duration (24 hours, 48 hours)	14, 15, 16, 17
No barehand contact with food (using gloves in food preparation area)	Frequency (wear and change, compliance according to Food Code when engaging in food preparation)	11, 18
Handwashing	Frequency (compliance in restrooms and before engaging in food preparation and while changing gloves) and efficacy	12, 18, 19, 20

^aAll details of scenarios are described in Table III. All scenarios are to be compared with scenario 1 (baseline) representing existing knowledge of current practices and food employee behavior in retail food establishment.

Table V. Fig. 3 illustrates model results on the relative amount of norovirus transmitted via each pathway in the model for three representative scenarios.

In the baseline scenario, including an exclusion period of 24 hours after symptom resolution and a compliance rate P_C of 74%, the expected proportion of contaminated servings (>0 GEC NoV) is 9.7% and the proportion of highly contaminated servings ($> 1,000$ GEC NoV) is 0.5%, leading to an expected number of infected and sick customers of 74 and 1.7, respectively, over a total number of 2,000 servings. In this scenario, as is true for all scenarios, a high variability in the number of contaminated servings and in the number of resulting infections and illnesses is observed from store to store, as a function of the specific set of parameters characterizing this store. As an example, the 5th, the median, and the 95th percentiles of the numbers of infected customers estimated from the 1,000,000 simulated stores are 2.1, 48, and 233.7, respectively, in the baseline. This variability reflects notably the variability in the characteristics of the sick food employee (illness duration, shedding level, compliance with exclusion period).

In the lower baseline (scenario 2), in which no food employee is sick but 15% are asymptomatic shedders, the proportion of contaminated servings was evaluated at 1.3%, the proportion of highly contaminated servings at 0.04%, and the mean number of infections and illness at 9.6 and 0.1, respectively. In the upper baseline (scenario 3), where all ill FE-1 did not declare illness and worked while ill (“*noncompli-*

ant 3”), the mean number of infected customers increased by 226% compared to the baseline scenario.

The three prevention strategies leading to the smallest numbers of infected customers included either full compliance with handwashing and glove use and no barehand contact (scenario 18, estimated as 58% of infected customers relative to the baseline) or increased handwashing efficiency (additional 1 or 2 \log_{10} reduction during handwashing, scenarios 19 (62%) and 20 (53%), respectively).

Fig. 3 illustrates the norovirus transmission in the retail environment over five shifts for scenario 1 (baseline), scenario 13 (no contact between hands, faucet, and door in restrooms), and scenario 18 (full compliance with handwashing in restrooms, full compliance with handwashing, and wearing and changing gloves when engaging in food preparation), when FE-1 is sick and from category “*non compliant 2*,” with FE-2 and FE-3 nonill and nonshedders. The main route of contamination is the direct contact with hands in the restrooms (during defecation and vomiting) of the ill food employee (FE-1), with high levels of norovirus removed during handwashing ($>6 \log_{10}$ over five shifts) in the three scenarios. Fig. 3(a) shows a high level of norovirus transmission to FE-2 hands ($>5 \log_{10}$ over five shifts) and to FE-3 hands ($>4 \log_{10}$ over five shifts), while this food employee is not in contact with FCS and foods. Figs. 3(b) and 3(c) show that the level of transmission to food servings and nonill employees is reduced with prevention strategies.

Table IV. Scenarios

#	Descriptions of the Scenario	Compliance with $P_e/P_{NC,1}/P_{NC,2}$ $/P_{NC,3}$ (%)	Exclusion Period after Symptom Resolution	Compliance with Exclusion	Compliance with Handwashing in Restrooms	Compliance with Handwashing When Engaging in Food Preparation	Compliance with Wear Gloves When Engaging in Food Preparation	Compliance with Change Gloves When Engaging in Food Preparation
1	Baseline Scenario: FE-1 is ill, FE-2 and FE-3 are asymptomatic shedders in 15% of the stores. Restrooms and NFCs are washed before shift each day. FCSs are washed every four hours. Current practices regarding level of compliance with exclusion from work of 24 hours after symptom resolution + current practice with regard to level of compliance with handwashing in restrooms, handwashing when engaging in food preparation, and glove use when engaging food preparation. ^a	74 / 6.0 / 7.0 / 13	24 hours	Current ^a	Current	Current	Current	Current
2	Baseline + no ill food employees, FE-1, FE-2, and FE-3, are asymptomatic shedders in 15% of the stores.	–	–	–	Current	Current	Current	Current
3	Baseline + no compliance with exclusion from work (all sick employees work while ill, $P_{NC,3} = 100\%$).	0 / 0 / 0 / 100	–	None	Current	Current	Current	Current
4	Baseline + full compliance with exclusion from work while symptomatic and for 24 hours after symptom resolution.	100 / 0 / 0 / 0	24 hours	Full	Current	Current	Current	Current
5	Baseline + full compliance with exclusion from work while symptomatic and for 48 hours after symptom resolution.	100 / 0 / 0 / 0	48 hours	Full	Current	Current	Current	Current
6	Baseline + exclusion from work of 48 hours after symptom resolution.	74 / 9.1 / 3.9 / 13	48 hours	Current	Current	Current	Current	Current
7	Baseline + slight decreased compliance with exclusion from work while symptomatic and for 48 hours after symptom resolution.	64 / 12.6 / 5.4 / 18	48 hours	Decreased	Current	Current	Current	Current

(Continued)

Table IV (Continued)

#	Descriptions of the Scenario	Compliance with Exclusion Time $P_c/P_{NC,1}/P_{NC,2}$ $/P_{NC,3}$ (%)	Exclusion Period after Symptom Resolution	Compliance with Exclusion	Compliance with Handwashing in Restrooms	Compliance with Handwashing When Engaging in Food Preparation	Compliance with Wear Gloves When Engaging in Food Preparation	Compliance with Change Gloves When Engaging in Food Preparation
8	Baseline + significant decreased compliance with exclusion from work while symptomatic and for 48 hours after symptom resolution.	54 / 16.1 / 6.9 / 23	48 hours	Decreased	Current	Current	Current	Current
9	Baseline + increased compliance with exclusion from work while symptomatic and for 24 hours after symptom resolution.	84 / 3.7 / 4.3 / 8	24 hours	Increased	Current	Current	Current	Current
10	Baseline + restrooms washed every four hours.	74 / 6.0 / 7.0 / 13	24 hours	Current	Current	Current	Current	Current
11	Baseline + employees always wearing gloves without necessarily changing gloves.	74 / 6.0 / 7.0 / 13	24 hours	Current	Current	Current	Full	Current
12	Baseline + employees always wash their hands in the restrooms.	74 / 6.0 / 7.0 / 13	24 hours	Current	Full	Current	Current	Current
13	Baseline + touchless faucet and door handles in restrooms.	74 / 6.0 / 7.0 / 13	24 hours	Current	Current	Current	Current	Current
14	Baseline + FE-3 replacing FE-1, FE-1 is excluded from the food preparation area (no contact with food and FCS, contact with NFCS every 10 minutes) during 24 hours, FE-1 is not replaced when he does not declare illness at all (category noncompliant 3).	74 / 6.0 / 7.0 / 13	24 hours	Current	Current	Current	Current	Current
15	Baseline + 48-hour exclusion after symptom resolution + FE-3 replacing FE-1, FE-1 is excluded from the food preparation area (no contact with food and FCS, contact with NFCS every 10 minutes) during 24 hours, FE-1 is not replaced when he does not declare illness at all (category noncompliant 3).	74 / 6.0 / 7.0 / 13	48 hours	Current	Current	Current	Current	Current
16	Baseline + FE-3 replacing FE-1, FE-1 is excluded from the food preparation area (no contact with food and FCS, contact with NFCS every 10 minutes) during 48 hours, FE-1 is not replaced when he does not declare illness at all (category noncompliant 3).	74 / 6.0 / 7.0 / 13	24 hours	Current	Current	Current	Current	Current

(Continued)

Table IV (Continued)

#	Descriptions of the Scenario	Compliance with Exclusion Time $P_c/P_{NC,1}/P_{NC,2}$ $/P_{NC,3}$ (%)	Exclusion Period after Symptom Resolution	Compliance with Exclusion	Compliance with Handwashing in Restrooms	Compliance with Handwashing When Engaging in Food Preparation	Compliance with Wear Gloves When Engaging in Food Preparation	Compliance with Change Gloves When Engaging in Food Preparation
17	Baseline + full compliance with exclusion from work + FE-3 replacing FE-1, FE-1 is excluded from the food preparation area (no contact with food and FCS, contact with NFCS every 10 minutes) during 24 hours, FE-1 is not replaced when he does not declare illness at all (category noncompliant 3).	100 / 0 / 0 / 0	24 hours	Current	Current	Current	Current	Current
18	Baseline + full compliance of handwashing in restrooms + full compliance with handwashing in food preparation area, wearing and changing gloves when engaging in food preparation according to the FDA Food Code.	74 / 6.0 / 7.0 / 13	24 hours	Current	Full	Full	Full	Full
19	Baseline + improved handwashing efficacy (+1 log ₁₀).	74 / 6.0 / 7.0 / 13	24 hours	Current	Current	Current	Current	Current
20	Baseline + improved handwashing efficacy (+2 log ₁₀).	74 / 6.0 / 7.0 / 13	24 hours	Current	Current	Current	Current	Current
21	Baseline + considering all food employees who worked while symptomatic are noncompliant type 3 (i.e., all come to work during the whole symptomatic period).	80 / 0 / 0 / 20	24 hours	Equivalent ^b	Current	Current	Current	Current
22	Baseline + considering all food employees who worked while symptomatic are noncompliant type 3 (i.e., come to work during the whole symptomatic period) + exclusion from work of 48 hours after symptom resolution.	80 / 0 / 0 / 20	48 hours	Equivalent ^b	Current	Current	Current	Current

^aCurrent: Based on observational surveys; see Table I for the value of parameters; -; not used.

^bIn the baseline and in scenarios 21 and 22, 20% of food employees came to work while symptomatic and 80% came to work after symptom resolution. In the baseline, categories $P_{NC,2}$ (7%) and $P_{NC,3}$ (13%) came to work while symptomatic (7+13=20%), and categories P_c (74%) and $P_{NC,1}$ (6%) came back to work after symptom resolution (74 + 6 =80%).

