

General Interest

Scientific Evidence Supports the Use of Alcohol-Based Hand Sanitizers as an Effective Alternative to Hand Washing in Retail Food and Food Service Settings When Heavy Soiling Is Not Present on Hands

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ABSTRACT

Suboptimal food worker health and hygiene has been a common contributing factor in foodborne disease outbreaks for many years. Despite clear U.S. Food and Drug Administration (FDA) Model Food Code recommendations for hand washing and glove use, food worker compliance with hand washing recommendations has remained poor for >20 years. Food workers' compliance with recommended hand washing guidelines is adversely impacted by a number of barriers, including complaints of time pressure, inadequate number and/or location of hand washing sinks and hand washing supplies, lack of food knowledge and training regarding hand washing, the belief that wearing gloves obviates the need for hand washing, insufficient management commitment, and adverse skin effects caused by frequent hand washing. Although many of the issues related to poor hand washing practices in food service facilities are the same as those in health care settings, a new approach to health care hand hygiene was deemed necessary >15 years ago due to persistently low compliance rates among health care personnel. Evidence-based hand hygiene guidelines for health care settings were published by both the Centers for Disease Control and Prevention in 2002 and by the World Health Organization in 2009. Despite similar low hand washing compliance rates among retail food establishment workers, no changes in the Food Code guidelines for hand washing have been made since 2001. In direct contrast to health care settings, where frequent use of alcohol-based hand sanitizers (ABHSs) in lieu of hand washing has improved hand hygiene compliance rates and reduced infections, the Food Code continues to permit the use of ABHSs only after hands have been washed with soap and water. This article provides clear evidence to support modifying the FDA Model Food Code to allow the use of ABHSs as an acceptable alternative to hand washing in situations where heavy soiling is not present. Emphasis on the importance of hand washing when hands are heavily soiled and appropriate use of gloves is still indicated.

HIGHLIGHTS

- Research indicates that 31% of hand washing opportunities involve visibly clean hands.
- Heavy soiling is unlikely in five of nine “when to wash” Food Code activities.
- Alcohol-based solutions are better than soap when soil is light to moderate.
- New alcohol-based solutions have increased activity against noroviruses.
- Hand washing and alcohol-based solutions are both effective when used separately.

Key words: Alcohol-based hand sanitizers; Food Code; Hand hygiene; Hand washing; Organic matter

The incidence of foodborne illness in the United States has remained largely unchanged in recent years (141) despite efforts by the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture Food Safety Inspection Service (USDA FSIS), and the Centers for Disease Control and Prevention (CDC). FDA efforts include regulations such as the Food Safety Modernization Act (162) and the juice (158) and seafood (154) hazard analysis and critical control point (HACCP) rules. The USDA FSIS

efforts include the pathogen reduction HACCP rule (155). The CDC (29) efforts include PulseNet, the Integrated Food Safety Centers of Excellence, and recent advances in whole genome sequencing.

Foodborne illnesses place a major burden on public health. CDC (28) estimates indicate that ca. 48 million people become ill, 128,000 are hospitalized, and 3,000 die as a result of foodborne illness every year in the United States. An estimated 9.4 million illnesses are caused by 31 known foodborne pathogens, and another 38.4 million are caused by unspecified pathogens (131, 132). In 2017, 841 outbreaks of foodborne illness were reported to the CDC's

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Foodborne Disease Outbreak Surveillance System (40). The economic costs associated with foodborne diseases also are substantial. The estimated average cost of foodborne illness is \$1,068 to \$3,630 per case, and the estimated annual costs in the United States are \$36 billion to \$77.7 billion (104, 134). The societal costs of foodborne illness have been estimated as 51,400 to >61,000 quality-adjusted life years (QALYs) lost annually (10, 104). A full discussion of QALYs is beyond the scope of this article, but QALYs is a commonly used measure of disease burden, which includes lives cut short by disease and lives affected by the long-term sequelae of disease.

The types of food items commonly implicated in foodborne illness include raw or undercooked meat and poultry, raw or lightly cooked eggs, unpasteurized milk, and raw shellfish (26) and contaminated vegetables and fruit (140). The five most common foodborne pathogens in the United States, in order of decreasing frequency of cases, are norovirus, non-typhoidal *Salmonella*, *Clostridium perfringens*, *Campylobacter* species, and *Staphylococcus aureus* (28). Norovirus accounted for 61% of outbreaks in retail food establishments reported to the National Environmental Assessment Reporting System from 2014 to 2016 (89). Although transmission of foodborne pathogens can occur in multiple settings (e.g., catering, institutional facilities, delicatessens, home kitchens, and grocery stores), analyses of data from the last two decades revealed that 56 to 80% of reported foodborne illness outbreaks were related to restaurants (2, 40, 89).

Multiple factors affect the occurrence of foodborne illness, including contamination of meat, poultry, eggs, and fresh produce related to on-farm practices, animal vaccination programs, regulatory changes, inspection policies, and food handling throughout the food chain (2, 140). Suboptimal food worker health, personal hygiene, and hand washing practices have been cited as some of the most common contributing factors in outbreaks (2, 11, 12, 61, 63, 95). From 1988 to 1992, improper holding temperatures of foods and poor personal hygiene among food handlers were cited as the two most common practices contributing to foodborne disease outbreaks (11). Between 1990 and 1999, poor hand washing by food workers was reported as a contributing factor in 31% of outbreaks in Washington State (145). Recent studies spanning 1998 to 2016 revealed that food worker health and hygiene were implicated as contributing causes in 59 to 76% of outbreaks of norovirus infection (2, 89, 97). Continuing to work while ill with vomiting and/or diarrhea undoubtedly contributes to outbreaks of foodborne illness, including those due to norovirus (18, 23, 139). When affected workers do not use proper hand washing techniques after using a restroom, as recommended in the FDA Food Code (161), hands may remain contaminated with norovirus (18). Surfaces or ready-to-eat food items that workers subsequently touch also may become contaminated, resulting in transmission of this pathogen to customers or other workers (18).

FDA MODEL FOOD CODE AND HAND WASHING

The FDA Food Code (161) includes specific recommendations on when and how retail food service workers

should clean their hands. Washing hands with soap and water is recommended for all listed indications. Soap is strictly defined as one or more salts of fatty acids containing at least eight carbon atoms. In common usage, soap means any hand washing compound, including true soap. Soaps may also be formulated to contain antimicrobial agents. Research has shown that antimicrobial soaps can be more effective than plain soaps by at least a modest (0.5 log CFU) but still significant amount (108). Because of concerns about the efficacy of alcohol-based hand sanitizers (ABHSs) in the presence of soil or nonenveloped viruses, the use of ABHSs is permitted only after hand washing (52, 100, 101). The World Health Organization (WHO) (173) has summarized the various components that are often found in ABHSs. The primary ingredient is ethanol or isopropyl alcohol, with a minimum concentration of 60%. Although methanol is also antimicrobial, it is not recommended because of its toxicity to humans. Water is typically the second ingredient. The water used must be of good sanitary quality. Glycerol and/or other humectants or emollients are often added to increase the acceptability of the product and protect the skin. The WHO recommends the use of low concentrations of hydrogen peroxide to help eliminate bacterial spores. Gelling agents, fragrances, and other ingredients can be added to improve user acceptability.

The goals of this article are (i) to review the rationale supporting Food Code hand washing recommendations taking into consideration hand washing compliance rates among food workers and barriers to hand washing, evidence regarding the relative microbiological efficacy of hand washing versus alcohol-based solutions including ABHSs in the presence of soil, and efficacy against nonenveloped viruses such as norovirus, and (ii) to offer science-based advice about when ABHSs could be used as an equally effective alternative to soap-and-water hand washing to improve hand hygiene compliance in retail food service establishments.

In section 2-301.12, the Food Code guidelines state that food workers should wash their hands and exposed portions of their arms in a hand washing sink using a “cleaning compound” (referred to in section 6-301.11 as hand cleaning liquid, powder, or bar soap) for at least 20 s. Hand washing should include rubbing the hands together for at least 10 to 15 s, followed by thorough rinsing and drying.

Evidence that supports these Food Code recommendations on when to wash hands is reviewed briefly below. The Food Code states that workers shall clean their hands and exposed portions of their arms “immediately before engaging in food preparation including working with exposed food, clean equipment and utensils, and unwrapped single-service and single-use articles” (161). This recommendation relates to workers whose hands may already be contaminated upon arrival at the food facility (42, 71, 83). Provisions of Food Code section 2-301.14 specifying when hands should be washed are listed below.

