Scientific, Regulatory and Behavioral Considerations of Hand Hygiene

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ABSTRACT

Addressing the effectiveness of hand hygiene strategies involves scientific, regulatory and behavioral considerations. In the United States, norovirus is the pathogen reported most frequently in outbreaks associated with lapses in hand hygiene; however several bacterial pathogens have also been implicated. Effectiveness of any hand hygiene regimen involves many factors, including the product type (e.g., soap, hand antiseptic), amount applied, application method, duration and pathogen of concern. Handcare products making antimicrobial claims are regulated as drugs in the United States. Through 2011, no antimicrobial hand hygiene products for food handler applications have FDA-approved claims for antiviral effectiveness. However, the antiviral profile of several commercially available products has been assessed in peer-reviewed literature, demonstrating that some products can achieve significant reductions. Hand hygiene behavioral issues involve use of proper procedure and a commitment to perform the task, thus understanding human factors is important to enhance hand hygiene compliance. Behavioral and risk assessment research that evaluates the magnitude of risk reduction achieved by varying forms of hand hygiene actions (i.e., nothing, rinsing, hand sanitizing, washing, or washing and brushing) would be useful to move from an all-or-nothing approach in every situation, to one recognizing that different procedures may be suitable for different situations.

INTRODUCTION

The main purpose of washing hands is to cleanse the hands of soil, pathogens and chemicals that can potentially cause disease. Transmission of pathogenic bacteria, viruses and parasites to food from contaminated surfaces, raw food or ill workers by way of improperly washed hands continues to be a major factor in the spread of foodborne illnesses. In this report, hand hygiene products available to reduce the risk of spreading infectious agents are categorized as:

- handwashing agents (plain soaps or antimicrobial soaps)
- hand wipes (plain and antiseptic) and
- hand antiseptics (antiseptic waterless agents)

Handwashing with plain soap suspends microorganisms and mechanically removes them by rinsing with water. Plain bar soap, foam and liquid preparations are comprised of detergents with surfactant (surface-active agents), which increase the cleaning properties of water and gives the product the ability to remove soil from surfaces, such as human skin. Microbial reduction using plain soap is due to the physical removal of foreign material or microorganisms, not a biocidal effect.

An *antimicrobial soap* combines the cleaning action of plain soap (i.e., physical removal of foreign material) with antiseptic agents that kill microorganisms. The antimicrobial agents used in antimicrobial soaps (e.g., chloroxylenol, quaternary ammonium compounds, chlorhexidine gluconate, iodine/iodophors and triclosan) have an immediate effect that reduces the number of microflora on skin and in certain cases may exhibit residual or sustained activity that continues to reduce the number of microbial flora after the handwash is complete. The effectiveness of these agents is primarily directed toward vegetative bacteria.

Antimicrobial wipes are towelettes or paper towels that are saturated with an antimicrobial solution that has been shown to reduce the numbers of microorganisms on skin. The antimicrobial ingredient is typically isopropyl or ethyl alcohol and/or a quaternary ammonium compound. There are also some specialized products with other antimicrobial ingredients.

Hand antiseptics (also called hand sanitizers) are waterless agents with antiseptic properties that decrease the number of microorganisms present. For the purposes of this paper, hand antiseptics do not require the use of water. Alcohol-based hand antiseptics are the most common type and typically contain ethanol or isopropanol and may contain n-propanol or a combination of these agents. Hand antiseptics are typically not designed as hand cleansers and thus are usually intended to be used on visibly clean hands as a single application. However, most hand antiseptics contain emollients, emulsifiers and water, all of which can act as cleaning agents when assisted by hand-to-hand rubbing and physical removal with a paper towel, in a manner similar to a hand wipe.

FOODBORNE PATHOGENS ASSOCIATED WITH HAND HYGIENE-RELATED OUTBREAKS

The CDC (*6*) provides a list of infectious diseases that are transmitted through handling the food supply, which is summarized in Table 1 and in Annex 3 Section 2-201.11 of the 2009 Food Code. Two categories are identified – 1) those pathogens that are *often* transmitted by food when handled by an infected person and 2) those pathogens that are *occasionally* transmitted thorough handling by an infected worker but usually transmitted by contamination at the source or in food processing or by non-foodborne routes. Those “often” involving infected workers include pathogens with low infective dose (e.g., the viruses, *Salmonella* Typhi and *Shigella*) and those that are shed in high numbers when an active infection exists (e.g., the viruses, *Staphylococcus aureus* and *Streptococcus pyogenes*). The 2009 Food Code Sections 2-201.12 and 2-201.13 specify exclusion or restriction of food workers from a food establishment when certain diagnoses or symptoms listed in Table 1 exist. Annex 3 of the 2009 Food Code (page 337) specifically notes that “exclusion of food employees exhibiting or reporting diarrhea symptoms is an essential intervention in controlling the transmission of norovirus from infected food employees’ hands to RTE food items.” This recognizes that even thorough hand hygiene may not be sufficient to prevent transmission of disease when food is handled by symptomatic food handlers.

CDC (*5*) also published foodborne illness contributing factors that were reported for outbreaks occurring from 1998-2002. In that time period, of the 3072 outbreaks for which contributing factors were reported, 25% identified bare-hand contact, 20% identified infected persons and 6% identified gloved-hand contact as factors contributing to these outbreaks. Table 2 summarizes the CDC (*5*) data by etiology for foodborne illness outbreaks reported as being associated with hand contact (with or without gloves) or handling by an infected person as a contributing factor. Norovirus was the dominant etiology for outbreaks involving these contributing factors, and bacterial etiologies were reported for 40% of the bare-hand contact outbreaks, 35% of gloved-hand outbreaks and 35% of infected person outbreaks involved bacterial agents. Only one parasite (*Giardia intestinalis*) and no chemicals were reported to be associated with hand hygiene related outbreaks in this time period.