Table V. Simplified Description and Results of the Scenarios (Scenario 1 Is Considered as the Baseline)

#	Compliance with Exclusion Period $P_c/P_{NC1}/P_{NC2}$ $/P_{NC3}$ (%)	Exclusion Period after Symptom Resolution	Simplified Description of the Scenario	Proportion of Servings (%) with			Number of (on 2,000 Servings)			%Baseline Number of Servings >1,000
				> 0 NoV	> 100 NoV	> 1,000 NoV	Infected Customers, Mean [90% Variability Interval]	Sick Customers, Mean [90% Variability Interval]	%Baseline Number of Infected Customers	
1	74 / 6.0 / 7.0 / 13	24 hours	Baseline	9.7	1.7	0.54	74.0 [2.1, 233.7]	1.7 [0.0, 7.9]	100	100
2	-	-	FE-1 not sick, 15% asymptomatic shedder (lower baseline)	1.3	0.1	0.04	9.6 [0.0, 61.0]	0.1 [0.0, 0.4]	13	7
3	0 / 0 / 0 / 100	-	FE-1 always work while ill (upper baseline)	21.5	4.9	1.76	167.4 [29.0, 357.7]	5.2 [0.1, 17.2]	226	324
4	100 / 0 / 0 / 0	24 hours	Full exclusion compliance, 24 hours	7.4	1.0	0.31	55.8 [1.4, 176.4]	1.0 [0.0, 4.8]	75	58
5	100 / 0 / 0 / 0	48 hours	Full exclusion compliance, 48 hours	6.8	0.9	0.26	51.2 [1.1, 165.5]	0.8 [0.0, 4.1]	69	48
6	74 / 9.1 / 3.9 / 13	48 hours	Exclusion extension	8.9	1.5	0.47	67.9 [1.7, 222.8]	1.5 [0.0, 7.1]	92	87
7	64 / 12.6 / 5.4 / 18	48 hours	Exclusion extension, slight decrease in compliance	9.7	1.7	0.55	74.2 [1.8, 240.3]	1.7 [0.0, 8.1]	100	101
8	54 / 16.1 / 6.9 / 23	48 hours	Exclusion extension, significant decrease in compliance	10.5	1.9	0.63	80.5 [2.1, 255.1]	1.9 [0.0, 9.1]	109	116
9	84 / 3.7 / 4.3 / 8	24 hours	Improved compliance	8.7	1.4	0.45	66.3 [1.8, 211.6]	1.4 [0.0, 6.6]	90	82
10	74 / 6.0 / 7.0 / 13	24 hours	Wash restrooms every four hours	9.4	1.6	0.53	71.7 [2.1, 225.4]	1.6 [0.0, 7.7]	97	98
11	74 / 6.0 / 7.0 / 13	24 hours	No barehand contact, 100% wear gloves, current compliance with changing gloves	11.1	1.7	0.49	84.1 [1.4, 266.9]	1.6 [0.0, 7.8]	114	91
12	74 / 6.0 / 7.0 / 13	24 hours	Full handwashing compliance in restrooms, 100% wash hands in restrooms	9.2	1.5	0.48	69.9 [1.7, 223.7]	1.5 [0.0, 7.2]	94	89
13	74 / 6.0 / 7.0 / 13	24 hours	Touchless faucet and door in restroom	7.3	1.3	0.46	55.8 [0.7, 191.3]	1.4 [0.0, 6.8]	75	85
14	74 / 6.0 / 7.0 / 13	24 hours	Food handling restriction, FE-3 replaces FE-1 during 24 hours	10.1	1.7	0.56	77.0 [2.1, 237.3]	1.7 [0.0, 8.2]	104	103

(Continued)

Table V (Continued)

#	Compliance with Exclusion Period $P_c/P_{NC1}/P_{NC2}$ / P_{NC3} (%)	Exclusion Period after Symptom Resolution	Simplified Description of the Scenario	Proportion of Servings (%) with			Number of (on 2,000 Servings)		%Baseline Number of Infected Customers	%Baseline Number of Servings >1,000
				> 0 NoV	> 100 NoV	> 1,000 NoV	Infected Customers, Mean [90% Variability Interval]	Sick Customers, Mean [90% Variability Interval]		
15	74 / 6.0 / 7.0 / 13	48 hours	Food handling restriction, FE-3 replaces FE-1 during 24 hours	9.3	1.5	0.48	70.5 [1.7, 225.8]	1.5 [0.0, 7.3]	95	89
16	74 / 6.0 / 7.0 / 13	24 hours	Food handling restriction, FE-3 replaces FE-1 during 48 hours	10.4	1.8	0.57	79.3 [2.1, 241.3]	1.8 [0.0, 8.5]	107	105
17	100 / 0 / 0 / 0	24 hours	Full exclusion compliance + food handling restriction, FE-3 replaces FE-1 during 24 hours	7.7	1.1	0.33	58.5 [1.5, 181.9]	1.0 [0.0, 5.0]	79	60
18	74 / 6.0 / 7.0 / 13	24 hours	100% wear gloves, 100% change gloves, 100% wash hands while changing gloves and in restrooms	5.7	0.7	0.17	42.6 [0.0, 160.0]	0.6 [0.0, 3.1]	58	31
19	74 / 6.0 / 7.0 / 13	24 hours	Handwashing efficacy (additional 1log ₁₀ reduction)	6.1	0.8	0.25	45.9 [0.7, 152.0]	0.8 [0.0, 3.9]	62	46
20	74 / 6.0 / 7.0 / 13	24 hours	Handwashing efficacy (additional 2log ₁₀ reduction)	5.2	0.7	0.20	38.9 [0.3, 133.3]	0.7 [0.0, 3.3]	53	37
21	80 / 0 / 0 / 20	24 hours	Baseline + considering only compliant and noncompliant type 3 (did not declare illness and worked while symptomatic)	10.1	1.8	0.6	77.3 [2.1, 246.9]	1.8 [0.0, 8.7]	104	111
22	80 / 0 / 0 / 20	48 hours	Baseline + considering only compliant and noncompliant type 3 (did not declare illness and worked while symptomatic) + 48 hours	9.7	1.7	0.56	73.9 [1.7, 243.4]	1.7 [0.0, 8.3]	100	100

P_c : Proportion of compliant food employees regarding the Food Code exclusion recommendation; P_{NC1} : proportion of noncompliant food employee type 1, P_{NC2} : proportion of noncompliant food employee type 1, P_{NC3} : proportion of noncompliant food employee type 1 (see text and Fig. 2 for further details). FE-1: food employee 1 (see text and Fig. 2 for further details). The 90% variability interval represents the 5th and the 95th percentiles of the distribution of the number of infected and sick customers over 1,000,000 stores.

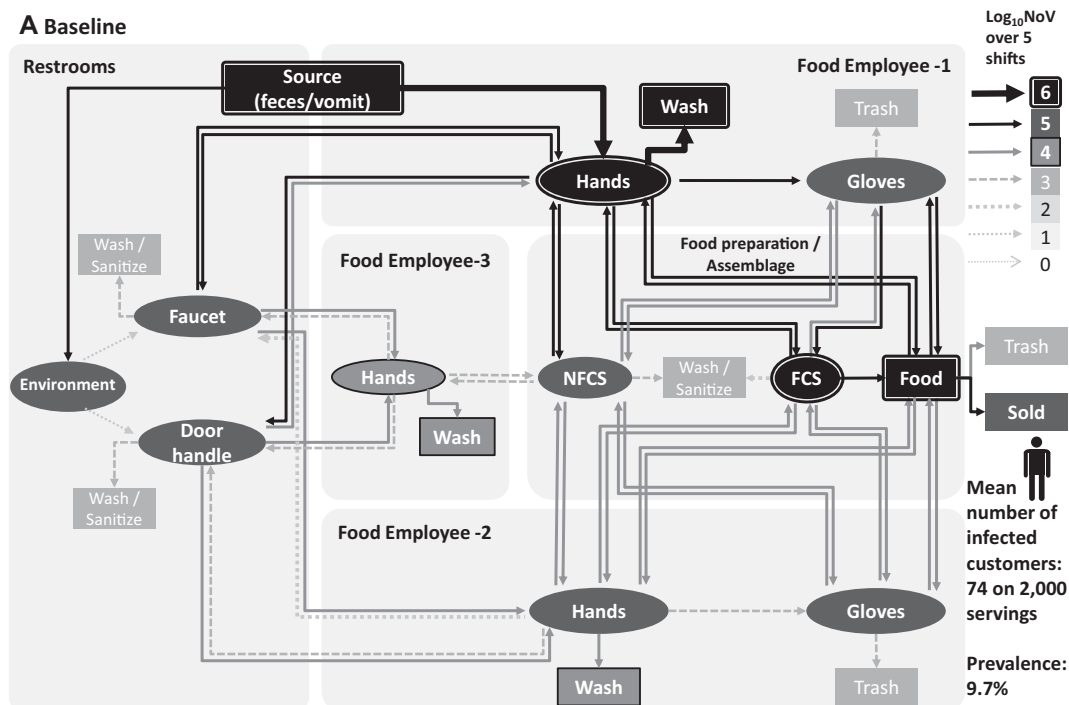


Fig. 3. Transmission of norovirus in the retail environment for three scenarios: (A) baseline, (B) scenario 13: no contact with the faucet and the door handle in the restrooms, and (C) scenario 18: no barehand contact, 100% compliance with changing gloves and handwashing while changing gloves according to the FDA Food Code. Food employee 1 is sick and considered *noncompliant* 2 regarding exclusion period, food employee 2 and food employee 3 are nonshedders. Thickness and gray level of arrows and objects represent the mean value of 1,000 iterations of norovirus transmitted over five shifts.

4. DISCUSSION

4.1. Limitations of the Model/Data

Federal agencies have recommended a number of prevention strategies for mitigating the risk of foodborne illness from norovirus in the retail setting. Even though these prevention strategies are each science based,⁽¹⁴⁾ it is difficult not only to measure their relative and combined impacts, but also the relative impact of their level of compliance on public health. Large-scale experiments would be the gold standard to obtain a better understanding of these impacts, but issues linked to ethics, feasibility, and costs limit the possibility of obtaining data through such experiments. Risk assessment models are a useful alternative in these situations and can inform risk managers on which prevention strategies can best reduce the considered risk of foodborne illness.⁽³⁶⁾

Building a model for all these settings was out of the scope of this article. The situation modeled here is typical of what can be observed and, even though the absolute estimate of the risk may vary

in different settings, the relative impact of various preventions and the conclusions of this study are expected to be generalizable. Presymptomatic shedding of the food employees,⁽³⁷⁾ transmission of norovirus between food employees, presence of infected and/or ill customers contaminating the environment, emesis in the kitchen or in the dining room, and presence of contaminated incoming products⁽³⁸⁻⁴⁰⁾ were not included in this study. These features could certainly be included in this discrete event framework.