¶ (A) After touching bare human body parts other than clean hands and clean, exposed portions of arms. Normal human skin and hair are colonized with a variety of bacteria, most of which seldom cause foodborne illness.

However, at any given time, the skin of a substantial portion of individuals in the general population are transiently or persistently colonized at multiple body sites (especially the nose) with *S. aureus*, an important cause of foodborne illness (51, 78). Several surveys of food workers revealed that 24 to 27% had *S. aureus* nasal colonization (21, 85). Ho et al. (66) found that 16.6% of 548 workers in catering establishments had *S. aureus* on their hands. Some strains of *S. aureus* that colonize food workers can produce one or more staphylococcal enterotoxins (51). Because food workers often may touch their nose, mouth, hair, or other body sites while at work (34), transfer of *S. aureus* to food items may occur when hands are not washed after touching colonized body sites. However, food items contaminated by *S. aureus* are unlikely to cause foodborne illness unless the items are subsequently held under conditions that permit production of sufficient amounts of enterotoxins to cause staphylococcal food poisoning. We found no published evidence that touching the face, hair, or other exposed body parts results in hands becoming visibly dirty or soiled with substantial amounts of organic material.

¶ (B) After using the toilet room. Norovirus, *Salmonella*, and *Shigella* are common causes of foodborne illness that can be transmitted from food workers who are ill or are asymptomatic carriers of these enteric pathogens (145). Failure to wash hands adequately after using the toilet can result in transfer of the pathogen from contaminated hands to food contact surfaces or directly to food. The Food Code (section 2-201.12) also requires that the person at the food establishment who is responsible for the operation exclude ill workers symptomatic with vomiting or diarrhea and food workers diagnosed with asymptomatic infections. Because hand washing is of limited effectiveness (i.e., <2-log reduction in microbial populations on hands) (20, 118) and those made ill from these organisms can often shed very high levels (e.g., >8 log norovirus cDNA copies per g of stool (84); ~7 log CFU/g *Salmonella* and *Shigella* (127, 128)), exclusion probably is a far more effective risk reduction measure than proper hand washing.

¶ (C) After caring for or handling service animals or aquatic animals as specified in ¶ 2-403.11 (B). Service animals (e.g., dogs) may occasionally be colonized or infected with pathogens such as *S. aureus*, *Giardia*, *Cryptosporidium*, *Salmonella*, or *Campylobacter jejuni* (50, 64). Although enteric pathogens have been recovered from feces of dogs, it is not clear how often such organisms would be found on the fur of dogs. Although contact with such animals could result in contamination of food worker hands, we found no published reports of foodborne illness cases attributed to contact with service animals. Contact with aquatic animals (e.g., raw oysters, clams, fish, and lobsters in display cases) that may be colonized with foodborne pathogens such as *Salmonella*, *Shigella*, *Vibrio*, and enteric viruses could also contaminate the hands of food workers (68). Foodborne disease outbreaks linked to cross-contamination from raw seafoods are well documented

(166) and have been linked to a variety of foods (e.g., finfish and squid) and agents of foodborne disease (e.g., *Vibrio* and *Salmonella*) in a variety of settings, including restaurants (62, 72, 174).

¶ (D) Except as specified in ¶ 2-401.11(B), after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking. A substantial proportion of the general population is colonized with transient or persistent nasal and/or oral *S. aureus* (51, 78). Coughing, sneezing, or using a handkerchief or disposable tissue could result in hand contamination. Outbreaks of *Streptococcus pyogenes* infection have occurred when food workers sneezed on foods that were subsequently stored improperly (144). We found no published evidence that sneezing, coughing, or handling a contaminated or used handkerchief results in hands that are visibly dirty or visibly contaminated with proteinaceous material.

¶ (E) After handling soiled equipment or utensils. Equipment, utensils, and other surfaces used in food preparation can be contaminated with pathogens (77, 102, 136). In one survey, workers touching dirty equipment accounted for 36% of all observed activities that required subsequent hand washing (60).

¶ (F) During food preparation, as often as necessary to remove soil and contamination and to prevent cross-contamination when changing tasks. Food workers' hands may be contaminated with microorganisms that are carried by the worker or that are present in foods. In the absence of appropriate hand hygiene, these pathogens can be transmitted to surfaces and ready-to-eat foods (31, 32, 35, 38, 106, 133, 137, 165).

¶ (G) When switching between working with raw food and working with read-to-eat food. Raw animal products (e.g., beef, pork, and chicken) present in various departments of meat processing plants and in retail facilities can be contaminated with a variety of pathogens (136). A recent meta-analysis revealed that the frequency of contamination by *Campylobacter* and *Salmonella* was 60.9 and 14.3%, respectively, in postchill poultry samples in U.S. processing plants and 59.2 and 19%, respectively, in retail samples (55). Laboratory studies have revealed that handling artificially contaminated raw animal products may result in contamination of food workers' hands, sometimes at high levels (32, 35, 106, 165, 178). Hands contaminated in this fashion could subsequently transfer microorganisms to food items (106, 165).

Handling ready-to-eat foods with bare hands can result in cross-contamination of foods by pathogens present on food handlers' hands (175). An FDA report (159) on food service risk factors stated "preventing bare hand contact with ready-to-eat foods is a major control measure for limiting the spread of harmful bacteria and viruses from the hands to ready-to-eat food." This statement is important because workers touching nonfood contact surfaces prior to handling ready-to-eat food accounted for 67 to 86% of

TABLE 1. Summary of four studies using notational analysis of food establishment hand washing

Authors	Year	Audience	No. of workers	No. of businesses	Hours ^a	No. of potential hand washing events	Events/h
Clayton and Griffith (34)	2004	Catering	115	29	143	2,453	17.1
Green et al. (60)	2006	Food worker	321	321	255	2,195	8.6
Strohbehn et al. (138)	2008	Retail food service	80	16	240	3,413	14.2
Lubran et al. (92)	2010	Retail deli	33	9	19	712	38.1
Total			549	375	657	8,773	13.3

^a In some studies, the number of hours spent was not available in the article but could be estimated from the data provided.

actions for which hand washing was indicated in various types of retail delicatessen departments (92).

¶ (H) **Before donning gloves to initiate a task that involves working with food.** The hands of food workers can become contaminated with pathogens by handling contaminated raw food, dirty surfaces, or themselves during a variety of activities (66, 106, 133, 165, 175). In a laboratory-based study where hands were artificially contaminated with a foodborne pathogen surrogate, washing hands before donning gloves significantly reduced contamination of the outside of the gloves and reduced contamination of food subsequently handled with gloved hands (122).

¶ (I) **After engaging in other activities that contaminate the hands.** Other examples of when hands could be contaminated include handling soiled tableware, money, cash registers, trash, menus, other surfaces, or dirty clothing (99, 160). Despite the potential for hands to become contaminated following such activities, we found no evidence that touching the items listed above has resulted in foodborne illness.

COMPLIANCE WITH FOOD CODE RECOMMENDATIONS

Despite the Food Code's clear recommendations for hand washing and glove use, food worker compliance with recommendations on how and when to wash hands has remained poor for >20 years (25, 56, 61, 92, 156, 159). Multiple studies performed in food processing and manufacturing plants (49, 137) and a variety of retail food service facilities (1), including restaurants and delicatessens (112, 138, 176), have revealed that workers frequently do not perform hand washing for the recommended amount of time. Other deficiencies in hand washing techniques include failure to use soap (49, 60, 112, 138), not rubbing all parts of the hands and fingers while washing hands (49), and failure to dry hands as recommended (49, 60, 112, 138).

Food workers often fail to wash their hands with soap and water at times recommended in the Food Code. In a 2005 study of self-reported practices of food workers, 23% did not always wash their hands when indicated, 60% reported that they did not always wear gloves when handling ready-to-eat foods, and 33% did not always change gloves between handling raw meat and touching ready-to-eat foods (58). Todd et al. (143) reported that

failure to wash hands when indicated was an important factor in 73 of 861 outbreaks of foodborne illness.