It cannot be determined from these data how many outbreaks “involving infected persons or carrier” included symptomatic food handlers, for which handwashing may not be adequate to prevent spread of illness as previously discussed. It is interesting to note that for each of the pathogens listed by CDC as “*often* transmitted through food contaminated by infected persons” (see Table 1), the number of outbreaks reported to be handled by an infected person was frequently much greater than the number involving bare-hand contact. Conversely, for “pathogens *occasionally* transmitted by food contaminated by an infected handler,” the number of outbreaks associated with bare-hand contact was higher than the number associated with infected persons handling food.

Vegetative bacterial pathogens are generally more easily inactivated by chemical agents used in antimicrobial hand care products than the viruses and parasites of foodborne illness concern. While bacterial spores are also more resistant than vegetative bacteria, sporeformers of foodborne illness concern must be in their vegetative state and grow in the food to a high level to present a food safety risk. Thus inactivation of spores is not a major concern for hand hygiene in a food handler setting.

This analysis suggests that norovirus is the most common pathogen associated with hand hygiene-related foodborne illness outbreaks. Thus when addressing “the efficacy/risk reduction strategies of alternative hand hygiene regimes compared to handwashing,” norovirus should be considered.

METHODS TO EVALUATE EFFECTIVENESS OF HAND HYGIENE SOLUTIONS

Ideally, well-controlled and statistically valid epidemiological outcome studies would be available to determine the relative effectiveness of hand hygiene products and regimens. Unfortunately, these types of studies are very rare and pose fundamental design and execution challenges. As a result, the primary methods used to evaluate effectiveness of hand hygiene products are laboratory-based, including *in vivo* (using living subjects) and *in vitro* (not using living subjects) testing, and to a limited extent risk modeling.

The type of test used to evaluate the effectiveness of hand hygiene solutions can have a significant impact on the results generated. Because of this, it is important to understand how a test was conducted when attempting to compare the effectiveness of hand hygiene solutions and it is difficult to compare the results from one study to another. It is important to note that, the most common pathogen associated with transmission of foodborne illness via hands, human norovirus, cannot be cultured in the laboratory. Murine norovirus and feline calicivirus have been used as surrogates to estimate reductions in infectivity, but the scientific debate on the "best" surrogate continues because the mode of inactivation for different antimicrobial agents varies (e.g., *3*, *18*). Currently, human norovirus results can be studied using polymerase chain reaction (PCR) technology, which reflects destruction of ribonucleic acid (RNA) as an indirect measure of loss of infectivity. However, it is possible for a virus to lose infectivity without destruction of RNA.

While standardized methods (e.g., ASTM, EN standards) exist for both *in vivo* and *in vitro* tests, methods used in the literature vary widely in their procedures and approach. This section provides a brief overview of the different types of tests used and the variation that can occur. It is not the intent of this report to recommend any specific type of test.

***In vivo* tests**

In vivo tests evaluate performance of hand hygiene measures using the hands of human test subjects. Many different *in vivo* tests, using a wide variety of methodologies, have been used to evaluate the performance of hand hygiene measures. Key differences include use of an inoculum, handwash technique and sampling method.

Use of an inoculum. In some cases the area being washed is inoculated with a marker organism (e.g., *E. coli*, *Staphylococcus aureus* or *Serratia marcescens*). Although *Serratia* is not commonly found on hands, its red pigment makes it easy to distinguish from background flora when conducting tests. *Serratia* is referred to as a "transient" hand microbe because it is only present for a short time on the hands, typically on the surface of skin. This is in contrast to "resident" hand microbes that are almost always present on hands, sometimes deep in the skin tissue. The use of a marker organism like *Serratia* can help to evaluate the performance of the handwash process on transient rather than resident flora, and to standardize the starting concentration of microorganisms on the skin of the test subjects.

In some *in vivo* tests, no inoculum is used. The level and nature of microorganisms present on human skin varies from person to person and over time for a given individual. These factors must be taken into account when interpreting these test results. Montville and Schaffner (*16*) found that choice of the specific marker organism makes little difference, but that the choice between marker organisms and resident flora has a substantial impact on the results. According to their analysis, this appears to be primarily due to a difference in starting concentration. Quantifying differences is easier when starting with a uniformly high concentration because it helps to keep endpoint numbers above the level of detection.

Handwash technique. Standardized *in vivo* tests use a prescribed handwash method, but not all studies in the literature use standardized test methods. Some allow the test subject to wash their own hands and others have a technician conduct the wash. This can influence the variation observed in procedures practiced by human subjects. More variation is typically observed when each subject performs the hand hygiene procedure.

Sampling method. There are many ways to enumerate the organisms remaining on the skin after washing. For example, in the *glove juice test*, the test subject dons disposable gloves, a sampling fluid is added to the gloves, the subject's hands are massaged and the microbes in the sampling fluid in the glove are enumerated. Other sampling techniques include collecting wash fluid into basins and enumerating organisms in the collected fluid, rubbing fingertips in Petri dishes containing a sampling fluid, placing a cylinder on the skin, adding a sampling fluid to cylinder and scrubbing the skin using a sterile swab, or simply pressing the finger tips to an agar plate.