In risk assessment models, limitations rely on included data and assumptions. The main assumptions of the model are presented in Table VI in three categories: assumptions related to employee practices/behavior and retail setting; assumptions related to illness and norovirus; and assumptions related to data and statistical analysis. It is important to ensure that model results are driven by robust literature data. Our model is based on an extensive literature review and meta-analyses regarding the survival, disinfection, and transfer of norovirus, hand hygiene, and food employee behavioral practices, including compliance with prevention strategies such

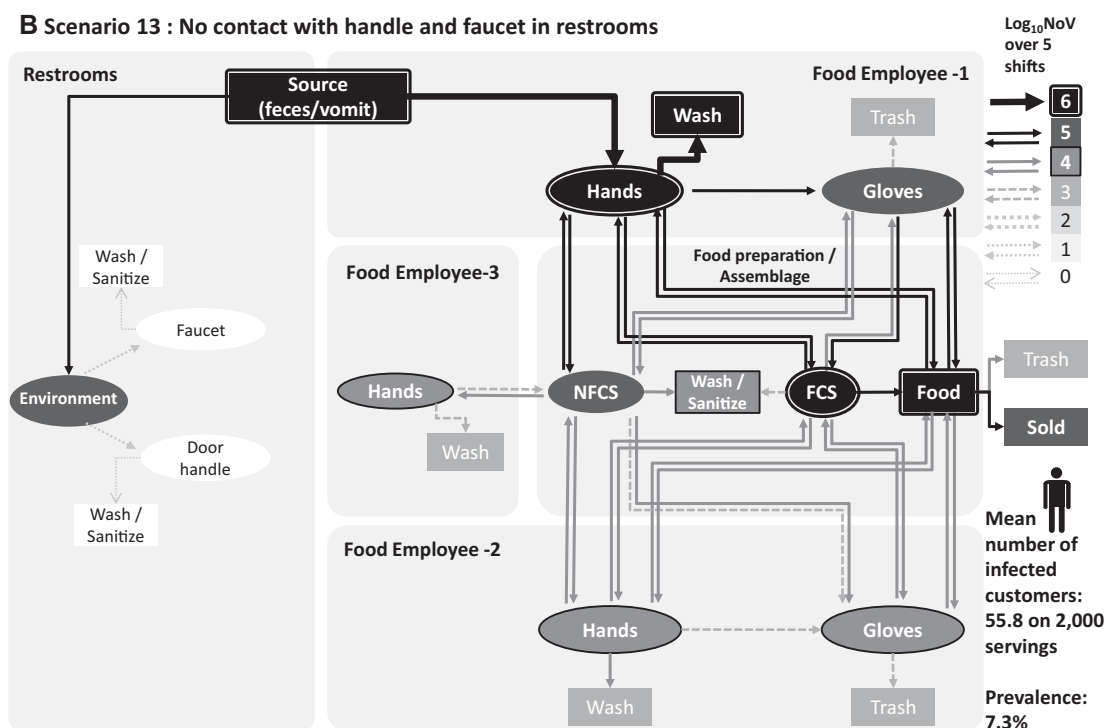


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as no barehand contact with RTE food. Although many efforts were made during the last decade to conduct observational studies of food employee behavior,^(20,25,26,41) some practices are not always observable and were assumed in this model such as the number of contacts between food, hands, FCS, and NFCS during food preparation.

The number of infected consumers was used as the major output of our risk assessment model. Teunis *et al.*'s⁽³²⁾ dose-response model leads to a high probability of infection for a low dose that plateaus when a high dose of norovirus is ingested. Indeed, according to this model, the probability of being infected following the ingestion of exactly one norovirus is 0.42; it is 0.67 following the ingestion of 10^6 norovirus for an Se+ individual, for a 50% human infectious dose (HID_{50}) of 18 norovirus. This dose-response relationship leads to almost direct proportionality between the estimated number of infected individuals and the prevalence of contaminated products (>0 GEC NoV). In contrast, according to these authors, the probability of illness once infected is low if infected with a low dose, and increases with the ingested dose. The probability of symptomatic illness once infected following the ingestion of one norovirus is 9.2×10^{-5} ; it is 0.33

following the ingestion of 10^6 norovirus. We took into account preexisting immunity of negative secretors (nonsusceptible population due to a lack of soluble blood group antigens that are believed to interact with the virus)⁽³⁴⁾ but did not include immunity associated with prior episodes of norovirus infection or the fact that genetic susceptibility factors of different norovirus strains may differ from what has already been described for the prototype virus.^(32,42) Actually, the accuracy and applicability of this dose-response model is still debated.⁽⁴²⁻⁴⁵⁾ Atmar *et al.*⁽⁴³⁾ suggested that the 50% human infectious dose for norovirus could be higher, i.e., 2,800 GEC NoV for Se+ individuals. We propose the prevalence of servings with more than 100 and more than 1,000 GEC NoV as an alternative output to the number of infected or sick consumers.

4.2. Discussion of the Results

4.2.1. Routes of Contamination

The contamination of hands in the restrooms, directly from the source or from objects, is the major route of norovirus transmission to the retail environment (Fig. 3). Removing hand contact in the

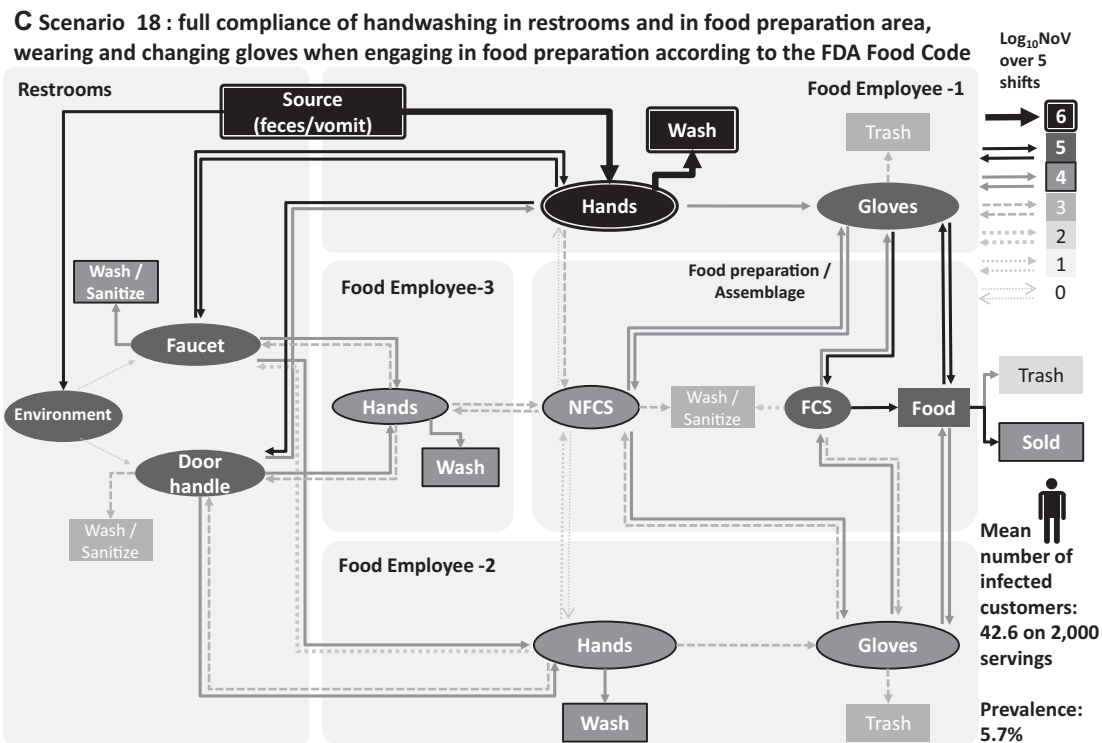


Fig. 3. Continued.

restrooms through the installation of touchless faucets and doors (scenario 13) is much more efficient in reducing the mean number of infected customers (75% compared to the baseline) than increasing the frequency of cleaning restrooms (scenario 10, 97% compared to the baseline).

In contrast to earlier studies,^(18,19) emesis in the restroom in addition to diarrhea was incorporated in our model. Vomiting has been recognized to contribute significantly to norovirus transmission, especially in confined environments such as food establishment settings.^(46,47) Our analysis found that norovirus particle transfer to objects through aerosolization is much less important than direct hand contact (Fig. 3). This is because a very small number of norovirus particles are transferred through the aerosol to surfaces that the food employees touch.

4.2.2. Impact of Exclusion

Our results confirm the importance of removing symptomatic employees from food establishments as recommended by Hall *et al.*⁽⁴⁸⁾ For example, the model estimates a 226% increase in the number of

infected customers when ill food employees are not excluded (scenario 3) and a decrease to 75% compared to the baseline with full compliance with the exclusion period (scenario 4).

The importance of removing ill food employees from work can be further illustrated by the mean number of infected customers according to the category of ill food employee present in the store. In fact, if an ill employee was compliant with the exclusion period, or “noncompliant 1,” and hence did not work while ill (as explained in Fig. 2), the mean number of infected customers was estimated to 56 or 60 in the baseline scenario, respectively. However, for the categories “noncompliant 2” and “noncompliant 3,” who worked while ill, the mean number of infected customers was estimated to 109 and 164, respectively. The high levels of infected customers when food employees worked while ill are explained by the high level of norovirus introduced in the retail environment by the ill food employee (FE-1) due to frequent visits to the restrooms to vomit or defecate. Those visits to the restrooms lead to hand contamination of the ill employee (FE-1) who then directly contaminate their gloves, the FCS, the NFCs, and the food, or indirectly contaminate the hands of the other food

Table VI. Major Assumptions of the Model

Assumptions Related to Employee Practices/Behavior and Retail Setting

The food establishment includes one food preparation area and one restroom
 Three workers are present in the food establishment, and two of these workers are food workers
 Five shifts of eight hours were simulated, with 200 servings per food worker and per shift (total of 2,000 servings)
 The food serving includes three ingredients, one of the ingredients is cooked
 Food preparation and assembly tasks take place in five-minute sequences
 Contact between food, hands/gloves, and FCS occurs twice for each ingredient during food preparation and assembly
 Contact between hands/gloves and NFCS occurs once for each ingredient during food preparation and assembly
 The pace of sandwich assembly is 1 per minute
 The pace of ingredient preparation is 20 pieces per minute
 Restroom had two hand-touch points: the hand sink faucet handle and the restroom door handle.
 Settings studied in the literature used for the meta-analyses are representative or comparable to this setting
 Category “noncompliant 3” represents 50% of the proportion of total noncompliant

Assumptions Related to Illness and Norovirus

Ingredients are initially free of norovirus
 Restroom, food facility, and food contact equipment are initially free of norovirus
 Transmission of norovirus to customer only occurs through food
 Only one employee (FE-1) is symptomatic
 Symptomatic employees always experience diarrhea
 All assumptions from Teunis *et al.*⁽³²⁾ dose-response models (infection and illness)

Assumptions Related to Data and Statistical Analysis

RT-PCR data represent the number of norovirus particles in the dose-response model
 All actions on norovirus particles (transfer, survival, washing, and disinfection) are applied independently on each particle
 Norovirus surrogates have similar properties (up to a scaling factor) as norovirus (survival, transfer, handwashing, and disinfection)
 Norovirus genogroup GI and GII have similar properties and infection probability

employees, as shown in Fig. 3(a). The impact of a symptomatic food employee in contaminating RTE food items is so strong that other prevention strategies cannot prevent the norovirus contamination of RTE food if a symptomatic food employee is in the food establishment (Figs. 3(b) and 3(c)).