At least four peer-reviewed studies on hand washing behavior in commercial food preparation facilities subject to Food Code guidance have been published (Table 1). Clayton and Griffith (34) pioneered the use of notational analysis in their study of catering operations in the United Kingdom during which they observed 115 workers from 29 businesses over ca. 140 h. Green et al. (60) observed 321 workers each from a separate business over ca. 255 h, Strohbehn et al. (138) observed 80 workers at 16 businesses over 240 h, and Lubran et al. (92) observed 33 workers at 9 businesses for ca. 18 h. Although all four studies used a similar approach and compared the results against similar work activities, each used slightly different categories, which can make direct comparison challenging. A summary of all four studies is presented in Table 2. Observations made on separate subpopulations (e.g., Green et al. (60)) were pooled, and cases that did not clearly map with Food Code requirements (e.g., Strohbehn et al. (138)) are noted as such in the table. The hand washing compliance with Food Code requirements across these four studies was 5 to 31%.

Table 3 presents an analysis of data consolidated for all four studies. The first column is the relevant text from either the Food Code or the other hand washing opportunities provided by Strohbehn et al. (138). The table is sorted by overall success rate where success is defined within each study as an appropriate hand washing event. The last column in the table presents a general descriptor of whether hands were likely to be soiled or unsoiled or of variable status depending upon the nature of the activity. The five least successful hand washing opportunities were from the study by Strohbehn et al. and could not be clearly matched to the descriptions in section 2-301.14 of the Food Code. The lowest ranking Food Code provision was (A): after touching bare human body parts other than clean hands and clean, exposed portions of arms. Poor compliance may occur because food workers may not realize that they have touched themselves or may feel that it is impractical to wash hands after touching themselves (60). Researchers have found that individuals touch their faces an average of 2.6 to 23 times per h (70, 79, 110), which suggests that hand washing after each instance would be very time-consuming and impractical. Washing hands with soap and water also is unlikely to be necessary because touching the face, hair, or other exposed skin is likely to result in hands that are not highly soiled.

TABLE 2. Data extracted from four studies using notational analysis of food establishment hand washing for observations of when hand washing was needed (N), was attempted (A), and successfully met Food Code requirements (S)^a

Food Code or other text ^b	Clayton and Griffiths (34)			Green et al. (60)			Strohbehn et al. (138)			Lubran et al. (92)		
	N	A	S	N	A	S	N	A	S	N	A	S
Before engaging in food preparation	486	70	68				145	79	15			
(A) After touching bare human body parts other than clean hands and clean, exposed portions of arms	274	34	25	197	25	19	149	3	0	10	4	4
(B) After using the toilet room												
(C) After caring for or handling service animals or aquatic animals as specified												
(D) Except as specified after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking	59	45	31	90	27	23	174	25	7	3	1	1
(E) After handling soiled equipment or utensils	795	342	196	786	215	181	641	145	53	530	0	0
(F) During food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks				514	237	209						
(G) When switching between working with raw food and working with read-to-eat food	600	447	343	384	121	89	39	1	0	15	14	13
(H) Before donning gloves to initiate a task that involves working with food				224	82	67	270	57	15	138	59	56
(I) After engaging in other activities that contaminate the hands	239	158	101				129	15	2	16	3	3
After touching clothing							330	0	0			
Before handling different types of food products							134	11	2			
After handling potentially hazardous food							42	10	0			
When changing tasks							942	74	31			
When entering food prep area							141	81	25			
After cleaning equipment, utensils							259	44	13			
After cleaning							18	10	2			
Total no. (%) of observations	2,453	1,096	764 (31)	2,195	707	588 (26.8)	3,413	555	165 (4.8)	712	81	77 (10.8)

^a Blank cells indicate that the action was not observed.

^b (A) through (I) are provisions of the Food Code (section 2-301.14).

TABLE 3. Summary of success rate for Food Code compliant hand washing from four studies using notational analysis of food establishments, including information on likely status of soil on the hands

Food Code or other text ^a	Needed	Attempted	Succeeded	Attempt rate (%)	Success rate (%)	Soil status
Strohbehn et al. (138): after touching clothing	330	0	0	0.0	0.0	Clean
Strohbehn et al. (138): after handling potentially hazardous food	42	10	0	23.8	0.0	Variable
Strohbehn et al. (138): before handling different types of food products	134	11	2	8.2	1.5	Variable
Strohbehn et al. (138): when changing tasks	942	74	31	7.9	3.3	Variable
Strohbehn et al. (138): after cleaning equipment, utensils	259	44	13	17.0	5.0	Variable
(A) After touching bare human body parts other than clean hands and clean, exposed portions of arms	630	66	48	10.5	7.6	Clean
Strohbehn et al. (138): after cleaning	18	10	2	55.6	11.1	Variable
Strohbehn et al. (138): before engaging in food preparation	631	149	83	23.6	13.2	Clean
(E) After handling soiled equipment or utensils	2,752	702	430	25.5	15.6	Variable
Strohbehn et al. (138): when entering food prep area	141	81	25	57.4	17.7	Clean
(D) Except as specified after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking	326	98	62	30.1	19.0	Clean
(H) Before donning gloves to initiate a task that involves working with food	632	198	138	31.3	21.8	Clean
(I) After engaging in other activities that contaminate the hands	384	176	106	45.8	27.6	Variable
(F) During food preparation, as often as necessary to remove soil and contamination and to prevent cross-contamination when changing tasks	514	237	209	46.1	40.7	Variable
(G) When switching between working with raw food and working with ready-to-eat food	1,038	583	445	56.2	42.9	Dirty
(B) After using the toilet room	0	0	0			Variable
(C) After caring for or handling service animals or aquatic animals	0	0	0			Variable

^a (A) through (I) are provisions of the Food Code (section 2-301.14).

Other situations with lower success rates were before beginning food preparation; (D) except as specified after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking; and (H) before donning gloves to initiate a task that involves working with food. In these situations, hands are likely to be free of debris. In the four studies summarized in Table 3, the highest rate of a successful hand washing was seen when switching between working with raw food and working with ready-to-eat food (provision G). Perhaps the presence of noticeable debris on workers' hands from working with raw food makes workers more inclined to wash their hands appropriately. However, in multiple subsequent studies, compliance with provision G continued to be suboptimal (2, 17, 89, 97).

For all four studies (Table 1), the total number of hand washing opportunities was 8,773 and the estimated total number of observation hours was 657, with an estimated overall average of 13.3 hand washing events per h (8.6 to 38.1 per h) (60, 92). Assuming a 20-s hand washing event plus a 30-s round trip to find a hand washing sink, ca. 7 to 32 min of every hour would be spent washing hands to comply with the Food Code provisions.

Based on the total number of required hand washing opportunities in which hands are likely to be clean, or may or may not be clean, an estimated 31% of hand washing opportunities would involve visibly clean hands, where an ABHS might be used. The dominant provision addressing hands that may or may not be dirty is (E): after handling

soiled equipment or utensils. Unfortunately, many of the studies included no details about the nature of the soiled equipment or utensils. In studies that included details, activities that are unlikely to result in visible debris on the hands included touching a deli scale touch pad, touching a deli case handle (92), or handling soiled dishware (138).

Periodic FDA inspections of food service facilities between 2000 and 2014 revealed that the percentage of restaurants that were out of compliance with avoiding bare hand contact with ready-to-eat foods had decreased significantly, from 58 to 12.5% in fast food restaurants ($P < 0.0001$) and from 75 to 33.6% in full-service restaurants ($P < 0.0001$) (Table 4) (156, 159, 160, 163). However, no appreciable reduction was found in the percentage of such facilities that were out of compliance with proper hand washing. The data confirm that getting food workers to comply with Food Code provisions for washing their hands with soap and water continues to be a substantial problem for restaurants. This problem is likely to continue unless real and perceived barriers to hand washing can be reduced.

BARRIERS TO HAND WASHING

Food workers' compliance with recommended hand washing practices is adversely impacted by a variety of barriers, some of which are related to the type of facility. Reported barriers include time pressure (especially during peak business hours) (60, 67, 146, 176), inadequate number and/or location of hand washing sinks and hand washing

TABLE 4. Percentage of fast food and full-service restaurants out of compliance with proper hand washing and prevention of hand contamination (workers do not contact exposed ready-to-eat food with bare hands)

Report yr	Fast food				Full service			
	<i>n</i> ^a	% out of compliance	<i>n</i>	% did not avoid bare hand contact	<i>n</i>	% out of compliance	<i>n</i>	% did not avoid bare hand contact
2000 (156)	103	53.0	102	58.0	106	81.0	105	75.0
2004 (159)	104	53.8	105	50.5	99	72.7	93	57.0
2009 (160)	98	38.8	99	26.6	95	75.8	95	46.3
2013–2014 (163)	422	65.6	425	12.5	392	82.4	396	33.6

^a *n*, number of observations.

supplies (1, 56, 67, 146), lack of food worker knowledge regarding hand washing and inadequate training (2, 56, 67), belief among some workers that wearing gloves obviates the need for hand washing (57), insufficient engagement and commitment by managers and companies to promote hand hygiene (59, 146), and dry skin caused by frequent exposure to soap and water for hand washing (4, 63, 67). The high frequency of activities for which hand washing is recommended (6 to 38 hand washing opportunities per h in various settings) also makes it difficult for workers to comply (34, 60, 92, 112, 138). Lack of food worker accountability for hand washing (146) might be due in part to insufficient periodic monitoring of hand washing practices and feedback to workers regarding their performance. Although routine monitoring of food worker hand washing by a person in charge has been recommended since at least the 1997 Food Code, we found no published data about methods used by food service managers to routinely monitor hand washing in food processing and food service facilities or the results of routine monitoring activities. As of 2014, poor food worker compliance with hand washing recommendations may also be partly explained by the lack of adoption of Food Code recommendations to avoid bare hand contact with ready-to-eat food and to wash hands before donning gloves by 24 and 22% of states, respectively (74).