The large inherent variability with any *in vivo* test coupled with differences in enumeration methodology leads to one of the major disadvantages of *in vivo* testing – conflicting, inconsistent and often non-comparable results. The variability also contributes to another disadvantage – cost. Multiple subjects are needed to estimate variability and it is not uncommon for a single test on a single subject to cost in excess of a thousand dollars. The variability of *in vivo* testing often requires high numbers of test subjects to statistically demonstrate differences, thus studies can be quite expensive. Use of pathogens for *in vivo* testing presents ethical issues that must be carefully considered.

Despite the disadvantages associated with *in vivo* hand hygiene efficacy testing, an advantage is that *in vivo* testing may provide information on how effectively a hand hygiene procedure will reduce microbial levels on hands in actual use. However, *in vivo* tests described do not prove that a tested hand hygiene procedure will actually prevent or reduce illness in the real world. At best, it provides a surrogate endpoint for the hand hygiene procedure's ability to prevent or reduce the risk of disease. Clinical trials to evaluate prevention of disease are rarely, if ever, performed.

In vitro tests

In vitro studies do not involve human or animal test subjects. The most common type of *in vitro* test for hand hygiene products is the suspension or "time-kill" test. In these studies, the test microorganism is suspended in a solution containing the test product. After a specified exposure time, an aliquot of solution is removed, the antimicrobial activity is typically neutralized and any surviving microorganisms are determined. As with *in vivo* tests, many variables must be considered for *in vitro* testing, including product and test organism concentrations, types of organisms, the presence and concentration of interfering substances such as soil or hard water, the use of different temperatures, different neutralizer systems and various exposure times. Typically, greater reductions are observed for *in vitro* tests than for *in vivo* tests because of the direct exposure of the microorganism to the antimicrobial agent. Even seemingly trivial variations in test procedures, such as growing the inoculum on solid versus liquid media or the number of times the test cultures have been transferred, can affect the results. As with *in vivo* testing, this can make comparison of results between different studies difficult.

An advantage of *in vitro* tests is that they are relatively easy and inexpensive to do. This makes it easier to study more organisms and to collect sufficient replicates in a reproducible manner to demonstrate statistical significance even when the data are variable. The largest drawback of *in vitro* testing is that they are further removed from the clinical endpoint than *in vivo* tests. Just as an *in vivo* test is not a perfect predictor of a clinical endpoint, so an *in vitro* test is not a perfect predictor for an *in vivo* result.

The CFP 2010-2012 Hand Hygiene Committee summarized advantages and disadvantages of *in vivo* and *in vitro* efficacy testing in Table 3. Both types rely on enumeration of viable microbial targets to measure the extent of reduction after a treatment, which is possible for many pathogens involved in foodborne illness transmitted via hands, but currently not human norovirus.

EFFICACY OF HAND HYGIENE APPROACHES AT REMOVING PATHOGENS AND REDUCING RISK

As discussed above, the wide variety of test methods used to study hand hygiene procedures makes it very difficult to compare the efficacy of handwashing to alternative hand hygiene regimes. Recent peer-reviewed papers summarize much of the available science on this topic. Todd et al. (*23*) provide an extensive review of nearly 250 publications addressing the impact of washing and drying of hands to reduce microbial contamination. Montville and Schaffner (*15*) looked more specifically at a quantitative comparison of antimicrobial versus non-antimicrobial hand soaps and evaluated the impact of methodological differences in the extent of reduction achieved. Both of these reviews reported that many factors influence the efficacy of handwashing, including the type and volume of soap used, friction, and duration of washing. Some of the findings of these reviews include:

- Using <1mL portion of hand soap appeared to be less effective than using 1ml or more.
- Vigorous washing is an important factor in that it removes or loosens microorganisms with mechanical action.
- On average, use of antimicrobial soaps results in fewer microorganisms on hands.
- Todd et al. (*23*) found that duration of handwashing is an important factor and duration of at least 15 seconds is needed. They concluded that while washing up to 30 seconds may provide somewhat greater microbial removal from hands, this further reduction may not be meaningful as it involves removing resident microorganisms that are not generally associated with transmission of foodborne illness. Various studies have indicated that the average wash duration by the general public and food handlers is about 10 seconds, in spite of the 15 second recommendations.
- Frequency of handwashing is also an important factor. Several studies suggest that while most individuals (>85%-95%) self-report washing hands after using the bathroom, observational studies indicated that the frequency (particularly among men) was considerably lower (ca. 70%). In food settings the frequency of handwashing at appropriate times may be as low as 30% during peak business hours. However, training and specific interventions could increase that to over 50%.
- Temperature has relatively little impact on the efficacy of handwashing. Temperatures that are too high (over 110°F) increase the risk of skin damage and reduce handwashing compliance.

- Drying, particularly using towels, removes ca. 90% of the organisms that remain after washing. Removal of microorganisms by air dryers is more questionable. Moreover, the time needed to dry hands with many air drying systems is often longer than towel drying, so hands often remain wet for people who do not wait. Wet hands have been shown to harbor and transfer organisms more easily than dry hands. There is also some concern that the airflow from certain air driers may be a source of contamination.