An increase of the exclusion period from 24 to 48 hours after symptom resolution leads to a relatively small decrease in estimated numbers of infected customers when compared with other prevention strategies explored in this risk assessment. This is true whether food employees are fully compliant with the exclusion requirement (8% reduction, scenarios 4 and 5) or not (8% reduction, baseline and scenario 6, or 4% reduction, scenarios 21 and 22). The small decrease in estimated numbers of infected customers when extending the exclusion period to 48 hours primarily arises via the decrease in the level of norovirus in feces during these additional 24 hours away from work, and results from recent human volunteer challenge studies suggest that this decrease is slow.⁽⁹⁾ Moreover, norovirus shedding continues long after symptoms have resolved.⁽¹¹⁾ The larger impact of the exclusion period extension predicted for the 24 hours (baseline)/48 hours (scenario 6) pair compared with that for the 24 hours (scenario 21)/

48 hours (scenario 22) pair arises from preventing some food employees who would have had active symptoms (returned to work too soon before symptom resolution) in the food establishment from working while ill (shift of food employees from NC-2 to NC-1 category). In other words, requiring food employees to stay away from work an extra 24 hours could reduce the impact of food employees prematurely declaring the end of symptoms and this is reflected in the overall 8% reduction predicted for scenario 6 as compared with the baseline. The impact of extending the exclusion period depends on the distribution of food employees working while ill among categories NC-2 and NC-3.

If implementation of an extended exclusion period to 48 hours after symptom resolution leads to a reduction in compliance with the exclusion, the reduction of norovirus transmission associated with the extended exclusion period shown in scenario 6 could be completely eliminated (scenario 7) or could even lead to an increase in infections and illnesses (scenario 8), depending on the magnitude of the reduction in compliance and the distribution of food employees working while ill among categories NC-2 and NC-3. More data are needed to quantify the impact of an extended exclusion period on food employee

compliance. Previous studies suggested that as many as 60% of food employees have worked while ill and 20% while experiencing diarrhea or vomiting.^(25,26) Many of the influential factors cited by food employees leading to working while ill, such as loss of pay,⁽⁴⁹⁾ (lack) of severity of illness, and not wanting to leave co-workers short staffed,^(25,50) may become even more important when the period of exclusion is extended.

The model results indicate that a decrease in infected customers comparable to that achieved by extending the exclusion period from 24 to 48 hours could be achieved if compliance with the current 24-hour exclusion period is increased (compare scenario 6 and 9).

4.2.3. *Impact of Restriction*

Restricting food employees from preparing food after being ill seems to be counterproductive (scenarios 14 and 16) in our setting. Norovirus transfers from the restricted food employee FE-1 to hands and gloves of the other food employees FE-2 and FE-3 via contamination of the restroom environment and via contact with NFCS (compare scenarios 1 and 14). This result is highly sensitive to the level of interaction between the restricted food employee and the food preparation environment (our results, not shown). We modeled one contact between the hand of the restricted food employee and one NFCS every 10 minutes on average in our model. The increased risk of transmission from a restricted employee was observed because those restricted employees do not wear gloves and wash their hands much less frequently than if they were engaged in food preparation, thereby transferring more norovirus in the setting than they would while preparing food.

4.2.4. *Impact of Handwashing, Glove Use, and No Barehand Contact*

Our results suggest that handwashing and sanitation (scenarios 19 and 20), no barehand contact with RTE food via glove use in addition to handwashing (scenario 18), and no contact in the restrooms between faucet, door handle, and hands (scenario 13) are highly effective in reducing the transmission of norovirus compared to the baseline. However, glove wearing alone (scenario 11) with current compliance with changing gloves and handwashing when engaging in food preparation does not have a clear impact on decreasing the risk of norovirus transmission.

Interestingly, our results suggest that this scenario would increase to 114% the mean number of infected customers, while reducing to 91% compared to the baseline the number of heavily contaminated products (>1,000 GEC NoV). Note that, in our model, we consider norovirus transfer from hands to gloves while the food employee is putting on gloves, as observed in Casanova *et al.*⁽⁵¹⁾ and Ronnqvist *et al.*⁽⁵²⁾ This unexpected outcome may be explained by the higher norovirus transfer coefficients from gloves to surface and food items than from barehands (see meta-analysis results in Table I), as shown previously for bacteria.⁽⁵³⁾ This supports that wearing gloves without compliance with handwashing and changing gloves when engaging in food preparation is not enough to reduce the transmission of norovirus in retail settings and highlights the necessity to change gloves and wash hands as recommended in the FDA Food Code. Indeed, scenario 18 shows that it is highly efficient if the food employees regularly change their gloves and wash their hands when they engage in preparation and, importantly, wash their hands in the restrooms.

Interestingly, an increase in the efficiency of handwashing appears to be very successful in reducing the risk linked to norovirus transmission in the retail food service setting (scenarios 19 and 20). A typical handwashing procedure usually removes 1–2 logs of norovirus from the hands.^(54–56) Improving this efficiency, through better training, improved handwashing efficacy (such as through the use of soap that increases the level of friction on the hands, without damaging the skin), or other means would reduce the risk of norovirus transmission and foodborne illness in food establishments.

5. CONCLUSIONS

This risk assessment provides a better understanding of the norovirus transmission pathway from infected food employees to RTE food in food establishments and supports the importance of removing symptomatic food employees to prevent norovirus foodborne illnesses. Infected food employees who return to work too soon before full symptom resolution may continue to spread the virus and contaminate food. The effectiveness of exclusion as a preventive control depends on the level of compliance, which, in turn, depends on the reasons and motivations of why food employees may work while ill. This study evaluated the impact of extending the exclusion period after symptom resolution from 24 to 48 hours

and found that (1) reduction in mean numbers of infected customers is relatively small when compared with the other prevention strategies; (2) a comparable reduction could be achieved by increasing compliance with the 24-hour exclusion period; and (3) if compliance with the exclusion requirement is reduced as a consequence of the extension of the postsymptomatic exclusion period, the public health benefit could be reduced, eliminated, or lead to an increase in the mean number of infected customers. Whether or not a public health benefit results from the extension of the postsymptomatic exclusion period and the magnitude of that benefit/harm depend on food employee behavior and more specifically on the level of compliance with the exclusion provision and, among those not complying, the extent to which the change results in these food employees being excluded longer from the food establishment.

This risk assessment identified major areas of improvement to prevent norovirus transmission in these settings, including (1) avoiding the presence of any symptomatic food employees; (2) avoiding the transfer of norovirus from feces or vomit to the hands of food employees by using touchless faucets and eliminating hand contact with the door in restrooms; and (3) avoiding the transfer of norovirus from the hands of food employees to food through proper hand hygiene and the prevention of barehand contact with RTE food. Results of the impact of all preventive strategies on controlling norovirus foodborne illness are largely in line with what was expected in these settings such as the large impact of compliance with exclusion from work while ill, handwashing, or glove use when engaging in food preparation. This research has demonstrated that when evaluating the impact of preventive controls, level of compliance with each preventive strategy should be evaluated separately. More research is needed to identify factors influencing compliance with existing prevention strategies.

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Cleaning and Disinfectant Chemical Exposures and Temporal Associations with COVID-19 — National Poison Data System, United States, January 1, 2020–March 31, 2020

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On January 19, 2020, the state of Washington reported the first U.S. laboratory-confirmed case of coronavirus disease 2019 (COVID-19) caused by infection with SARS-CoV-2 (1). As of April 19, a total of 720,630 COVID-19 cases and 37,202 associated deaths* had been reported to CDC from all 50 states, the District of Columbia, and four U.S. territories (2). CDC recommends, with precautions, the proper cleaning and disinfection of high-touch surfaces to help mitigate the transmission of SARS-CoV-2 (3). To assess whether there might be a possible association between COVID-19 cleaning recommendations from public health agencies and the media and the number of chemical exposures reported to the National Poison Data System (NPDS), CDC and the American Association of Poison Control Centers surveillance team compared the number of exposures reported for the period January–March 2020 with the number of reports during the same 3-month period in 2018 and 2019. Fifty-five poison centers in the United States provide free, 24-hour professional advice and medical management information regarding exposures to poisons, chemicals, drugs, and medications. Call data from poison centers are uploaded in near real-time to NPDS. During January–March 2020, poison centers received 45,550 exposure calls related to cleaners (28,158) and disinfectants (17,392), representing overall increases of 20.4% and 16.4% from January–March 2019 (37,822) and January–March 2018 (39,122), respectively. Although NPDS data do not provide information showing a definite link between exposures and COVID-19 cleaning efforts, there appears to be a clear temporal association with increased use of these products.

The daily number of calls to poison centers increased sharply at the beginning of March 2020 for exposures to both cleaners and disinfectants (Figure). The increase in total calls was seen across all age groups; however, exposures among children aged ≤5 years consistently represented a large percentage of total calls in the 3-month study period for each year (range = 39.9%–47.3%) (Table). Further analysis of the increase in calls from 2019 to 2020 (3,137 for cleaners, 4,591 for disinfectants),

showed that among all cleaner categories, bleaches accounted for the largest percentage of the increase (1,949; 62.1%), whereas nonalcohol disinfectants (1,684; 36.7%) and hand sanitizers (1,684; 36.7%) accounted for the largest percentages of the increase among disinfectant categories. Inhalation represented the largest percentage increase from 2019 to 2020 among all exposure routes, with an increase of 35.3% (from 4,713 to 6,379) for all cleaners and an increase of 108.8% (from 569 to 1,188) for all disinfectants. Two illustrative case vignettes are presented to highlight the types of chemical exposure calls managed by poison centers.