REASSESSING THE EFFICACY OF HAND WASHING AND ALCOHOL-BASED SANITIZERS

Despite the continued problems of achieving acceptable compliance with Food Code recommendations for soap-and-water hand washing and glove use and numerous barriers experienced by food workers, no substantive changes in Food Code recommendations regarding when to wash hands with soap and water have been made since 2001. A PubMed Internet search using the terms “hand-washing OR hand hygiene” retrieved a total of 9,850 citations for articles published between January 2001 and 5 May 2020. Changing the search terms to “handwashing OR hand hygiene healthcare” retrieved 6,765 citations, suggesting that the preponderance of articles dealt with hand hygiene in health care settings. However, many of the issues related to poor hand washing practices in food service facilities are the same as those in health care settings (20, 53, 172).

Hand washing with soap and water was considered for 150 years one of the most important measures for preventing transmission of pathogens in health care facilities, where many ill and vulnerable individuals are cared for (20). However, health care personnel compliance with recommended hand washing procedures averaged only about 40% between 1981 and 2000 (20). Poor compliance with soap-and-water hand washing in health care settings was related to some of the same factors responsible for poor hand washing practices among food handlers, including suboptimal access to hand washing sinks, the time needed to perform appropriate hand washing, individuals feeling that they were too busy to wash their hands, the many situations in which hand washing is recommended, and the irritant contact dermatitis that can occur with frequent soap-and-water hand washing (20, 57, 67, 138, 146, 164).

Given the long-standing problem of poor hand washing compliance among health care personnel, a new approach to hand hygiene in health care was deemed necessary. Evidence-based hand hygiene guidelines for health care settings were published by the CDC in 2002 (20) and by the WHO in 2009 (172). The 2002 CDC hand hygiene guideline was published after the FDA Food Code provisions for hand washing were slightly expanded in 2001 (157). After conducting extensive reviews of scientific evidence regarding hand hygiene (which includes hand washing with soap and water, use of ABHSs, and use of gloves), both guidelines recommended washing hands with soap and water when hands are visibly soiled and when using a restroom and using ABHSs as the preferred method of hand hygiene in other clinical scenarios when hands are not visibly soiled (20, 172). These recommendations were based on the advantages ABHSs have over hand washing and on the results of 22 controlled laboratory studies in which alcohol-based solutions reduced bacteria on the hands to a greater extent than did hand washing (20). In 13 of the 22 studies, researchers compared plain or antimicrobial soap to alcohol-based solutions for their efficacy in reducing bacterial counts on artificially contaminated hands (20). Nine of the 13 studies provided quantitative information about the size of the inoculum applied to hands before testing products (Table 5) (6, 7, 9, 22, 115, 123–126). Hands or fingertips of volunteers were contaminated with test pathogens at >10,000 to >1 million CFU followed by application of various plain soap and/or antimicrobial soap or various alcohol-based solutions. In each of the nine studies involving heavily contaminated hands, alcohol or

TABLE 5. Relative efficacy of plain soap, antimicrobial soap, and alcohol solutions for reducing bacteria on artificially contaminated hands or fingertips

Author(s)	Assay method	Time (s)	Participants	Inoculum applied to hands or fingertips (CFU/mL)	Rank order of antimicrobial efficacy ^a
Ayliffe et al. (7)	Fingertip broth culture	30	Six staff volunteers	10 ⁷ -10 ⁸ <i>S. aureus</i> or <i>Pseudomonas aeruginosa</i>	70% EA = alc. CHG > P-I > 4% CHG > plain soap
Rotter (123)	Fingertip broth culture	60-120	15 volunteers	> 10 ⁴ <i>E. coli</i>	60% IPA > P-I > 4% CHG
Bartzokas et al. (9)	Fingertip broth culture	120	Five volunteers	> 10 ⁴ <i>E. coli</i>	Alc. triclosan > alc. CHG = 60% IPA = 0.3-2% triclosan soap
Rotter (124)	Fingertip broth culture	60	30 volunteers	> 10 ⁴ <i>E. coli</i>	n-P > IPA > EA > P-I > 4% CHG < phenolic soap
Rotter et al. (126)	Fingertip broth culture	60	30 volunteers	> 10 ⁵ <i>E. coli</i>	n-p > alc. CHG > P-I = phenolic soap
Ayliffe et al. (6)	Fingertip broth culture	30	10-15 volunteers	> 10 ⁵ <i>E. coli</i>	n-p > alc. CHG > IPA > P-I > triclosan > plain soap
Rotter and Koller (125)	Fingertip broth culture	60	16 healthy volunteers	> 10 ⁶ <i>E. coli</i>	60% n-P > plain soap
Paulson et al. (115)	Glove juice test	20	25 adults	> 10 ⁸ <i>Serratia marcescens</i>	65% EA > 0.6% PCMX soap > plain soap
Cardoso et al. (22)	Fingertip broth culture	30	Five healthy adults	10 ⁶ <i>Acinetobacter baumannii</i>	70% EA > P-I > plain soap > 4% CHG soap

^a EA, ethanol; alc. CHG, alcohol-based chlorhexidine gluconate; P-I, povidone-iodine; PA, isopropanol; n-P, n-propanol; PCMX, para-chloro-meta-xyleneol.

alcohol plus a low concentration of chlorhexidine gluconate was more effective than plain soap or antimicrobial soap for reducing bacteria on volunteers' hands or fingertips (Table 5). In Tables 5 through 8, the rank order of efficacy of agents is shown, but differences in rank were not always statistically significant according to the analyses of the respective authors. The volumes of soap and/or alcoholic solutions applied to volunteers' hands and the amount of time performing hand hygiene did not mimic the manner in which hand hygiene is often performed by health care personnel or food workers. In food service establishments, the amount of soap or ABHS applied to hands by food workers and the duration of hand hygiene is likely to be more variable than those achieved in laboratory settings. However, the studies cited in these tables accurately reflect the relative efficacy of the agents studied.

In at least 17 additional studies, 5 of which were cited in the CDC hand hygiene guideline, researchers have tested the relative efficacy of different soaps or alcohol-based formulations with health care personnel whose hands or fingertips were contaminated or soiled with bacteria acquired during their daily activities, not artificially contaminated (Table 6) (8, 16, 33, 36, 48, 54, 69, 73, 87, 93, 98, 111, 129, 151, 153, 169, 177). In these 17 studies, a variety of assay methods were used, and the duration of hand washing or hand rubbing with alcohol solutions or ABHSs varied from 15 s to as long as hand washing for 120 s in one study. In most studies, health care personnel were tested after performing standard patient care, which often involves direct contact with patients' skin or body fluids and contaminated objects near the patient (120, 129, 142). Because the skin and body fluids of hospitalized patients and items in their immediate environment are frequently contaminated with one or more pathogens (24, 44, 65), hands of health care personnel often become transiently contaminated with pathogens (6, 24, 43, 65, 119, 171) and may be soiled with minimal to moderate amounts of organic substances, although hands are usually not visibly soiled. In one study, staff touched wound dressings of patients who had sustained burns (111), and in another study, personnel touched the groins of patients whose skin was heavily colonized with gram-negative bacteria (48). In 16 of the 17 studies of the relative efficacy of various agents for hand hygiene, alcoholic solutions or commercially available ABHSs reduced bacteria on health care workers' hands more effectively than did plain soap or antimicrobial soap. In one study, results were comparable for ABHS and plain soap (Table 6). Because both the CDC and WHO guidelines for hand hygiene in health care settings recommend ABHSs as the preferred method of hand hygiene when hands are not visibly soiled, ABHSs currently are used in ca. 80% of all hand hygiene events in hospitals (5).