Todd et al. (*24*) provides a recent comprehensive, peer review of waterless hand antiseptics relevant to food handlers, including 150 references. They found that product type, concentration, volume and contact time influenced results. They concluded that “alcohol-based antiseptics should be combined with regular handwashing schedules and should not replace handwashing and drying or the use of fingernail brushes.” In regard to wiping methods, they indicated that food handlers may ignore some of the steps in two or three stage procedures, thus they did not recommend such procedures in general. However, they also stated that “because [two or three stage] wipe methods tested have been more effective than soap and water, they should be considered feasible, practical hand hygiene interventions for remote food service situations or where water availability is limited.”

The effectiveness of hand antiseptics against human norovirus was questioned by Todd et al. (*24*) based on the available literature at the time of their review. However, Park et al. (*18*) compared the effectiveness of seven hand antiseptics against murine norovirus (MNV) and feline calicivirus (FCV) as potential surrogates for human norovirus. One ethanol-based and one triclosan-based hand antiseptic reduced both MNV and FCV by >2.6 and ≥ 3.4 logs, respectively, using *in vitro* infectivity test methods. Four products demonstrated effectiveness against either MNV or FCV. The chlorhexidine product was not effective against either virus. Thus effectiveness varied among the different hand antiseptics. Liu et al. (*14*) studied inactivation of human norovirus using the *in vivo* finger pad test, reporting log reductions of RNA from 0.10 to 3.74 for six commercially available hand antiseptic products. This study also illustrated the large variation that can be observed among hand antiseptic products. These two studies did not include a measure of the reduction that could be achieved with handwashing treatments. Further, some of the products studied may not have “Food Code” compliant ingredients.

A number of *in vivo* studies have included handwashing and hand antiseptics in the same investigation. Some of these studies concluded that hand antiseptics were ineffective at reducing microbial levels on hands while others suggested that they are effective in either reducing numbers or reducing transfer of infection. Two examples of studies that concluded hand antiseptics were ineffective include the following.

- Courtenay et al. (*7*) compared washing with soap and water, rinsing with either warm or cool water, and ethanol-based hand antiseptics for reducing *E. coli* on hands. The soap and water washing demonstrated >2.6 log reduction, which was significantly greater than solely rinsing with warm water (2.2 log reduction), rinsing with cool water (1.5 log reduction) or ethanol-based hand antiseptic (0.2-0.7 log reduction).
- Lin et al. (*13*) studied the effect of six handwashing techniques on *E. coli* and FCV levels inoculated under natural and artificial fingernails. Washing techniques included use of tap water alone, soap and water, antimicrobial soap, hand antiseptic, soap plus hand antiseptic, and soap plus nailbrush. Only reductions in counts under the fingernails were reported. For *E. coli,* no significant difference was noted between any of the washing techniques except washing with soap using a nailbrush. The nailbrush technique reduced the *E. coli* population approximately 2.5 – 3 logs while other techniques reduced the population 1 – 2 logs. For FCV, soap with nailbrush washing also significantly reduced the population greater than 2 logs for both nail types. The hand antiseptic treatment resulted in a significantly lower reduction of FCV for both nail types (<1 log) than other treatments. Interestingly, there was no significant difference between log reductions of either *E. coli* or FCV from finger nails when tap water alone was compared to any of the handwashing methods using soap without a nail brush.

Conversely, a number of studies concluded that the use of hand antiseptics reduced organisms on hands the same or better than washing alone. For example:

- Brown et al. (*2*) evaluated reductions of microbial counts on uninoculated hands following washing with plain soap, antimicrobial soap or use of an alcohol-based hand antiseptic. Fingers were touched to agar plates before and after treatment, and qualitative assessment of the number of bacteria present was determined. The alcohol-based hand antiseptic reduced the relative counts significantly more than the plain or antimicrobial soap treatments.

- Schaffner and Schaffner (*22*) determined the effectiveness of an alcohol-based hand antiseptic on hands contaminated with a nonpathogenic surrogate for *E. coli* O157:H7, where the source of the contamination was frozen hamburger patties. The effectiveness of the hand antiseptic was similar to that for handwashing and glove use previously reported. The person-to-person microbial reduction variability from hand antiseptic use is similar to published data for glove use and was less variable than published data on handwashing effectiveness.
- Paulson (*19*) studied the reduction of *Serratia marcescens* for hand hygiene regimens including plain lotion soap, antimicrobial lotion soap, alcohol-based hand antiseptic, and combinations of these using the glove juice method. The alcohol treatment alone or in combination with handwashing, reduced the population almost 4 logs. The soap treatments alone provided a 2 – 3 log reduction in *Serratia* counts and there was no statistically significant difference between antimicrobial and plain soap treatments, although the antimicrobial treatment was consistently higher. A combined treatment was recommended.
- Michaels et al. (*15*) studied the impact of varying volumes of alcohol-based hand antiseptic on reducing inoculated transient microflora from previously washed hands, as well as the impact of the hand antiseptics on reducing levels of transient flora from under finger nails. Levels of hand antiseptic at 3mL or 6mL resulted in a significant reduction of transient flora over washing alone, while lower levels did not. Consistent with the results reported by Lin et al. (*13*), washing hands with a nail brush was required for significant reductions under fingernails.
- Restaino and Wind (*20*) reviewed literature available at the time and reported that appropriate alcohol preparations were more effective in reducing microbial counts that handwashing alone. They also commented on the need to use products that are non-irritating to the skin.

It is clear from the studies summarized that there is a large amount of variability between and within studies with behavioral aspects frequently compounding interpretations of data. Montville and Schaffner (*16*) concluded that “The inherent variability in handwashing seen in the published literature underscores the importance of using a sufficiently large sample size to detect difference when they occur."