Case 1

An adult woman heard on the news to clean all recently purchased groceries before consuming them. She filled a sink with a mixture of 10% bleach solution, vinegar, and hot water, and soaked her produce. While cleaning her other groceries, she noted a noxious smell described as “chlorine” in her kitchen. She developed difficulty breathing, coughing, and wheezing, and called 911. She was transported to the emergency department (ED) via ambulance and was noted to have mild hypoxemia and end-expiratory wheezing. She improved with oxygen and bronchodilators. Her chest radiograph was unremarkable, and she was discharged after a few hours of observation.

Case 2

A preschool-aged child was found unresponsive at home and transported to the ED via ambulance. A 64-ounce bottle of ethanol-based hand sanitizer was found open on the kitchen table. According to her family, she became dizzy after ingesting an unknown amount, fell and hit her head. She vomited while being transported to the ED, where she was poorly responsive. Her blood alcohol level was elevated at 273 mg/dL (most state laws define a limit of 80 mg/dL for driving under the influence); neuroimaging did not indicate traumatic injuries. She was admitted to the pediatric intensive care unit overnight, had improved mental status, and was discharged home after 48 hours.

The findings in this report are subject to at least two limitations. First, NPDS data likely underestimate the total incidence and severity of poisonings, because they are limited to

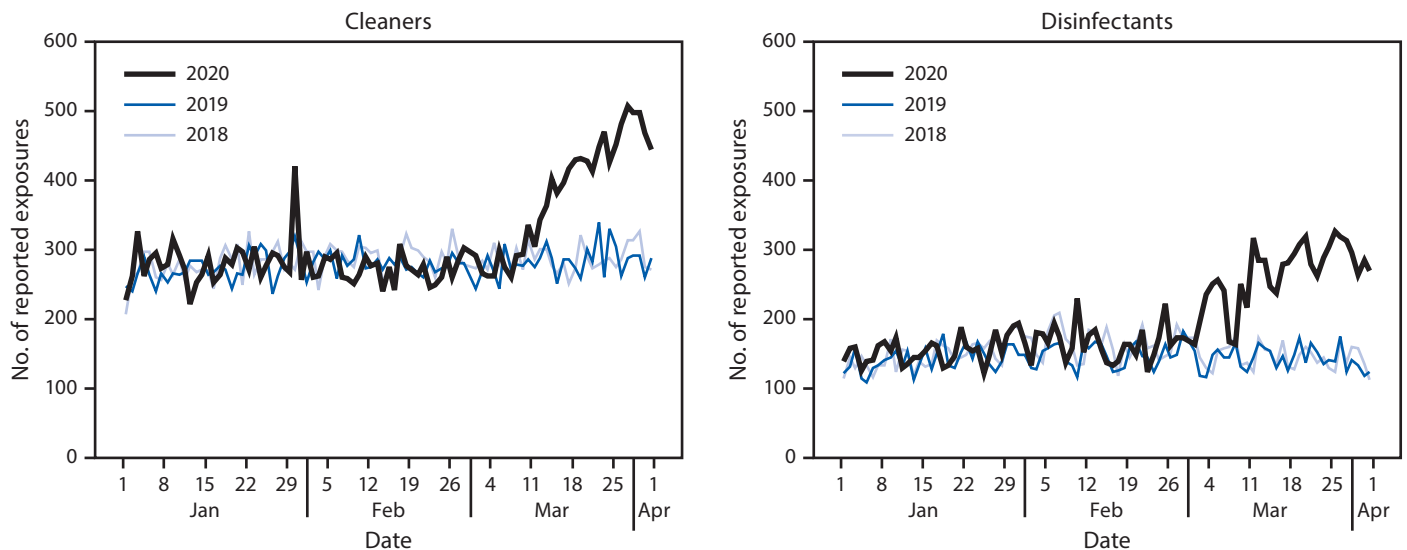
*Total cases include 1,282 probable cases, and total deaths include 4,226 probable associated deaths.

persons calling poison centers for assistance. Second, data on the direct attribution of these exposures to efforts to prevent or treat COVID-19 are not available in NPDS. Although a causal association cannot be demonstrated, the timing of these reported exposures corresponded to increased media coverage of the COVID-19 pandemic, reports of consumer shortages of cleaning and disinfection products (4), and the beginning of some local and state stay-at-home orders.

Exposures to cleaners and disinfectants reported to NPDS increased substantially in early March 2020. Associated with

increased use of cleaners and disinfectants is the possibility of improper use, such as using more than directed on the label, mixing multiple chemical products together, not wearing protective gear, and applying in poorly ventilated areas. To reduce improper use and prevent unnecessary chemical exposures, users should always read and follow directions on the label, only use water at room temperature for dilution (unless stated otherwise on the label), avoid mixing chemical products, wear eye and skin protection, ensure adequate ventilation, and store chemicals out of the reach of children.

FIGURE. Number of daily exposures to cleaners and disinfectants reported to U.S. poison centers — United States, January–March 2018, 2019, and 2020*,†



* Excluding February 29, 2020.

† Increase in exposures to cleaners on January 29, 2020, came from an unintentional exposure to a cleaning agent within a school.

TABLE. Number and percentage of exposures to cleaners and disinfectants reported to U.S. poison centers, by selected characteristics — United States, January–March 2018, 2019, and 2020

Characteristic	No. (%)					
	Cleaners			Disinfectants		
	2018	2019	2020	2018	2019	2020
Total	25,583 (100.0)	25,021 (100.0)	28,158 (100.0)	13,539 (100.0)	12,801 (100.0)	17,392 (100.0)
Age group (yrs)						
0–5	10,926 (42.7)	10,207 (40.8)	10,039 (35.7)	7,588 (56.0)	6,802 (53.1)	8,158 (46.9)
6–19	2,655 (10.4)	2,464 (9.8)	2,516 (8.9)	1,803 (13.3)	1,694 (13.2)	2,358 (13.6)
20–59	8,072 (31.6)	8,203 (32.8)	9,970 (35.4)	2,659 (19.6)	2,791 (21.8)	4,056 (23.3)
≥60	1,848 (7.2)	1,936 (7.7)	2,356 (8.4)	929 (6.9)	848 (6.6)	1,455 (8.4)
Unknown	2,082 (8.1)	2,211 (8.8)	3,277 (11.6)	560 (4.1)	666 (5.2)	1,365 (7.8)
Exposure route*						
Ingestion	16,384 (64.0)	15,710 (62.8)	16,535 (58.7)	11,714 (86.5)	10,797 (84.3)	13,993 (80.5)
Inhalation	4,747 (18.6)	4,713 (18.8)	6,379 (22.7)	540 (4.0)	569 (4.4)	1,188 (6.8)
Dermal	4,349 (17.0)	4,271 (17.1)	4,785 (17.0)	1,085 (8.0)	1,078 (8.4)	1,695 (9.7)
Ocular	3,355 (13.1)	3,407 (13.6)	3,802 (13.5)	984 (7.3)	1,067 (8.3)	1,533 (8.8)
Other/Unknown	182 (0.7)	169 (0.7)	166 (0.6)	89 (0.7)	95 (0.7)	147 (0.8)

* Exposure might have more than one route.

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Sanitizers and Disinfectants: A Retail Food and Foodservice Perspective

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SUMMARY

The coronavirus disease 2019 (COVID-19) pandemic has brought heightened attention to the importance of cleaning, sanitizing, and disinfecting in retail food and foodservice establishments. In response, major governmental agencies have emphasized the need to frequently disinfect high-touch surfaces. While this recommendation may seem straightforward and achievable, it is far more nuanced and complex. In the retail food and foodservice industry, sanitization is a routine, common practice defined and recommended in the U.S. Food and Drug Administration (FDA) Food Code. Hence, sanitizers, rather than disinfectants, are the main antimicrobial products used in these settings. It is important to emphasize that sanitizers and disinfectants are not interchangeable products, so they may be inadvertently misused. Therefore, end users need to understand the differences of when, why, and how both can be used in retail food and foodservice settings. The aim of this paper is to increase end users' knowledge and awareness about the proper use of sanitizers and disinfectants in retail food and foodservice establishments. This paper is organized into six sections—Antimicrobial Products: Sanitizers and Disinfectants, FDA Food Code, Regulation of Sanitizers and Disinfectants, Understanding EPA-Registered Labels, Emerging Issues, and Current and Future Trends in Sanitizing and Disinfecting. When used properly, sanitizers and disinfectants are powerful tools that can keep retail food and foodservice operations safe from pathogens that cause infectious disease.

OVERVIEW

COVID-19 has brought heightened attention to the importance of cleaning, sanitizing, and disinfecting in retail food and foodservice establishments. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19), is primarily transmitted through person-to-person contact via respiratory droplets from coughing, sneezing, talking,

and breathing. Based on what we currently know, it is not transmitted through food. Even so, concerns have been raised about its spread in retail food and foodservice establishments, resulting in changes in restaurant and grocery store operations, as well as contributing to the closure of thousands of restaurants across the United States (5, 17). In response, major U.S. government agencies (i.e., the Centers for Disease Control and Prevention, the Environmental Protection Agency [EPA], and the Food and Drug Administration [FDA]) published a series of recommendations, one of which promotes the frequent disinfection of high-touch surfaces (2, 12, 15). While this recommendation may seem straightforward and achievable, it is in fact far more nuanced and complex. In the retail food and foodservice industry, sanitization is a routine, common practice defined and recommended in the FDA Food Code. Hence, sanitizers, rather than disinfectants, are the main antimicrobial product used in the food industry. Sanitizers and disinfectants are not interchangeable products, but due to complex regulatory frameworks and lengthy labels, they may be inadvertently misused. Therefore, it is important to understand the differences in when, why, and how both can be properly used in retail food and foodservice establishments. The aim of this paper is to increase end users' knowledge and awareness about the proper use of sanitizers and disinfectants in retail food and foodservice establishments.