Given the compelling evidence of the superior efficacy of alcohol solutions and ABHSs for reducing hand contamination in health care personnel and the documented difficulties associated with achieving acceptable hand washing compliance rates among health care personnel and food workers, a review of studies comparing soaps to alcohol-based solutions in non-health care individuals is warranted to assess the potential for greater use of ABHSs

TABLE 6. *In vivo* studies of the relative efficacy of alcohol-based solutions versus hand washing with soap and water performed by health care personnel with hand contamination resulting from a variety of activities (not artificially contaminated)

Author(s)	Assay method	Time (s)	Participants	Type of activity, hand contamination, or soiling	Rank order of antimicrobial efficacy ^a
Ayliffe et al. (8)	Hand rub broth culture	NS ^b	Nurses working in two hospitals	Performed routine patient care	95% EA > plain soap
Lilly et al. (87)	Hand rub broth culture	120	Volunteers	“Socially clean” hands	Alc. CHG > 4% CHG > 70% EA > 0.5% aq. CHG soap > plain soap
Ojararvi (111)	Fingertip agar culture	15	55 hospital staff	Staff touched burn patient wound dressings and compresses	Alc. CHG > 94% EA > 4% CHG > 70% EA = 3% HCP > P-I > plain soap
Blech et al. (16)	Fingertip agar culture	60	Hospital clinical staff	Naturally occurring flora	90% EA > 70% EA > plain soap
Ehrenkranz and Alfonso (48)	Glove juice test	15	Six health care workers	Touched groins of multiple patients whose skin was heavily colonized (>10 ⁴ CFU) with gram-negative bacteria	ABHS (63% IPA) > plain soap
Zaragoza et al. (177)	Agar plate culture	NS	43 health care workers on wards and ICUs	Performed routine clinical patient care	ABHS (alc. mixture) > plain soap
Winnefeld et al. (169)	Modified glove juice test	NS	51 nurses	Performed usual hospital activities	ABHS (alc. mixture) > plain soap
McNeil et al. (98)	Sterile swab and microspatula used to sample fingernails	NS	30 health care workers wearing artificial nails, 30 health care workers with normal fingernails	Performed usual work activities	ABHS (60% EA) > PCMX soap
Lucet et al. (93)	Fingertip agar plate culture	Variable	43 health care workers from seven nursing units	Contact with patients, their environment, or body fluids	ABHS (alc. mixture) > antimicrobial soap > plain soap
Girou et al. (54)	Agar plate hand imprint culture	Variable	23 nurses and nursing assistants without visibly soiled hands	Direct contact with patient skin or any part of patient colonized with multiresistant bacteria	ABHS (alc. mixture) > 4% CHG soap
Trick et al. (151)	Modified glove juice test		66 surgical ICU nurses	Performed routine patient care; 33% of episodes involved direct contact with a patient's skin	ABHS (62% EA) > plain soap
Tvedt and Bukholm (153)	Agar plate culture	Variable	50 health care workers, 20 nurses	Performed routine patient care; touched patient's urinary equipment	ABHS (70% IPA) > plain soap
Kac et al. (73)	Hand imprint method	30	50 health care workers from wards and ICUs	Contact with patients and their environment	ABHS (alc. mixture) > plain soap
Creamer et al. (36)	Finger imprint method	NS	Health care workers	Contact with patients with MRSA ^c	ABHS > plain soap > 4% CHG soap
Chow et al. (33)	Modified glove juice test	Variable	60 medical personnel, 60 nurses	Direct contact with patient skin; performed routine care	ABHS (70% EA + 2.5% CHG) > 4% CHG soap
Salmon et al. (129)	Finger imprint method	NS	134 health care workers	Patient contacts, including skin, body fluids, secretions, or environmental surfaces	ABHS (alc. mixture + 0.5% CHG) > 4% CHG > plain soap
Jain et al. (69)	Agar plate culture	NS	40 health care workers	Contact with the skin of patients with MRSA or VRE ^d and their environment	ABHS = plain soap

^a EA, ethanol; alc. CHG, alcohol-based chlorhexidine gluconate; aq. CHG, aqueous CHG; HCP, hexachlorophene; P-I, povidone-iodine; IPA, isopropanol; n-P = n-propanol; ABHS, alcohol-based hand sanitizer; PCMX, para-chloro-meta-xyleneol.

^b NS, not specified.

^c MRSA, methicillin-resistant *Staphylococcus aureus*.

^d VRE, vancomycin-resistant enterococci.

TABLE 7. *In vivo* studies of the relative efficacy of alcohol-based solutions versus hand washing with soap and water performed by non-health care personnel with hand contamination resulting from a variety of activities (not artificially contaminated)

Authors	Assay method	Time (s)	Participants	Type of activity, hand contamination, or soiling	Rank order of antimicrobial efficacy ^a
Dineen and Hildick-Smith (41)	Fingertip agar culture	60	50 healthy persons	Naturally occurring flora	ABHS (50% EA) > HCP > plain soap
Larson et al. (82)	Sterile broth bag	15	University employees and students	Naturally occurring	ABHS (60% IPA) > 70% IPA > 4% CHG soap > alc. CHG > plain soap
Leyden et al. (86)	Agar plate image	30	University employees and students	Naturally occurring	IPA > ABHS (70% IPA + 0.5% CHG) > 4% CHG soap > P-I > 1% triclosan > plain soap
Larson and Bobo (81)	Sterile broth bag	15	University students and staff	1.2 mL of sheep's blood was rubbed over surface of hands and allowed to dry	ABHS (70% EA + 0.5% CHG) > 70% IPA > 4% CHG soap > plain soap > P-I
Pickering et al. (116)	Modified glove juice test	NS ^b	53 high school students, 127 mothers of children <10 yr old, 10 nurses in Tanzania	Naturally occurring hand contamination with <i>E. coli</i> (mean, 2.49 log CFU) and fecal streptococci (mean, 4.23 log CFU)	ABHS (62% EA) > plain soap
Miller et al. (103)	Agar plate culture	Variable	20 volunteers, including production workers, line workers, servers, bussers, dishwashers	Naturally occurring flora; timing relative to work activities not stated	Antimicrobial soap > plain soap > ABHS (60 and 62% EA)
Davis et al. (37)	Broth bag method	NS	Exhibitors at livestock show	Handled livestock (cattle, sheep, swine)	ABHS (62% EA) = antimicrobial soap
Traub-Dargatz et al. (150)	Sterile bag with phosphate buffered saline	NS	48 veterinary students	Touched horses' oral mucous membranes and multiple areas of skin; obtained rectal temperature; picked up each foot	ABHS (61% EA + 1% CHG) > ABHS (62% EA) > 0.3% triclosan soap
de Aceituno et al. (38)	Sterile bag with 0.1% peptone water	Variable	Farm workers	Picked tomatoes for 1–2 h; hands were visibly soiled and contaminated with small to large numbers of coliforms and <i>Enterococcus</i>	ABHS (70% EA) = plain soap (soap removed more dirt than did ABHS)
Charbonneau et al. (31)	Hand imprint image analysis	20	Four volunteers	Handled whole raw chicken for 45 s	Plain soap > ABHS (70% EA)

^a ABHS, alcohol-based hand sanitizer; EA, ethanol; HCP, hexachlorophene; IPA, isopropanol; CHG, chlorhexidine gluconate; alc. CHG, alcoholic CHG; P-I, povidone-iodine.