Few studies have attempted to assess the effect of hand antiseptics from a risk reduction perspective. Bidawid et al. (*1*) studied the transfer of feline calicivirus (FCV) from fingertips to a variety of surfaces. Finger pads were contaminated with FCV, allowed to dry, and then touched to various surfaces to evaluate the percent of transfer. Results (see Figure 1) demonstrated that treating hands with water, soap and water, or alcohol significantly reduced the percentage transferred, with less than 1% transferred following handwashing or a water rinse, ca. 1-3% transferred after treatment with alcohol, and 13-48% transfer if no hand hygiene intervention was used. While alcohol treatments were not as effective as soap and water or water alone, all of these hand hygiene interventions were significantly more effective than no hand hygiene treatment at all.

REGULATORY REQUIREMENTS RELATED TO EFFICACY OF HAND HYGIENE PRODUCTS

Approval process

Hand antiseptics that meet specific criteria described in Section 2-301.16 of the 2009 Food Code may be applied "only to hands that are cleaned as specified under Section 2-301.12" in retail and foodservice establishments. Annex 3 – Section 2-301.16 of the 2009 Food Code explains that hand antiseptics are drug products that must comply with FDA Center for Drug Evaluation and Research (CDER) regulations, and provides more information on where approved products are listed as well as other requirements not related to the effectiveness of the products against foodborne pathogens.

As drugs, hand antiseptics must be demonstrated to be safe and effective. This can be accomplished by one of two means:

1. The hand antiseptic may be approval by FDA under a new drug application (NDA). Drugs approved through this route are listed in Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book" (*11*).
2. The hand antiseptic may have an active ingredient identified by FDA (*9*) in the Tentative Final Monograph (TFM) for Health-Care Antiseptic Drug Products for OTC Human Use in the

handwash category, be listed with FDA as a drug, and comply with other relevant drug requirements.

The TFM specifies the active ingredients that can be contained within handwash products, as well as labeling, product testing and other general requirements. The *in vitro* and *in vivo* testing provisions in the TFM are well detailed and list specific organisms that products can make claims against. There is also a clinical study requirement depending on the final claim. The TFM antimicrobial spectrum tests determine the efficacy of products using Minimum Inhibitory Concentration (MIC) against 25 laboratory strains and 25 fresh clinical isolates included in a specific list of vegetative bacteria and the yeast *Candida*. Time kill tests are also required using “standard ATCC strains identified for the MIC tests. The TFM also requires an *in vivo* handwash assay using *Serratia* as the test organism. There are currently no virus tests listed on the TFM and therefore antiviral hand hygiene claims are not available through the TFM, despite the fact that as noted above, norovirus is by far the pathogen reported most frequently in outbreaks where inappropriate application of hand hygiene regimens were noted.

For hand antiseptics, the TFM classifies alcohol 60–95% and povidone iodine 5–10% as Category 1 – Generally Recognized as Safe and Effective. Many potential active ingredients for hand antiseptics including triclosan, triclocarban, benzalkonium chloride, benzethonium chloride and parachlorometaxylenol, are classified in Category III, requiring more data for final determination on safety and efficacy. Pending a Final Monograph, products based upon ingredients classified as Category III can be marketed provided they meet the performance testing requirements of the TFM. Premarket approval through the New Drug Application (NDA) process is required for products that contain active ingredients not listed in the TFM.

FDA guidance on hand antiseptics

While the CDC recommends alcohol-based hand gels as a suitable alternative to handwashing for health care personnel *“if hands are not visibly soiled*” (*4*), FDA (*10*) clarified that this recommendation is not applicable to food establishments. This exclusion is based on the differences in controlling common nosocomial pathogens in health care settings and common foodborne pathogens in retail and foodservice settings. FDA (*10*) also highlights that the pathogens most commonly transmitted by hands in health care settings differ from those in retail and food service settings, and the types and levels of soil on the hands of health care workers differ from foodservice/retail workers. The FDA (*10*) factsheet concluded:

> "Proper handwashing, as described in the Food Code continues to serve as a vital and necessary public health practice in retail and food service. Using alcohol gel in place of handwashing in retail and food service does not adequately reduce important foodborne pathogens on foodworkers' hands. Concern about the practice of using alcohol-based hand gels in place of handwashing with soap and water in a retail or food service setting can be summarized into the following points:
>
> - "Alcohols have very poor activity against bacterial spores, protozoan oocysts, and certain nonenveloped (nonlipophilic) viruses; and
> - "Ingredients used in alcohol-based hand gels for retail or food service must be approved food additives, and approved under the FDA monograph or as a New Drug Application (NDA); and
> - "Retail food and food service work involves high potential for wet hands and hands contaminated with proteinaceous material. Scientific research questions the efficacy of alcohol on moist hands and hands contaminated with proteinaceous material."

It is important to note that even in health care settings, alcohol-based hand gels are to be used as an alternative to handwashing "only if hands are not visibly soiled" according to CDC (*4*).

State and local jurisdictions

At least one regulatory jurisdiction allows the use of alternatives to Food Code compliant handwashing in certain settings where water is limited (*17*). It is important to understand the specific situations where such alternatives are allowed. Research on the impact of adoption of alternative procedures on hand hygiene compliance and potentially case control studies to investigate public health outcomes of such programs would be useful to further inform the discussion on alternatives to handwashing.