ANTIMICROBIAL PRODUCTS: SANITIZERS AND DISINFECTANTS

Sanitizers and disinfectants are often complex formulations that contain at least one or more active ingredient(s). These active ingredients provide the intended antimicrobial effect (i.e., reduction or elimination of targeted microorganisms). Characteristics of common active ingredients or their blends are presented in [Table 1](#). While [Table 1](#) describes

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TABLE 1. Attributes of common sanitizer and disinfectant active ingredients

Sanitizer	Spectrum of activity ^a	Advantages	Disadvantages
Free available chlorine (chlorine, hypochlorous acid, sodium hypochlorite)	Vegetative bacteria and enveloped and nonenveloped viruses	<ul style="list-style-type: none"> • Broad spectrum of activity • Good hard water tolerance 	<ul style="list-style-type: none"> • May be incompatible with some soft metals • Rapidly inactivated by soil • Limited shelf life that varies with pH • Can generate chlorine gas if mixed with acid or ammonia • Can be inactivated by organic matter
Quaternary ammonium compounds	Vegetative bacteria and enveloped and nonenveloped viruses	<ul style="list-style-type: none"> • Broad spectrum of activity • Compatible with most surfaces • Compatible with most surfaces • Very stable with long shelf lives • Less reactive with soil 	<ul style="list-style-type: none"> • Can be inactivated by hard water • Can be inactivated by some surfactants used in cleaners • May bind to cleaning cloths, reducing active levels in a solution • Food Code requires use above 24°C (75°F)
Peroxides	Vegetative bacteria and enveloped and nonenveloped viruses	<ul style="list-style-type: none"> • Minimal residue • Formulated for good hard water tolerance 	<ul style="list-style-type: none"> • May require elevated levels to be effective against catalase-positive organisms. • May be incompatible with some soft metals
Peracids	Vegetative bacteria and enveloped and nonenveloped viruses	<ul style="list-style-type: none"> • Broad spectrum of activity (note that antifungal activity may require a mixture of peracid) • Compatible with most surfaces • Minimal residue 	<ul style="list-style-type: none"> • Pungent odor • Limited shelf life • Inactivated by some types of soil • May be incompatible with some metals
Acid anionics	Vegetative bacteria and enveloped and nonenveloped viruses	<ul style="list-style-type: none"> • Compatible with residual cleaners if rinsing is incomplete • Good cleaning performance • Good material compatibility • Good hard water tolerance 	<ul style="list-style-type: none"> • May be incompatible with some soft metals and some plastic surfaces • Can generate chlorine gas if mixed with chlorine products
Alcohol	Vegetative bacteria and enveloped viruses	<ul style="list-style-type: none"> • Can be used in environments where aqueous sanitizers or disinfectants are undesirable^b • No residue • Limited impact on organic matter 	<ul style="list-style-type: none"> • High flammability • Some alcohols display poor compatibility with certain plastic materials • RTU format only

^aNote that the specific spectrum of activity will vary depending on the formulation and will be reflected on the product and EPA approved labels. Consult the label and the supplier of the disinfectant or sanitizer for detailed information.

^bLow-water-activity food production areas.

limitations of common active ingredient(s), the final product formulation may include a blend of active ingredients, as well as additional inert ingredients, to help overcome these limitations. Inert ingredients can be added for various reasons (e.g., improved cleaning performance, aesthetics, formulation

stability, and hard water tolerance). Surfactants are added to improve the cleaning performance of both disinfectants and sanitizers in combination products (i.e., detergent-sanitizers and detergent-cleaners), which are described below. Chelating agents are added to some formulations to

improve product performance in the presence of hard water. Thickeners or solvents are sometimes used to control the flow of the formulation, affecting how the product is dosed or diluted for use. Both active and inert ingredients are carefully chosen by the manufacturer to meet the efficacy and usability needs of the end user.

Sanitizers

A sanitizer is defined as “a substance, or mixture of substances, that reduces the bacteria population in the

inanimate environment by significant numbers but does not destroy or eliminate all bacteria” (9). The testing and efficacy required for food-contact and nonfood-contact surface sanitizers are presented in [Table 2](#). It is important to note that efficacy tests for sanitizers can only be performed with bacteria and not with other microorganisms, such as viruses, fungi, and yeast. Other bacteria can be added to claims on the product label based on proven efficacy and customer needs. Two categories of sanitizers will be discussed in this paper—food-contact surface sanitizers and nonfood-

TABLE 2. Definitions and regulatory requirements for disinfectants and sanitizers

Disinfectants			Sanitizers		
Agent that destroys or irreversibly inactivates bacteria, fungi, and viruses but not necessarily bacterial spores in the inanimate environment [40 CFR § 158.220(c) (9)]			Agent that reduces the number of bacteria in the inanimate environment by significant numbers, but does not necessarily destroy or eliminate all bacteria [40 CFR § 158.220(c)(9)]		
Product type	Requirements (organisms and time)		Product type	Requirements (organisms and time)	
Hospital	<i>Staphylococcus aureus</i> and <i>Pseudomonas aeruginosa</i>	Must pass required disinfectant laboratory test (wipe, spray, and liquid versions exist); contact time can be no longer than 10 min	Food Contact	Halide-based products (i.e., products with active ingredients including chlorine, iodine, and bromides): <i>S. aureus</i> or <i>Salmonella enterica</i>	Halide-based products must demonstrate equivalency to 50, 100, or 200 ppm of available chlorine
				Nonhalide-based products (products with nonhalide active ingredients, e.g., peracids, quats and alcohol): <i>S. aureus</i> and <i>Escherichia coli</i>	Nonhalide-based products must achieve 5-log reduction in laboratory test in 30 s, although claim must be listed as 1 min (wipe version exists)
General	<i>S. aureus</i> and <i>P. aeruginosa</i> or <i>S. enterica</i>		Non-food contact	<i>S. aureus</i> and <i>Klebsiella pneumoniae</i> or <i>Klebsiella aerogenes</i>	Must achieve 3-log reduction in laboratory test within 5 min
Limited	<i>S. aureus</i> or <i>S. enterica</i>				

Note: Once the basic requirements have been met, a company may test and add a variety of additional microorganism kill claims to the label through the registration process.

contact surface sanitizers. The FDA Food Code specifically addresses sanitization for food-contact surfaces, whereas it does not address sanitization of nonfood-contact surfaces. Nonetheless, retail food and foodservice operators may choose to sanitize both surface types to minimize the risk of cross-contamination.

Disinfectants

A disinfectant is defined as a “substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment” (9). The testing and efficacy required for disinfectants are listed in [Table 2](#). The EPA separates disinfectants into three categories—limited, broad, and hospital disinfectants. The broad and hospital categories of disinfectants are most often used due to their wider range of antimicrobial claims. The FDA Food Code only mentions the use of disinfectants in Section 2-501.11, “Clean-up of Vomiting and Diarrheal Events” (15).

Recently, disinfectants have become an increasingly important tool for retail food and foodservice operations because of their efficacy against microorganisms not claimed by sanitizers, such as noroviruses or coronaviruses. The product label identifies the specific microorganisms against which the disinfectant has been tested and approved by the EPA. In general, disinfectant use is confined to places or surfaces where there may be a greater risk of human or animal pathogen transfer, such as high-touch surfaces (door handles, light switches, dispenser buttons, dining room chairs, and tables) and bathrooms. In some instances, food-contact surfaces should be disinfected after certain contamination events. Examples include controlling the spread of pathogens associated with blood, vomit, or diarrheal events or cleaning up the facility for reopening after a suspected or confirmed foodborne disease outbreak. Traditional food-contact surface sanitizers are not designed to meet the decontamination challenges presented by viruses that may have contaminated surfaces during these events. If virus control or generally higher-level microbial control is required, it is necessary to disinfect (not sanitize) the contaminated food-contact surface. For surfaces that are visibly dirty, the general protocol is to clean, rinse with potable water, disinfect according to label instructions for the disinfectant, rinse again with potable water, and then sanitize with a food-contact sanitizer before reusing the surface. The rinse step before disinfection of a food-contact surface is essential to prevent reducing the efficacy of the disinfectant, and rinsing after disinfection is important to prevent chemical cross-contamination with foods attributed to disinfectant residue and to prevent potential inactivation of sanitizer with residual disinfectant. If the surface is visibly clean and the product is labelled as a one-step disinfectant, one can eliminate the cleaning step, so the general protocol is disinfect, rinse with potable water, and sanitize with a food-contact sanitizer.

Combination products

Up to this point, sanitizers and disinfectants have been discussed as separate products. However, many manufacturers often formulate products to function as both a food-contact surface sanitizer and a disinfectant. Additional functions, such as sanitizing nonfood-contact surfaces (e.g., textiles, floors, drains, and walls), can also be added to product claims through testing and EPA approval to meet market or customer needs. It is not unusual for one product to be approved for use as a sanitizer at one concentration and as a disinfectant at a higher concentration with different contact times. For example, some quaternary ammonium products can be used as a food-contact sanitizer at 200 ppm and as a disinfectant at 450 ppm. Other combination or multifunctional products include those designed to deliver benefits other than microbial control, such as a detergent-disinfectant or detergent-sanitizer (commonly called cleaner-disinfectants or cleaner-sanitizers). Both can be of benefit to the end user through process simplification.

Packaging

Sanitizers and disinfectants can be purchased in a range of formats—wipes, aerosols, sprays, concentrated liquids, and tablets. Wipes, aerosols, and sprays are typically ready-to-use (RTU) formats, and concentrates (liquids or tablets) require dilution with water. As the names imply, RTU products can be used as purchased, whereas concentrates need additional handling (e.g., dispensing, dilution, and concentration confirmation). Concentrates are advantageous because they require less storage, use far less packaging, and are easier to ship than RTU products. However, safety of concentrated chemicals and the equipment and training needed for proper dilution of these products should be considered. Some manufacturers have developed tamper-proof packaging to prevent workers from gaining access to chemical concentrates, as well as sophisticated dispensing equipment to ensure dilution accuracy and safety.

FDA FOOD CODE

The FDA publishes the Food Code to provide a comprehensive and uniform approach to food safety management for retail food and foodservice establishments in the United States (15). Among the goals of the Food Code is the creation of common and standardized food safety language to improve communication between regulators and industry operators. Retail food and foodservice operators need to familiarize themselves with the Food Code so effective cleaning and sanitizing procedures become an integral part of their operation, as the Code has been widely adopted throughout the United States as the basis for state and local regulations.