^b NS, not specified.

among food workers. Table 7 provides a summary of 10 studies involving individuals engaged in a variety of activities with various levels of soiling of hands (31, 37, 38, 41, 81, 82, 86, 103, 116, 150). In four studies involving

healthy adults in various settings (with naturally occurring hand flora), ABHSs were more effective than plain or antimicrobial soap (41, 82, 86, 116). In contrast, in one study comparing soaps and ABHSs in a variety of food

service workers, both plain soap and antimicrobial soaps reduced bacteria on the hands, whereas use of all three ABHSs studied yielded counts higher than baseline (no reductions) (103). The results from that study are not consistent with the preponderance of evidence regarding ABHS and may have been related to the methods used. In that study, the amount of ABHS applied and the duration of rubbing were not reported, and cultures were made from only workers' fingertips, which are often missed when individuals do not apply ABHS appropriately (167). In another study where 1.2 mL of sheep's blood was rubbed over the surfaces of volunteers' hands (resulting in a visible degree of organic soiling), alcohol-containing solutions reduced bacterial counts on hands more effectively than did povidone-iodine soap or plain soap (81). Davis et al. (37) found that using an ABHS yielded results similar to those for washing hands with plain soap among exhibitors who handled cattle, sheep, or swine at an animal exhibit. Traub-Dargatz et al. (150) reported that an ABHS reduced bacteria on hands more effectively than did antimicrobial soap among veterinary students who contaminated their hands during physical examinations of horses (Table 4). Volunteers in both studies likely had light to moderate organic substances soiling their hands. Another study included a small group of farm workers who had harvested tomatoes for 1 to 2 h, resulting in workers' hands being heavily soiled and contaminated with coliforms and *Enterococcus*, and the efficacy of plain soap was compared with that of an ABHS with 70% alcohol (38). No significant difference in effectiveness was found between plain soap and the ABHS, although soap did remove more dirt. Charbonneau et al. (31) found that volunteers' hands contaminated with naturally occurring bacteria by handling whole, fresh raw chicken for 45 s (heavy organic soiling) were more effectively decontaminated by plain soap than by an ABHS containing 70% alcohol. Reduction was measured by using semiquantitative image analysis, but the results for soap versus ABHS were not assessed statistically. Thus, additional studies employing the methods utilized by Charbonneau (31) are needed to confirm the results of that study.

Table 8 provides a summary of 12 studies involving volunteers with hands that were artificially contaminated with various pathogens (or surrogates) combined with varying degrees of soil load to mimic light to heavy degrees of soiling (3, 14, 15, 46, 47, 88, 96, 100, 117, 133, 152, 170). In one study in which hepatitis A virus in 5% fetal bovine serum (light soil load) was applied to fingerpads of volunteers, an ABHS containing 62% alcohol reduced the virus by <1 log PFU and was less effective than plain or antimicrobial soap (14). These results are not surprising because nonenveloped viruses such as hepatitis A are well known to be relatively resistant to ABHSs. In another study with a light soil load (5% fetal bovine serum or an American Society for Testing and Materials composite soil load), a newer 70% ethanol-based ABHS containing polyquatium-37 and citric acid was used, which has greater efficacy against nonenveloped viruses. Treatment yielded a 1.3-log reduction of hepatitis A virus, a greater log reduction than achieved with 75% ethanol (2.48 versus 0.91 log PFU, respectively) against murine norovirus (MNV),

and >2.98-log reductions of adenovirus type 5, rotavirus, and poliovirus type 1 (96). In a subsequent study, the same ABHS reduced MNV on hands significantly better than did plain soap (47). These studies with newer ABHS products with an increased spectrum of activity should reduce concerns regarding the activity of ABHSs against non-enveloped viruses.

Wolfe et al. (170) compared hand washing and use of a hand sanitizer on hands contaminated with *Escherichia coli* or enveloped Phi6 phage with and without a moderate soil load. In the absence or presence of soil load, no significant difference in log reductions of *E. coli* were achieved with plain soap or hand sanitizer. Phi6 log reductions were similar with soap and sanitizer without soil load; however, hand washing yielded greater log reductions in the presence of a moderate soil load. In a more recent study in which moderate to heavy soil loads (0.5 mL of corn oil or 0.2 g of sterile dirt) were applied to volunteers' hands artificially contaminated with an average *E. coli* level of 10^7 CFU, no significant differences in the efficacy of an ABHS containing 62% alcohol was noted for hands that were clean versus those covered with oil or dirt (117). Similar efficacy was reported by Schaffner and Schaffner (133), who found that ABHS was efficacious despite the presence of visible meat debris on the hands.

Studies in which heavy soil loads have been applied to hands of volunteers for comparing soaps with alcohol-based solutions have produced variable results (Table 8). In a study in which hands were heavily contaminated with beef broth containing a high level of *E. coli*, ABHS was more effective than plain soap (46). In two studies in which volunteers pressed their fingernails into ground beef contaminated with *E. coli* at $\geq 10^8$ CFU, the authors found no significant differences in efficacy between plain soap, triclosan-containing soap, or an ABHS containing 62% alcohol. Combining soap with the use of a fingernail brush yielded significantly better efficacy than that of the ABHSs in one of the two studies (88, 100). Ansari et al. (3) applied fecal suspensions (heavy soil load) containing either rotavirus or *E. coli* at 9.9×10^4 CFU to volunteers' hands and found that alcohol-based solutions were more effective than plain or antimicrobial soap. In studies in which fecal suspensions of feline calicivirus (FCV), MNV, or human norovirus (HuNoV) were applied to volunteers' hands, plain and antimicrobial soaps were more effective than ABHSs (88, 152). These results are not surprising given the well-known reduced efficacy of most ABHS formulations against nonenveloped viruses, which lack a lipid membrane that is susceptible to alcohols.

The majority of the studies cited above (Tables 6 through 8) involving health care and non-health care personnel with naturally or artificially contaminated hands provide evidence that supports the following conclusion: alcohol-based solutions (including ABHSs) are more effective than plain or antimicrobial soaps for reducing bacterial counts on hands with naturally occurring flora or more than usual levels of bacterial contamination when hands are not soiled or are only lightly to moderately soiled with organic substances. Plain and antimicrobial soaps are usually more effective than alcohol-based formulations

TABLE 8. *In vivo* studies of the relative efficacy of alcohol-based solutions versus hand washing with soap and water performed by non-health care personnel whose hands were artificially contaminated with microorganisms and various types of soil load

Authors	Assay method	Time (s)	Participants	Type of contamination and soil load ^a	Relative efficacy ^b
Ansari et al. (3)	Fingerpad and whole-hand assay	10	Three adult volunteers	Fingerpads contaminated with 1.5×10^4 PFU rotavirus applied in fecal suspension, 9.9×10^4 CFU <i>E. coli</i> applied in fecal suspension	70% EA or IPA > Savlon/70% EA or IPA > Savlon > P-I > alc. CHG > antimicrobial soap > plain soap 70% IPA > Savlon/70% IPA > Savlon > plain soap
Bidawid et al. (14)	Fingerpad assay	20	11 volunteers	1.3×10^5 PFU of HAV suspended in 5% FBS placed on fingerpads	Antimicrobial soap = plain soap = 75% EA > ABHS (62% EA)
Lin et al. (88)	Electronic toothbrush used to scrub contaminated nails, then culture	15–25	18 volunteers	Artificial and natural fingernails contaminated with ground beef contaminated with 10^8 CFU/g <i>E. coli</i> ; artificial feces containing 10^5 TCID ₅₀ /g FCV	Triclosan soap > ABHS (62% EA) > plain soap for <i>E. coli</i> removal; triclosan soap > plain soap > ABHS (62% EA) for FCV removal
Michaels et al. (100)	Glove juice method for hands; electronic toothbrush for fingernails	Variable	Three volunteers for hand washing study; 18 volunteers for fingernail study	Fingernails were pressed four times into ground beef containing <i>E. coli</i> at 10^{10} CFU/25 g of meat	Soap + nail brush > 0.5% triclosan soap > ABHS (62% EA) > plain soap
Bidawid et al. (15)	Fingerpad method	Variable	Six adult volunteers	3×10^5 PFU of FCV with tripartite soil load was applied to fingertips	Plain soap > 75% EA > ABHS (62% EA)
Schaffner and Schaffner (133)	Glove juice method	Variable	32 volunteers	Each volunteer handled nine raw frozen beef patties contaminated with 2×10^5 CFU/cm ² <i>Enterobacter aerogenes</i> resulting in perceived or visible debris on hands	ABHS (60% EA) reduced <i>E. aerogenes</i> by mean of 2.58 log CFU
Macinga et al. (96)	Fingerpad method	15–30	Eight volunteers	Fingerpads contaminated with MNV with 5% FBS or ASTM composite soil load; fingerpads contaminated with adenovirus type 5, rotavirus, poliovirus 1 or HAV with 5% FBS or ASTM composite soil load	ABHS (70% EA) > 75% EA; ABHS (70% EA) reduced adenovirus, rotavirus, and poliovirus 1 by >2.98 log PFU and HAV by 1.32 log PFU
Edmonds et al. (46)	Modified FDA personnel hand washing method	Variable	Healthy adults	Hands contaminated three times with 1.5 mL of beef broth containing <i>E. coli</i> at 10^9 CFU/mL	ABHS (70% EA) > plain soap
Edmonds et al. (47)	Modified ASTM E2011-09 method using glove rinsate	Variable	Six participants	Hands contaminated with 1.5 mL of stock solution with 10^7 TCID ₅₀ of MNV in $\geq 5\%$ FBS	ABHS (70% EA) > plain soap