Regulatory status summary

Hand care products with antimicrobial claims are considered to be drugs, thus approval and registration are under the regulatory jurisdiction of FDA's Center for Drug Evaluation and Research. Antiviral hand hygiene claims are not available through the Tentative Final Monograph and to date no US antimicrobial hand care product with virucidal claims for food handler application has been approved through the New Drug Application (NDA) process. As a drug, antimicrobial hand care products should be used following label instructions. FDA's Center for Food Safety and Applied Nutrition provides guidance through the *Food Code* on when and where hand hygiene practices should be applied.

COMPLIANCE ISSUES AND BEHAVIORAL ASPECTS OF HAND HYGIENE

As previously discussed, many factors such as time, temperature, friction, product volume, product type, etc., influence the effectiveness of hand hygiene regimes. At the same time, motivating food workers to apply proper hand hygiene procedures at the right time is an important food safety need. Thus, procedures are important for effective hand hygiene. Operators make their final choice of protocols based on the requirements in the Food Code guidance and their risks, based on their customer mix, menu, facilities and system control. There is no one-size-fits-all protocol for the wide range of food service and retail establishment practices that exist. Procedures should be selected to assure their minimum cleanliness levels are maintained.

The Committee identified barriers to proper handwashing behaviors by discussing the question "If hand hygiene (hand antiseptic) was allowed in place of handwashing, would there be a significant increase in desired behaviors, either for use: 1) in place of handwashing or 2) in addition to handwashing?"

For this exercise, the Committee considered only behaviors and *not* necessarily effectiveness. The Committee discussed which factors encourage or discourage desired handwashing behaviors for both traditional soap and water wash, and use of approved hand antiseptic. Information reported in Tables 4-6 is based on expertise of the Behavior Sub-committee of the CFP Hand Hygiene Committee, with review by the full committee. No quantitative or qualitative data were reviewed during the Sub-committee's discussion.

Factors that may either encourage or discourage *how* handwashing or hand antiseptic behaviors performed are listed in Table 4. Many of the barriers apply equally to how hand hygiene is performed for either handwashing or hand antiseptic use. Perceived speed of application for use of single step hand antiseptic applications may remove a potential barrier that exists for handwashing. Hand antiseptics may also remove barriers associated with proximity to the supplies need to perform the task. While the issue of training applies equally to both types of hand hygiene, it was noted that much emphasis has been placed on the proper handwashing technique. This may vary for different hand antiseptic applications and may be less obvious (e.g., single application versus two-step process; need to fully cover fingers, finger tips and nail area).

Factors that may either encourage or discourage *when* desired handwashing or hand antiseptic behaviors are appropriate are listed in Table 5. Again, many potential barriers apply equally to both hand hygiene regimens. The perceived need is an area where differences exist. Some workers wash their hands when they are heavily soiled from a self-protection standpoint. Conversely, single step hand antiseptics are typically designed to be used on visibly clean hands; therefore the visual cue of hands looking dirty does not apply. The sub-committee thought that there were opportunities to reduce confusion on when to wash hands or use hand antiseptics, for example when used with gloves (see the section on when alternatives may be appropriate).

Factors that may either encourage or discourage regarding *why* to perform hand hygiene are listed in Table 6. Communication of the reasons why hand hygiene should be performed is very important for employee acceptance and increases the likelihood that proper hand hygiene will be performed. Most of the factors that can encourage hand hygiene behaviors apply equally to both washing and antiseptic use. However, explaining why there are different considerations for when hand antiseptics are appropriate, may cause confusion and thus create a barrier to compliance. This type of communication must be planned carefully.

PUBLIC HEALTH BENEFIT OF IMPROVED HAND HYGIENE COMPLIANCE

Several studies have evaluated the use of alcohol-based hand sanitizers in reducing infection rates in a variety of settings, including schools, day care settings, hospitals and long term care facilities. Two examples described below to illustrate the type of information that can be gained.

- Hilburn et al. (*12*) studied use of alcohol-based hand sanitizers in acute care facilities and reported a 36.1% decrease in infection rates when alcohol-based products were used. Key factors cited to contribute to this improvement included enhanced effectiveness against causative agents and increased hand care compliance because products were easy to use and gentle to the skin, which removes a barrier for hand hygiene application. The CFP Hand Hygiene Committee notes that these results may not be immediately transferable to food handling settings because the agents, and likely the hand sanitizer products, differ. However, research on compliance in foodservice settings may be beneficial to determine if a similar improvement is noted.

- Sandora et al. (*21*) studied use of alcohol-based hand sanitizer coupled with hand hygiene education with children enrolled in 26 child care centers. They monitored transfer of secondary illness to people in the home. The CFP Hand Hygiene Committee recognizes that the primary mode of transmission in this study is person-to-person and that the pathogens involved may not necessarily be foodborne pathogens. However, the secondary illnesses were significantly lower for families with alcohol-based hand sanitizers in the home compared to control families.

While the Hilburn et al. (*12*) "clinical end point" data demonstrate a benefit from hand sanitizers in clinical settings, the study was confounded with many other factors such as training, other interventions and increased handwashing. Therefore it is difficult to determine the effect of the hand sanitizers alone. Respiratory illness and gastroenteritis are seasonal events that occur with some frequency in institutional type settings. Foodborne illness outbreaks are less frequent thus conducting these types of studies specifically for food handing considerations will be problematic.