The objective of cleaning requirements outlined in the Food Code is to remove soil (e.g., food debris, proteins, fats, and carbohydrates) from both food-contact surfaces and nonfood-contact surfaces. Food-contact surfaces at

TABLE 3. Cleaning frequencies of food contact surfaces and utensils

Temp	Cleaning frequency
<5.0°C (41°F)	24 h
>5.0°–7.2°C (>41–45°F)	20 h
>7.2–10°C (>45–50°F)	16 h
>10–12.8°C (>50–55°F)	10 h
>12.8°C (>55°F)	4 h

room temperature (except for storage containers) should be cleaned as needed throughout the day and at least once every 4 hours. For cold rooms, such as a meat cutting room, food-contact surfaces can be cleaned and sanitized less frequently than every 4 hours (*Table 3*). Surfaces must be cleaned and rinsed with potable water before being sanitized to allow the sanitizer to achieve its expected efficacy. EPA-registered sanitizers must be used at the concentration and contact time (typically 1 minute) that are listed on the label instructions. It is important to note that shorter sanitizer contact times listed in the Food Code, which range from 7 seconds for chlorine-based products to 30 seconds for quaternary ammonium and iodine products, apply to dish machine applications, not to surface applications. Therefore, it is important to always follow the product label instructions.

Cleaning and sanitizing processes are addressed in several parts and subparts of Chapter 4 of the Food Code, which further elaborate the three-step process—cleaning, rinsing, and sanitizing of food-contact surfaces (i.e., equipment and utensils)—that is the foundation for procedures used in retail food and foodservice establishments. Below is a listing of where to find these procedural steps in the Food Code.

- **Cleaning.** Part 4-6 describes cleaning procedures for food-contact surfaces (i.e., equipment and utensils). Included are objectives, recommended cleaning frequencies, and cleaning methods. It is recommended that nonfood-contact surfaces be cleaned as needed, but it is not required that they be sanitized.
- **Frequency.** Section 4-602.11 describes how often food-contact surfaces need to be cleaned and sanitized under certain conditions, such as when handling food at room temperature or in a temperature-controlled room (i.e., a meat cutting room) (*Table 3*).
- **Rinsing.** Section 4-603.16 recommends the rinsing of cleaned equipment and utensils so that abrasives and cleaning chemicals are removed or diluted to aid in the effectiveness of the sanitizing step. (See “Detergent-Sanitizer” below for exceptions to this recommendation.) Section 4-904.14 states two conditions under which equipment and utensils can be rinsed after cleaning and

sanitizing: (1) when a rinse is applied directly from the potable-water supply by a dish machine and (2) when the EPA-registered label use instructions require a rinse after a sanitizer is applied in a commercial dish machine.

- **Sanitizing.** The Food Code states in Part 1-2, Definitions, that “sanitization” means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, equal to a 99.999% reduction, of representative disease microorganisms of public health importance. This definition aligns with the performance standards for a nonhalogen-based food-contact surface sanitizer (i.e., products with active ingredients, such as chlorine, iodine, or bromides) that is registered by the EPA. Part 4-7 specifies the frequency and methods for sanitizing food-contact surfaces, the final step prior to reuse of a food-contact surface. It includes two options for sanitizing cleaned and rinsed surfaces (i.e., use of hot water or chemical sanitizers). Important criteria for using chemical sanitizers, along with examples of the most commonly used chemicals, are in Section 4-501.114. All sanitizers must be used in accordance with the EPA-registered label use instructions.
- **Detergent-sanitizer.** This food-contact sanitizer product type is addressed in Section 4-501.115. These sanitizers can be used for both the cleaning and sanitizing steps and do not require a rinse between the two steps. Spray to clean the surface, which may include wiping if needed to remove soil, and then spray again with the same product to sanitize.
- **Nonfood-contact surfaces.** The Food Code does not address using sanitizers on nonfood-contact surfaces and recommends only cleaning these surfaces as needed. However, retail food and foodservice operators often use sanitizers on nonfood-contact surfaces to minimize the possible risk of cross-contamination.
- **Disinfectants.** Disinfectants are not defined in the 2017 Food Code, but their use is referenced in Section 2-501.11, “Clean-up of Vomiting and Diarrheal Events.” The Food Code specifically states that procedures to clean up after a vomiting or diarrheal event should

involve a more stringent process than routine sanitization: “It is therefore important that foodservice establishments have procedures for the cleaning and disinfection of vomitus and/or diarrheal contamination events that address, among other items, the use of proper disinfectants at the proper concentration.”

As stated above, disinfection is not a current regulatory requirement in retail food and foodservice establishments. However, when a disinfectant is used on a food-contact surface, special attention must be paid to the EPA-registered label use instructions (i.e., concentration, contact time, and application method), which typically includes a rinse step after use.

- **Concentration verification.** In Section 4-302.14, the concentration of the sanitizer is required to be measured to be sure it is used at a minimum concentration that ensures proper sanitization and that it does not exceed the level above which the sanitizer may not be safe. Therefore, “a test kit or other device that accurately measures the concentration in mg/L [ppm] of sanitizing solutions shall be provided.”

REGULATION OF SANITIZERS AND DISINFECTANTS

The U.S. EPA is the primary regulatory authority for antimicrobial products like sanitizers and disinfectants used in retail food and foodservice establishments. Antimicrobial products are identified as antimicrobial pesticides by the EPA, as they fit the statutory definition of products intended to reduce or eliminate microorganisms (7). Various physical and chemical attributes of sanitizers and disinfectants may differentiate them in the marketplace. Regardless of these differences, they all must meet certain regulatory standards to be legally sold in the United States. The EPA sets minimum levels of biocidal efficacy (i.e., the ability to reduce or eliminate targeted organisms under laboratory conditions) that must be met for a product to be called a disinfectant or sanitizer (11). Additional organisms can be added to the EPA-registered product label based on proven efficacy and shared in the marketing material of individual manufacturers. In addition, the EPA determines the human and ecological risks from exposure to antimicrobial products, which results in statutory precautionary and first aid labelling, including any personal protective equipment that may be required when the product is used. The EPA Antimicrobial Division manages the registration of antimicrobial products used on inanimate objects, such as sanitizers and disinfectants. Although not the focus of this paper, there are other regulated antimicrobial products used in retail food and foodservice establishments. For example, the FDA, not the EPA, has responsibility for regulating skin antiseptics (i.e., antimicrobial hand soaps and hand sanitizers).

A data package submitted to the EPA for the registration of an antimicrobial product must include microbiological data (i.e., efficacy data), chemistry data, stability (or

shelflife) data, and toxicology data (to help determine precautions and recommendations for personal protective equipment). The submission must also include a detailed master label containing first aid statements, precautionary language directions for use, efficacy claims (often a list of microorganisms and the contact times and product concentrations), and suitable marketing claims. The scientific experts at the EPA not only analyze the data submitted but make decisions on whether proposed marketing language is truthful and not “false and misleading.” Product ingredients are also reviewed carefully. In the case of food-contact sanitizers, all ingredients (i.e., active and inert) must be approved for food use, allowing the product to bear a “no rinse required” use instruction. Disinfectants do not have this requirement; therefore, disinfectants must be rinsed off if used on a food-contact surface, and then that same surface must be sanitized before reuse. If using a detergent-sanitizer or detergent-disinfectant, rinsing is not required if stated on the product label (8, 15). The EPA review process can take up to 4 months for the addition of a new claim or application and between 5 and 10 months for a new product. It might take several years if the product has been designed with a novel active ingredient.

Once the basic requirements have been met ([Table 2](#)), a manufacturer may test and add a variety of additional microorganism kill claims to the label through the registration process. Companies manufacturing sanitizers and disinfectants typically market claims that resonate with the retail food and foodservice industry (e.g., norovirus, *Listeria monocytogenes*, and *E. coli* O157:H7). Importantly, only additional bactericidal claims can be added to a sanitizer label, whereas additional bactericidal, virucidal, fungicidal, tuberculocidal, and sporicidal claims can be added to a disinfectant label. It should be noted that many products have proven efficacy as both food-contact and nonfood-contact surface sanitizers, in addition to disinfectant efficacy, often at different concentrations and contact times, so a product might have a long menu of efficacy claims listed on its master label. Therefore, it is important to read the label carefully to understand which claims apply when using the product as a food-contact surface sanitizer and which apply when using the product as a disinfectant. The labels of all EPA-registered sanitizers and disinfectants are listed in a searchable database available in the EPA Pesticide Product Labeling System (PPLS) (14) and at the National Pesticide Retrieval Information System (NPRIS) (1). In addition, to help users select an appropriate sanitizer or disinfectant to control microorganisms of interest, the EPA maintains specialized lists (13). Examples include List G, the EPA’s Registered Antimicrobial Products Effective Against Norovirus, and List N, Disinfectants for Use against SARS-CoV-2 (COVID-19). The latter (List N) will be described in greater detail later in this paper.

Antibacterial All Purpose Cleaner

ACTIVE INGREDIENTS

Active Ingredient	A X.YZ%
Active Ingredient	B X.YZ%
Active Ingredient	C X.YZ%
Active Ingredient	D X.YZ%
OTHER INGREDIENTS:	XX.YZ%
TOTAL:	100.00%

Danger
KEEP OUT OF REACH OF CHILDREN

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and protective (rubber or chemical resistant) gloves. Harmful if swallowed or if absorbed through the skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing eye.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling poison control center or doctor or going for treatment.

FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-XXX-XXXX OUTSIDE NORTH AMERICA, CALL 1-XXX-XXX-XXXX

EPA Reg. No. 1234-567-8900

EPA Est. No.: 1234-AB-1

DISTRIBUTED BY:

Company
1234 Main Street
Anytown, USA 12345

EPA Reg. No. 1234-567-8900

Base Registrant
Company Number

Product Number

Distributor or
Manufacturing Number

Not all products have a two-part EPA Registration Number.
Sub-registered products are three-parts.

FIGURE 1.

UNDERSTANDING EPA-REGISTERED LABELS

Once a product is registered with the EPA, its master label is accessible to the public through the PPLS or the NPRIS (see Regulation of Sanitizers and Disinfectants, above). The master label is a comprehensive document that contains a great deal of information about the product, such as functions, safety information, use directions, use sites, efficacy claims, and marketing claims. Commercial, package, or market labels are developed from the master label and are what the end users see on sanitizer or disinfectant containers. The label on the product container has the most relevant and useful information for the end user. This information cannot deviate from the language on the master label, which is registered with the EPA. Additional information from the master label may be used in marketing materials, such as brochures, websites, and other advertising forms. It is important to note that a product can be sold under a different name than the one that appears on the master label. The most important parts of a commercial antimicrobial product label are presented in *Figure 1* and are also described below.