TABLE 8. Continued

Authors	Assay method	Time (s)	Participants	Type of contamination and soil load ^a	Relative efficacy ^b
Pickering et al. (117)	Modified glove juice test	Not stated	15 university students and graduate students	Hands contaminated with <i>E. coli</i> at 10 ⁷ CFU and 0.2 g of sterile dirt or 0.5 mL of corn oil	ABHS (62% EA) yielded similar reductions (2.1–2.3 log CFU) of <i>E. coli</i> from hands that were clean or soiled with dirt or oil
Wolfe et al. (170)	Modified glove juice test	Variable	18 volunteers	Hands contaminated with <i>E. coli</i> or Phi6 phage with or without ASTM soil load	<i>E. coli</i> : ABHS (70% EA) with or without soil load = plain soap; Phi6: plain soap = ABHS without soil load, but plain soap > ABHS with soil load
Tuladhar et al. (152)	Fingerpad method	30	Three volunteers	Fingerpads were contaminated with MNV or two strains of HuNoV suspended in 1% sterile feces	Plain soap > ABHS (non-EA alcohol mixture) for infective MNV and genomic copy reduction of HuNoV

^a HAV, hepatitis A virus; FBS, fetal bovine serum; FCV, feline calicivirus; MNV, murine norovirus; ASTM, American Society for Testing and Materials.

^b EA, ethanol; IPA, isopropanol; P-I, povidone-iodine; alc. CHG, alcoholic chlorhexidine gluconate; ABHS, alcohol-based hand sanitizer.

when hands are heavily soiled with proteinaceous or greasy substances.

Several investigators have compared the efficacy of hand washing with soap and water alone to hand washing followed immediately by the application of an ABHS (47, 100, 107, 121). Michaels et al. (100) found that hand washing with plain soap followed by application of >3 mL of an ABHS was more effective than plain soap alone when hands were contaminated with *Serratia marcescens* at 10⁴ CFU. In a trial involving four individuals with dirty hands from catching chickens, the combination of soap followed by ABHS did not reduce hand contamination significantly better than did soap alone with low or medium levels of bacterial contamination. The sequential use of both regimens, however, was more effective when hands were heavily contaminated with coliform bacteria (121). In a study that included sequential regimens involving hands artificially contaminated with *E. coli* suspended in chicken broth (moderate soiling), regimens in order of increasing efficacy were plain soap < plain soap or para-chloro-meta-xylenol (PCMX) soap followed by 62% alcohol foam < plain soap or PCMX soap followed by a newer 70% alcohol gel with an increased spectrum of activity (47). When participants massaged ground beef containing *E. coli* at 5 × 10⁸ CFU per 4-oz (113-g) portion (heavy soiling), either PCMX soap or triclosan soap followed by 62% ethanol foam was less effective than using either type of soap followed by the newer 70% alcohol gel (47). The authors suggested that the combination of hand washing followed by the use of an ABHS might reduce the potential for pathogen transmission in situations in which there is a high risk of heavy soiling when handling foods.

Several studies have also addressed the lack of soap and water in some food handling settings by comparing hand washing to a two-step protocol wherein 3 mL of ABHS is applied to hands and rubbed for 15 s followed immediately by cleaning hands thoroughly with two paper towels when hands are still wet (step 1). An extra 1.5 mL of ABHS is next applied to hands, which are then rubbed until dry (step 2) (39, 46, 47). When hands were moderately soiled with beef broth contaminated with *E. coli* at 10⁹ CFU, the two-step technique with a 62% ABHS gel yielded reductions that were not significantly different from those obtained with plain soap. Use of a 62% ABHS foam and a 70% ABHS advanced formula gel both yielded log reductions significantly greater than those achieved with plain soap (46). When hands were heavily soiled by handling ground beef contaminated with *E. coli* at 5 × 10⁸ CFU per portion for 2 min, the two-step technique with 62% ABHS foam or a 70% ABHS gel yielded reductions equivalent to or slightly greater than those with plain or antimicrobial soap. The 70% ABHS with advanced formulation yielded a log reduction significantly greater than that with the two soaps (46). In another study of 80 farm workers with dirty and contaminated hands after picking tomatoes for 1 to 2 h, the two-step procedure with a 70% ABHS reduced bacterial counts on hands more effectively than did plain soap alone (39). The authors suggested that the two-step process may be useful in agricultural settings in which soap and water are not available.

Peer-reviewed data on the frequency and patterns of ABHS use in food processing and food service establishments are not currently available. Because the Food Code currently allows ABHS use only after hand washing,

ABHSs probably are not widely used in food service facilities. At least one restaurant chain is recommending that required hand washing episodes be routinely followed by the application of an ABHS containing at least 60% alcohol. During the COVID-19 pandemic, the CDC has recommended that restaurants and bars make ABHSs available on tables to promote hand hygiene (27). As a result, ABHSs are currently more frequently available in retail food service establishments.

GLOVE USE

The Food Code recommends that workers wear gloves to begin a task that involves food. This Food Code recommendation is supported by evidence that gloves help prevent contamination of food workers' hands. Gloves are especially important when dealing with raw animal products or when engaging in other activities that may result in hands becoming dirty or contaminated with large amounts of organic substances or high levels of pathogens (106). Wearing gloves can also prevent transmission of pathogens from bare hands to various food items, including ready-to-eat foods (105, 108, 122, 147, 175). The lack of specificity of the Food Code recommendation may account in part for differences in glove policies in retail establishments. In a 2014 to 2016 survey, most establishments required gloves when handling ready-to-eat foods and when workers had cuts or other skin injuries, but only half required gloves to be worn at all times when working in a kitchen (89). The same survey revealed that bare-hand contact by potentially infectious workers (food handlers and preparers) was one of the top 10 factors contributing to outbreaks in retail food service establishments (89). Failure to wear gloves consistently when recommended, not changing gloves between handling raw meat and ready-to-eat foods, and wearing contaminated gloves for prolonged periods are other factors that have contributed to outbreaks (2, 17, 63, 94, 147). Wearing gloves may also result in food workers not washing their hands as often as they should (147). Some food workers may be unaware that hands may become contaminated due to leaks in gloves or during the process of removing gloves (106, 147) and may not be aware that hand hygiene should be performed after glove removal.

RESEARCH AGENDA

Updates of the FDA Food Code provide an opportunity to review and potentially revise a variety of its current recommendations, including those related to ABHS use and hand washing. ABHSs are currently allowed only after hand washing has been performed and are not recommended as an alternative to hand washing. The FDA has stated that its two major reservations regarding the use of ABHSs in food processing or food service establishments are related to (i) the ability of ABHSs to adequately reduce pathogens on hands with varying degrees of soiling and (ii) the relatively poor activity of many ABHSs against norovirus (133). Further exploration of both objective and subjective criteria (e.g., visible soiling) for classifying hand soiling experienced by food workers in different settings is needed (109). Field trials comparing the efficacy of hand washing versus

use of ABHSs among workers with defined levels of soiling could better establish the situations in which use of ABHSs is an appropriate alternative to hand washing (148). Such trials could be conducted in food service settings in which food workers have little hand soiling and in other settings in which workers have more soil or fat on their hands. Outcome measures could include hand contamination during and after the end of a shift for workers with identical activities who routinely used soap-and-water hand washing versus ABHSs. In settings in which the use of ABHS alone (without hand washing) results in a low risk of pathogen transmission, greater use of ABHS would be appropriate. Conducting such trials in food service establishments could be challenging because of the reluctance of managers to have research personnel on the premises. Managers may be concerned that research personnel might call out workers with deficient hand hygiene or might report deficiencies to health officials (176).

The relative paucity of current data on food workers' hand washing compliance rates warrants additional studies in various types of food processing and food service establishments (149). The dearth of published data on facility managers' routine monitoring of workers' hand washing performance indicates the need for research on methods currently used in food service. Experiences from the health care field indicate that the methods used to measure hand hygiene compliance differ substantially between facilities and can greatly influence estimated compliance rates (19). Food service establishments may want to consider implementing methods used in health care facilities for monitoring hand hygiene, such as periodic observational surveys by trained observers and/or the use of automated hand hygiene monitoring systems (19).