Settings where alternatives to handwashing may be appropriate

The Committee considered the information above and practical aspects of preparing, holding and serving food in its consideration of identifying settings where alternatives to handwashing are appropriate. From a practical and behavioral matter, the Committee thought it useful to clarify situations when and where alternatives to handwashing, such as hand antiseptics are not the best option. These include:

- Anywhere there is a properly functioning hand sink
- After toilet use
- At the start of a shift
- After lunch break
- Between handling raw and RTE foods
- After sneezing into hands

- If person has cuts, skin infections
- When hands look or feel soiled

The Committee also recognized that there are situations where alternatives to handwashing may be appropriate as a risk reduction strategy. For example, when hands are not visibly soiled hand antiseptics may *potentially* be an option:

- Between glove use
- After touching hair
- After coughing / sneezing / drinking
- In areas where there is environmentally no water
- In water outages / boil water situations
- During temporary events
- In farm stands
- For mobile vendors

The Committee recognized that there are water-short situations where the specific dual step hand cleanser-sanitizer protocol (*8*) may be a potential alternative to water/soap handwashing as a risk reduction strategy. Some may question if providing an alternative may drive operators to use hand-antiseptics in place of traditional handwashing. The product costs of alcohol washing versus water washing will strongly favor traditional handwashing where running potable water is conveniently available. The committee was unable to make specific recommendations. However, given time and integration of scientific and behavioral considerations, specific recommendations may be possible using a risk management approach.

RESEARCH NEEDS

Much of the research conducted on hand hygiene is done in areas other than food-related settings. There is a need for such studies to be conducted to inform decision making. Potential questions that could be addressed through research include:

- If hand antiseptic use was allowed in lieu of soap and water handwashing, would there be a significant increase in desired behaviors and would this reduce foodborne illness?

- Does providing options (soap and water vs. alternative hand hygiene methods) in foodservice or retail settings increase real-world compliance? If so, what is the public health benefit?
- Can studies on hand hygiene behaviors in hospitals be extrapolated to foodservice environments?
- What handwashing / hand hygiene options increase frequency of use?
- Why are food handlers not washing their hands?
- What is the range of temperatures that are considered to be comfortable for handwashing?
- Can new risk assessment and risk management models be applied to hand hygiene in food services settings to quantify the changes in risk when different interventions are applied?
- Can case-control epidemiological studies be conducted to study hand hygiene related foodborne illness outbreaks comparing regulatory jurisdictions allow the use of alternatives to handwashing, to those that do not?
- What is the clinical endpoint effect of various hand hygiene practices in a food setting?

Data supported answers to the above questions would help inform decision making on proposing alternatives to handwashing in certain situations to protect public health.

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Table 1 CDC* listing of infectious and communicable diseases transmitted through handling the food supply

Category	Agent	Modes of transmission	Symptoms that indicate infection that could be transmitted to others through food
Pathogens *often* transmitted by food contaminated by infected persons who handle food	Viruses - Norovirus - Hepatitis A virus - Sapovirus Bacteria - *Salmonella* Typhi - *Shigella* species - *Staphylococcus aureus* - *Streptococcus pyogenes*	• Failure of food handlers to: - wash hands, - wear clean gloves, or - use clean utensils • Also transmitted person to person	• Diarrhea • Vomiting • Open skin sores, boils • Fever • Dark urine • Jaundice
Pathogens *occasionally* transmitted by food contaminated by infected persons who handle food, but *usually* transmitted by contamination at the source or in food processing or by non-foodborne routes	Bacteria - *Campylobacter jejuni* - Enterohemorrhagic *E. coli* - Enterotoxigenic *E. coli* - Non-typhoidal *Salmonella* - *Vibrio cholera* - *Yersinia enterocolitica* Parasites - *Cryptosporidium* species - *Entamoeba histolytica* - *Giardia intestinalis* - *Taenia solium*	• Usually intrinsically contaminated or cross-contaminated during processing or preparation • Occasionally transmitted by infected food handler with acute diarrhea • Bacterial pathogens often require multiplication in the food before they will cause disease	• Acute diarrheal illness

*Adapted from: CDC (*5)*

Table 2 Hand contact contributing factors reported for foodborne illness outbreaks 1998-2002 in the United States*

Etiology		**Bare-hand contact** n (% of confirmed)		**Gloved-hand contact** n (% of confirmed)		**Infected person or carrier** n (% of confirmed)	
Bacterial	Non-typhoidal *Salmonella*	37	(15)	4	(7)	64	(18)
	Staphylococcus aureus	17	(7)	5	(9)	30	(9)
	Shigella	12	(5)	3	(5)	16	(5)
	Escherichia coli	12	(5)	1	(2)	6	(2)
	Clostridium perfringens	8	(3)	2	(4)	2	(1)
	Campylobacter	5	(2)	2	(4)	1	(<1)
	Vibrio parahaemolyticus	2	(1)	1	(2)	1	(<1)
	Bacillus cereus	1	(<1)	1	(2)	1	(<1)
	Streptococcus	0	(0)	0	(0)	1	(<1)
	Total Bacterial	***94***	***(40)***	***19***	***(35)***	***122***	***(35)***
Viral	Norovirus	129	(54)	30	(55)	202	(58)
	Hepatitis A	13	(5)	4	(7)	16	(5)
	Total Viral	***142***	***(59)***	***34***	***(62)***	***218***	***(62)***
Parasitic	*Giardia intestinalis*	1	(<1)	0	(0)	2	(1)
Multiple etiologies		2	(1)	1	(2)	7	(2)
Total confirmed etiology		**239**	**-**	**55**	**-**	**349**	**-**
Unknown etiology		**526**	**-**	**132**	**-**	**251**	**-**

*Adapted from: CDC (*4*)

Table 3 Advantages and disadvantages of *in vivo* and *in vitro* tests to demonstrate efficacy of hand hygiene solutions.