- **EPA registration number.** On the product label, the registration number is displayed as “EPA Reg. No.” followed by two or sometimes three sets of numbers. Because products may be marketed and sold under different brand names, they might have the same EPA registration number. Products made by a supplier or distributor (i.e., not a manufacturer) have three sets of

numbers; the last set of numbers identifies the supplier, who is not the same as the manufacturer. If the first two sets of numbers match a registration number that is on one of the EPA lists (e.g., List N), the product is equivalent to the listed product. For example, if “EPA Reg. No. 12345-12” is on List N, then all products labeled EPA Reg. No. 12345-12-#### are an equivalent product, because the last set of numbers identifies the supplier or distributor.

- **Format.** The product label indicates if the product is in an RTU format (does not require any dilutions) or if it is a concentrate (liquid or powdered) that needs to be diluted as specified by the label before being used.
- **Directions for use.** The use instruction section presents valuable information on dilution, contact time (see below), and whether the product can be sprayed, wiped, mopped, and so on. It also lists precleaning steps or whether or not a potable-water rinse is required.
- **Dilution.** A concentrated product will have precise instructions for use, listing ounces per gallon and ppm to help the end user achieve the correct concentration. The efficacy of some antimicrobial products may be affected by the hardness of the water used to prepare the diluted product. For this reason, manufacturers test the efficacy of the product in hard water. The label will indicate the water hardness level at which efficacy testing was done, such as an instruction to dilute 2 oz/gal of sanitizer in

water up to 500 ppm hardness. The efficacy of the product will be negatively impacted if the product is used in water above the hardness stated on the product label. Water hardness varies throughout the United States. For information about a specific location, one should contact the local health agency or local water utility.

- **Contact time.** Antimicrobial products have minimum contact times listed on their product labels. These contact times can vary based on the product type, the target organism, or a specific use. The required contact time for food-contact hard surface sanitizers is typically 1 minute, with the exception of sanitizing in a dish machine (see FDA Food Code), and for non-food-contact sanitizers, it can be up to 5 minutes. Disinfectants can list various contact times for different bacteria, viruses, or fungi but generally do not exceed 10 minutes. If a product has multiple contact times for the same application, it is recommended to use the most conservative contact time for routine disinfection, meaning the longest contact time and the strongest dilution. In cases when a specific organism is targeted, the contact time for that organism listed on the label should be used. Note that for a disinfectant to be effective, the surface must be wet with the disinfectant for the full duration of the contact time. It is important to note that some disinfectants with longer contact times might need to be applied more than once to achieve the full required contact time.
- **Claims.** A claim is a statement about a product supported by evidence or data and has been approved by the EPA. Claims can range from simply naming a product as a sanitizer or disinfectant to specifics about its ability to kill a particular virus or bacterium or claims that it will sanitize a particular surface type. An example is an efficacy claim, which lists organisms for which the product has been shown to have efficacy.
- These claims are specific to the intended use as a sanitizer or disinfectant, and they are also specific to the concentration and a contact time. Any product marketing materials or associated literature are regarded as “labelling” by the EPA, and therefore, claims listed on these materials are subject to the same rules as claims on product packaging and physical labels. Another type of claim to note is an emerging viral pathogen claim, used during a pandemic, such as the COVID-19 pandemic. This type of claim will only appear on a master label (this will be discussed below in Emerging Issues).
- **Surface type and compatibility.** Some products may have information about surfaces for which the product is intended (e.g., stainless steel, glazed tile, cabinets, or floors). Product labels may also mention the surfaces that may become damaged through use of the product; for example, peracid products should not be used on soft metals like copper.

- **Shelf life.** The EPA requires that shelf life (expiration date) be listed on the label of a product only when the shelf life is less than 1 year. The shelf life is determined for an unopened container by the product manufacturer. For products that are in use (e.g., wiping cloth solution), the concentration must be checked according to Section 4-302.14 in the FDA Food Code.
- **Storage and disposal.** Any specific instructions regarding storage or disposal are listed on the EPA-registered product label.
- **Statutory precautionary statements.** These statements alert the user to the hazards associated with misuse of the product and necessary first aid procedures if injury should occur.
- **Phone number.** A phone number must be listed for the user in order to access additional information or file a complaint about the product.

EMERGING ISSUES

Antimicrobial resistance

Discussions about the increased use of antimicrobial products, such as disinfectants and sanitizers, have centered around the potential risks associated with the misuse of these products. In particular, concerns have been raised about the possibility of the development of reduced antimicrobial susceptibility, often described in the scientific literature or media as antimicrobial resistance. The current research evaluating antimicrobial resistance of bacterial isolates recovered from food environments has focused on methodology and concentrations which are not relevant to the food industry (3). These studies are typically run following test methods common in antibiotic research, where use concentrations are very low and close to the minimum inhibitory concentration (MIC). The concentrations of sanitizers and disinfectants used in the food industry are typically hundreds of times higher than the MIC. Currently, no empirical data exist to indicate that the proper use of sanitizers or disinfectants leads to antimicrobial resistance under conditions present in food handling environments as part of a comprehensive sanitation program (4).

It is imperative that sanitization or disinfection processes be easy to follow. Sanitizer rotation has been discussed as a way to mitigate resistance development, without consideration of whether it is truly needed. This could bring additional challenges to an already complicated world of sanitizers, which may in turn further reduce cleaning and sanitization compliance.

Emerging viral pathogens

In August 2016, the EPA released guidance on disinfectant claims against emerging viral pathogens (EVP). The guidance allows companies to make EVP claims against new and emerging viruses during an outbreak by relying on historical data on similar or harder-to-kill viruses. In the

event of an outbreak of an EVP, there is an immediate need for disinfection solutions against this pathogen. However, there may be a lack of virus availability or laboratory expertise for testing disinfectant efficacy against this new virus. Therefore, in the interest of public health, the EPA developed a hierarchical approach to predict the effectiveness of disinfectants against EVP (10).

Viruses can be categorized into three groups based on their structure. The organisms that are the hardest to kill (most resistant) are the small nonenveloped viruses, followed by large nonenveloped viruses, and the easiest to kill (less resistant) are enveloped viruses. If a product is registered for use against a virus in a more resistant category, it can be assumed it will be effective against viral pathogens in a less resistant category. However, this is a temporary measure until the virus becomes available for testing and products can be tested to determine their true efficacy against the new pathogen.

In the case of SARS-CoV-2, a coronavirus which is an enveloped virus (easiest to kill), it is logical to assume that it will be inactivated with common disinfectants with proven, registered efficacy claims against viruses that are harder to kill, such as the nonenveloped virus type (e.g., norovirus, poliovirus, or rhinovirus). However, products that have small or large nonenveloped viruses listed on their labels cannot claim efficacy against less resilient viruses identified as emerging or reemerging pathogens until the EPA has granted an EVP claim. For example, to claim SARS-CoV-2 control based on this assumption, one needs either an EVP claim or a human coronavirus claim. The EVP guidance was “triggered” early in 2020 as COVID-19 quickly became a public health threat, which allowed manufacturers to communicate the expected effectiveness of certain disinfectant products that were preapproved by the EPA. In addition, the EPA compiled a searchable list of products with EVP claims that are appropriate for environmental disinfection and control of SARS-CoV-2. As the pandemic took hold, the EPA added products based on additional criteria, such as efficacy against viruses similar to SARS-CoV-2, to help alleviate shortages of effective products. This list is known as List N (12). Meanwhile, the EPA, testing laboratories, and manufacturers have been working to test the efficacy of many products specifically against SARS-CoV-2. As this publication was being prepared, the first few products tested against SARS-CoV-2 were becoming available on the market. The EPA has added these products to List N and continues to promote the use of any products on the list for disinfection of SARS-CoV-2.

Two points need to be emphasized. First, under pandemic conditions, such as the COVID-19 pandemic, it is imperative that antimicrobial products be used according to the viricidal disinfection directions and not the sanitization directions if the product can be used as both a sanitizer and a disinfectant. Second, it is highly recommended that, during the COVID-19 pandemic, those within the retail food and

foodservice industry should continue to use their sanitizers for routine procedures and use disinfectants where necessary, such as treating high-touch surfaces, cleaning bathrooms, and decontaminating the facility when there is known exposure.

CURRENT AND FUTURE TRENDS IN SANITIZING AND DISINFECTING

The SARS-CoV-2 pandemic has emphasized the importance of sanitizing and disinfecting unlike anything seen before in the retail food and foodservice industry. Even before the pandemic, efforts were underway to enhance cleaning, sanitizing, and disinfecting through innovative formulation and application. Retail food and foodservice establishments can be challenged by the complexities of sanitization programs, including multistep processes, the availability or need for multiple products with different use instructions, and low-moisture cleaning processes. The additional pressures of limited time and space for complicated procedures, high staff turnover, and the necessity for frequent training make time saving or simplification of sanitization (and disinfection) very desirable. Novel products are continually being developed and introduced to the market to help overcome some of these challenges by reducing risk, simplifying procedures, and helping to ensure compliance.

The recent development of procedures for reopening establishments that have been closed during the pandemic or for enhanced cleaning during operation have led to an increase in the availability and popularity of large area application techniques, such as fogging, misting, and electrostatic spray. However, the efficacies of these are unknown at this time, so there is some uncertainty and confusion about their usability. One of the greatest concerns is the potential for their misuse. The safety of workers and bystanders, in addition to effectiveness, should be paramount in decision making around these application options. Moreover, the regulatory requirements for products used through these systems are evolving.

In times of crisis, novel technologies and applications become very visible in the marketplace. It is important to note that pesticidal devices like UV and other nonchemical technologies do not go through the same regulatory rigor as traditional chemical products, and no standard efficacy methods exist for these products. Unlike chemical pesticides, the EPA does not routinely review the safety or efficacy of pesticidal devices and, therefore, does not confirm whether or under what circumstances such products might be effective against the spread of SARS-CoV-2 or other organisms. Some devices have limitations in how they are used and in general should only be used as an adjunct to routine sanitation practices. It is illegal to make false claims about the effectiveness of a pesticidal device, so any supporting science for such products should be carefully and critically assessed before adoption.

CONCLUSIONS

Historically, sanitizers have been the most commonly used antimicrobial product in retail food and foodservice establishments. That is changing as a result of the COVID-19 pandemic. Moving forward, we presumably will see disinfectants play a more important role in retail food and foodservice settings. Sanitizers and disinfectants are designed for different purposes, and these products must be used properly in order to achieve the desired public health outcomes. Therefore, it is important that industry professionals clearly understand when and how

to use a sanitizer and when and how to use a disinfectant. Most importantly, retail and foodservice industry training programs should emphasize the importance of proper use of sanitizers and disinfectants. When used properly, sanitizers and disinfectants are powerful tools that can keep retail food and foodservice operations safe.

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