Additional studies of the activity of ABHSs containing at least 70% ethanol against MNV or HuNoV should include assays of the impact of these ABHSs on viral capsid proteins because PCR assays of viral RNA do not accurately reflect the presence of viable virus (13, 75, 91, 113). Such studies are needed in light of the high virus loads shed by those with symptomatic norovirus infections and the relative limited ability of hand washing to eliminate these viruses. Organizations responsible for minimizing food-borne illness would presumably welcome continued research by industry to develop novel formulations of ABHSs that have improved activity against norovirus (96, 168).

DISCUSSION

Despite persistently low hand washing compliance rates among workers in retail food service establishments, no changes in the Food Code's indications for hand washing have been made since 2001 (161). Unlike health care settings, where frequent use of ABHSs has improved hand hygiene compliance rates and reduced infections, the Food Code continues to permit the use of ABHSs only after hands have been washed with soap and water. Based on a 2016 literature review, Foddai et al. (52) concluded that ABHSs are not appropriate for use in food service. The authors cited concerns about the ability of ABHS to reduce microorganisms on hands in the presence of food debris or non-enveloped viruses. However, based on our review of the

current body of evidence, we believe the conclusion by Foddai et al. must be reassessed.

Among 23 studies in which ABHSs were compared with soap-and-water hand washing among individuals whose hands were not artificially contaminated, in 18 (78.3%) of those studies researchers found that ABHSs reduced the number of viable bacteria on hands to a greater extent than did hand washing (Tables 6 and 7) (33, 36, 41, 48, 54, 73, 81, 82, 86, 93, 98, 116, 129, 150, 151, 153, 169, 177). In 3 (13%) of these 23 studies, ABHS yielded results similar to those for plain soap (37, 38, 69). Soap and water reduced bacteria more effectively than did ABHSs in two studies, one of which involved workers whose hands were heavily soiled after handling raw chicken for 45 s (31, 103). ABHSs outperformed soap-and-water hand washing in five of six hospital studies in which direct contact of personnel with patients' skin was specifically noted (33, 48, 54, 129, 151). In the remaining study, ABHS yielded results similar to those of soap and water (69). These findings are relevant to Food Code section 2-301.14 ¶ (A), which currently requires hand washing after touching bare human body parts (161).

Despite the need for frequent hand hygiene in health care facilities, retail food service establishments, and food processing facilities, little published information has addressed the amount of soiling that occurs on hands in these settings. In the studies listed in Table 6, ABHSs were almost always more effective than soap and water among health care personnel, whose hands most likely had minimal to light soiling with various types of organic substances but were unlikely to have been visibly soiled. In several studies in Tables 7 and 8 involving individuals whose hands had light to moderate degrees of soiling, ABHSs reduced viable bacteria more effectively than did soap and water (133, 150). In two studies, ABHS yielded results similar to those of hand washing with antimicrobial soap (37, 170). ABHSs outperformed hand washing in several studies in which hand were heavily soiled (46, 81). ABHS reduced bacteria by 2.58 log CFU on hands moderately soiled with visible food debris (133) and by >2.0 log CFU on hands contaminated with dirt or corn oil (117). Hand washing with soap and water reduced viable bacteria more effectively than did ABHS among food handlers with heavy soiling of their hands due to handling raw animal products (e.g., hamburger or chicken) (31, 88, 100). The results of these studies support the use of ABHS in retail food service establishments as an alternative to hand washing by workers who have not handled raw animal products and do not have visibly soiled hands after performing other activities.

New evidence is available that can address concerns regarding the relative efficacy of hand washing versus ABHSs against norovirus. In three *in vivo* studies, washing hands with plain soap reduced FCV, MNV, or HuNoV by <2.0 log PFU (15, 47, 88), with inexplicably high reductions (>3.0 to 6.2 log PFU) reported in a single study that utilized PCR methods (152).

Several early *in vivo* studies in which ABHSs were reported to have poor activity against norovirus actually utilized FCV (15, 76, 80, 88, 130), which is no longer

considered an appropriate surrogate for testing the activity of ethanol-based ABHSs against HuNoV (130). *In vivo* studies of ethanol-based ABHSs have yielded 2.48- to 4.25-log reductions of MNV (47, 96, 114, 130, 135). Reductions of HuNoV have ranged from 0.14 to 0.34 log PFU with a 62% ABHS (91) and 0.3, 2.04, 2.27, 3.74, and 4.0 log PFU with various formulations of 70% ABHSs (90).

The FDA quantitative microbial risk assessment for norovirus is an important document for both risk assessment and food safety (45). This assessment is complex and detailed even though the system they sought to model was quite simple (three workers in a restaurant that makes a single simple food: a bacon, lettuce, and tomato sandwich). This complexity highlights the nature of the problem of norovirus transmission within a restaurant. One key finding was that norovirus transmission to food could not be prevented when a symptomatic employee was present in the food establishment because of virus cross-contamination among surfaces, even when that employee was assigned duties that did not involve food preparation. The assessment also states that "efficient" hand washing can reduce the mean number of infected customers to 58% of the baseline. This claim warrants further investigation given a related finding included in the assessment in which full hand washing compliance (i.e., everyone always washes their hands after using the toilet) yielded only a 6% reduction in illnesses from baseline.

The FDA norovirus risk assessment (45) included a meta-analysis of literature data to produce the baseline distribution of hand washing effectiveness resulting in a Pert distribution, with parameters (0.17; 0.45; 6.0), defined as the minimum, most likely, and maximum effectiveness (in terms of log reductions). The FDA simulated improved hand washing effectiveness by simply adding 1- or 2-log reductions on top of the original distribution. Although this solution is computationally simple, it is not clear that it can be justified scientifically because adding a 2-log reduction would translate to mean minimum, most likely, and maximum effectiveness parameters of 2.17, 2.45, and 8.0 log CFU, respectively. FDA suggests that additional log reductions can be achieved through better training, improved hand washing efficacy (e.g., use of a soap that increases the friction on the hands without damaging the skin), or other unspecified means. However, no citations were provided in support of any of these claims.

CONCLUSIONS

In general, the evidence suggests that ABHSs are less effective than hand washing with soap and water for reducing bacteria when hands are heavily soiled with feces or organic substances, such as encountered when handling raw animal products. The CDC's hand washing guidance for the general public recommends washing hands with soap and water and states that ABHSs may not be as effective as hand washing when hands are visibly dirty or greasy (30). The guidance does recommend that when soap and water are not readily available, an ABHS containing at least 60% alcohol can be used instead.

The Food Code should be modified to emphasize the importance of hand washing when hands are heavily soiled

and allow the use of ABHS as an acceptable alternative to hand washing in situations where heavy soiling is not present and should continue to recommend use of gloves as currently indicated. Activities listed in the Food Code (section 2-301.14) during which heavy soiling is unlikely to be present are listed below:

- (A) after touching bare human body parts other than clean hands and clean, exposed portions of arms;
- (C) after caring for or handling service animals;
- (D) after coughing, sneezing, using a disposable tissue, using tobacco, eating, or drinking;
- (H) before donning gloves to initiate a task that involves working with food [except after handling raw animal products]; and
- (I) after engaging in other activities that contaminate hands [as long as hands are not visibly soiled].

The combination of hand washing followed by use of an ABHS can reduce bacterial counts on hands to a greater extent than either processes alone and might be considered in situations where heavy hand contamination is likely. A two-step process utilizing only ABHSs may be useful in some settings in which soap and water are truly not available (e.g., on large farms).

Although representatives of federal agencies have expressed a concern that availability of ABHSs as an alternative to hand washing for some activities might lead food workers to abandon hand washing in situations in which it is clearly preferred, experience in the health care sector does not support this view. Although ABHSs have been widely available in health care settings since 2002, health care personnel still choose to perform hand hygiene ca. 20% of the time by washing their hands with soap and water and 80% of the time with an ABHS (5), which is the preferred method in health care settings when hands are not visibly dirty or contaminated with proteinaceous material or visibly soiled with blood or other body fluids (20).

Further studies of hand contamination, amount of soiling associated with different food-related activities, and comparison of hand washing versus use of ABHSs in various food handling settings are needed to identify food worker activities in which there is minimal risk of heavy soiling and ABHSs can be used as an alternative to hand washing. Because ABHSs do not require the presence of sinks, take less time to use, and cause less irritant contact dermatitis than frequent hand washing, expanded use of ABHSs combined with continued efforts to improve hand washing practices may lead to greater hand hygiene compliance among food workers, thus reducing the risks of foodborne illness.

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