Test method	Advantages	Disadvantages
In vivo (uses human subjects)	• Closer to clinical endpoints • May demonstrate impact of full hand hygiene procedure (i.e., rinsing, friction, duration)	• Significant person-to-person variation • Expensive and difficult to conduct • Concerns with human exposure to certain pathogens
In vitro (does not use human subjects)	• Typically less variable than *in vivo* methods • Can study more organisms in a controlled manner • Less expensive	• Further removed from clinical endpoints

Table 4 What encourages / discourages desired behaviors regarding ***how*** to perform hand hygiene? (Note: effectiveness of the application is not considered in this comparison)

Potential barriers	Handwashing	Hand antiseptic or alternative
Water temperature	Too hot or cold discourages Just right encourages	Not applicable
Type of product (Like or dislike scent, feel etc.)	How well does it lather? Does it cause dry hands or maintain skin health? Does it sting?	Does it make hands sticky? Does it cause dry skin or maintain skin health? Does it sting?
Towel vs. hand dryer	Slow drier discourages Empty or malfunctioning towel dispensing discourages	Drier not applicable. Towel may be needed (wipes or two-step procedure), thus availability or malfunctioning situations are similar.
Urgency / pressure / motivation	Must go to sink to perform	Can be applied “on the go” for a one step process
Proximity of product and equipment, ease of reaching	Need sink (plumbing), soap, drying equipment	Portable or easy installation in multiple locations. Potentially closer to work station.
Training (need to know how, when and why)	Applies equally. Potentially more material available on procedure.	Applies equally
Supplies available and working	Applies equally	Applies equally
Laziness	Applies equally	Applies equally
Ease – automated vs. manual. Method of dispensing	Automatic options may encourage or discourage. Must be functioning	Automated dispensing quicker when functioning. Must be functioning.
Time	Takes too long (perception)	Fewer steps for single application
Double handwashing	Takes too long	Applicable to two-step process
Policy – management commitment and enforcement	Applies equally	Applies equally
Job aids – detailed instructions	Applies equally	Applies equally
Hand hygiene signs	Applies equally	Applies equally
Behavior modeled by co-workers and management	Can motivate or de-motivate	Can motivate or de-motivate
Requirement for employment	Applies to both	Applies to both
Existence of regulations	Encourages policy, not employees	Currently hinders adoption
Visible / type of soil	Adjust to soil type	Appropriate for visibly clean hands only. May be unpleasant on heavily soiled hands
Pleasant experience	Applies equally	Applies equally

Table 5 What encourages / discourages desired behaviors regarding ***when*** to perform hand hygiene?

(Note: effectiveness of the application is not considered in this comparison)

Potential barriers	**Handwashing**	**Hand antiseptic or alternative**
Perceived need	Wash when hands look or feel dirty. Workers wash to protect themselves (e.g., after clearing a messy table)	Perceived need for single step may change because this should be done on clean hands. Likely the same for a two step process
Touch points / requirements (too many)	Applies equally	Applies equally
Policy– management commitment and enforcement	Applies equally	Applies equally
Training – urgency	Applies equally	Applies equally
Focus on the why	Applies equally	Applies equally
Clarifying specifics in Food Code / misinterpretations	Potentially reduce confusion on requirements	Potentially reduce confusion on requirements and interpretation of regulations
In concert with glove use / confusion with glove use	Potentially reduce confusion on requirements	Potentially reduce confusion on requirements
Clarifying examples	Potentially reduce confusion on requirements	Potentially reduce confusion on requirements
Motivation	Applies equally	Applies equally
Proximity / ease	Need sink (plumbing), soap, drying equipment	Portable or easy installation in multiple locations. Potentially closer to work.
When need to wash – settings / relevance	When they look or feel dirty	Apply to visibly clean hands
Requirement to stay employed	Applies equally	Applies equally
Visibility of kitchen	Depends on customers – are they more interested in the food techniques or hygiene?	Less time away from food prep
Pleasant experience (some products make hands feel and / or smell good)	Applies equally	Applies equally
Hand antiseptic is a second barrier	May be tempted to skip washing	May do it more often if it is quicker

Table 6 What encourages / discourages desired behaviors regarding ***why*** to perform hand hygiene? (Note: effectiveness of the application is not considered in this comparison)

Potential barriers	**Handwashing**	**Hand antiseptic or alternative**
Buy-in / encouragement	Handwashing is a recognized foundation for food safety and healthy living.	Explaining the differences of when handwashing is appropriate versus when alternatives are appropriate may complicate the message and confuse the "Why"
Expected practice / culture of hand hygiene	Applies equally	Applies equally
Not a lot of training tools; print training vs. activity based	Applies equally	Applies equally
Trainer effectiveness	Applies equally	Applies equally
Oral vs. written	Applies equally	Applies equally
Proximity	Getting staff to the sink	Getting to the product
Lack of motivation	Applies equally	Applies equally
Expectation of customers	Visibility of kitchen	Visibility of kitchen
Pleasant experience	Applies equally	Applies equally
Location / availability of supplies	Applies equally	Applies equally, but may be easier to have sanitizer available in some locations
Equipment working correctly	Applies equally	Applies equally

Figure 1 Feline calicivirus transfer from inoculated finger pads to ham, lettuce and stainless steel surfaces after treatment with various hand hygiene regimens. Adapted from Bidawid et al. (*1*)