

Hand Washing, Hygiene, CGMP, and Science

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“Microbiology Topics” discusses various topics in microbiology of practical use in validation and compliance. We intend this column to be a useful resource for daily work applications.

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KEY POINTS

The following key points are discussed in this article:

- Good personal hygiene is a requirement of all pharmaceutical activities, from operating on the line through laboratory good manufacturing practice (GMP) studies. However, studies show poor hand washing compliance is the rule in a variety of occupations.
- Poor hand washing technique may result in increased absenteeism, particularly in time of a potential H1N1 pandemic.
- Limited availability to adequate facilities may lead to poor compliance or poor efficacy of washing if performed. These facilities include appropriately constructed and sourced water supply, soap supply and, perhaps most importantly, adequate provisions for thorough drying of hands. This is the basis for the current good manufacturing practice (CGMP) requirement for adequate facilities.
- While “antibacterial” label claims do no harm, they should not be relied upon to protect against poor practice.
- Jewelry can interfere with adequate cleansing and should be removed before washing. Jewelry should be discouraged in areas where hand cleanliness is important.
- Training for compliance in hand washing is difficult. There have been numerous reports of the difficulty in training and the subsequent monitoring of healthcare workers for compliance with hand washing requirements. Suggestions for training and a potentially useful monitoring tool are provided.
- Many studies use extended periods of time during the wash (1.5-2 minutes in some). This is not a practical regimen. A hand wash-

ing regiment is suggested for pharmaceutical industry workers based on Centers for Disease Control (CDC) hand washing protocol.

- Personnel should carefully evaluate common practices when microbial control is required. It is likely that simple processes, such as hand washing, are generally assumed to be under control. They may, however, be an undetected source of product or sample contamination.
- Hand scrubs are not currently covered by GXP, but there may be a role for their use in a compliant facility in addition to hand washing.

EVERYONE KNOWS HOW TO WASH HIS OR HER HANDS, RIGHT?

The US current good manufacturing practice (CGMP) guidelines have clear expectations for hygiene and cleanliness. 21 Code of Federal Regulations (CFR) 211 states the following:

“21CFR 211.28 Personnel responsibilities.

“(a) Personnel engaged in the manufacture, processing, packing, or holding of a drug product shall wear clean clothing appropriate for the duties they perform. Protective apparel, such as head, face, hand, and arm coverings, shall be worn as necessary to protect drug products from contamination.

“(b) Personnel shall practice good sanitation and health habits.

“(c) Only personnel authorized by supervisory personnel shall enter those areas of the buildings and facilities designated as limited-access areas.

“(d) Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drug products shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of drug products. All personnel shall be instructed to report to supervisory personnel any health conditions that may have an adverse effect on drug products” (1).

This is a basic contamination control issue for the quality of our finished product, in both the ster-

ile and the non-sterile process. In addition to the concern over process control, there is a personnel consideration as well. Proper hand washing technique is the most effective means to slow the spread of disease in our facilities. Proper hand washing is particularly important in this time of increased concern over global pandemic. There have been a score of recent articles on the best ways to minimize the spread of the H1N1 virus transmission (2, 3). Recent work has shown that hand washing maybe an extremely effective and economical way to slow the spread of the virus (4).

An obvious consideration in trying to establish the efficacy of hand-washing regimens is the method to determine that efficacy. An in-depth review of methodology is outside the scope of this article, but the interested reader is referred to American Society for Testing and Materials (ASTM)-E1174-00, *Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel or Consumer Hand Wash Formulations*, or the two European standards Preliminary European Norm (prEN) 12054 (describing suspension tests) and prEN 12791 (describing the *in vivo* test). We will not discuss the testing methodologies any further, but the reader is cautioned that all results reported by the different studies will, of course, be dependent on how the regimen was tested.

FACILITIES

The CGMP for basic requirements is as follows:

“21 CFR 211.52 Washing and toilet facilities. Adequate washing facilities shall be provided, including hot and cold water, soap or detergent, air driers or single-service towels, and clean toilet facilities easily accessible to working areas” (1).

Water

Some aspects of the availability of soap and water (in terms of sinks) are self-evident. First of all, there should be soap and water available to those entering and leaving the lab or manufacturing area. The water should be of sufficient quality (at least potable). The mechanism to operate the water flow should not encourage the recontamination of the hands immediately after washing. This is commonly accomplished

through the use of elbow faucets or foot switches to turn the water on and off. The importance of this consideration was emphasized in the study of Griffith et al. (5), who showed a positive correlation between surface filth and recontamination of hands—the faucets were the most consistently contaminated feature of the immediate environment.

Current best practice suggests sinks conveniently located near entrance and exit points, with suitable control mechanisms, and the availability of soap.

Soap

The type of soap, and in particular the design of the soap dispenser, is another important aspect of the efficacy of hand washing. We have three major choices: Bar soap, refillable liquid soap, and sealed liquid soap. Bar soap is not suitable as it is a proven reservoir for bacteria (6). This leaves us with liquid soap.

Liquid soap dispensers come in two general designs. In the first, liquid soap can be added to a reservoir when required. Best practice is to completely clean out this reservoir before filling it again to prevent bacterial buildup as microorganisms can survive in soap (7, 8). It is not recommended to merely “top-off” the soap to refill the reservoir. So, in choosing between removing the residual soap and thoroughly washing out the reservoir before refilling, and the other choice of lifting the lid and topping it off, which is the more likely practice? This does not even consider the nozzle that gets touched by the user’s hand as soap is dispensed (to prevent that last drop from falling onto the counter), and is very likely to have dried soap caked to its exterior.

The other variety of public area liquid soap dispenser has a sealed bag with an integral nozzle. Regardless of the formulation contained within the bag, this system enables a clean startup with each refill of the soap container. Check out the next liquid soap dispenser you see and come to your own decision after you look closely at a few of the nozzles and compare reservoir-style dispensers to sealed-bag dispensers. I would urge the use of the sealed bag system in the lab and manufacturing area. There is no sense in risking the contamination of your hands by the soap if this risk can be minimized.

Antibacterial Additives

The concept of antibacterial additives to soap sounds good. Take soap, arguably the most important medical advance in the last few hundred years, and make it better by adding a biocide to it. The problem with this scenario is that the vendor is not actually required to show that the biocide works in the soap, only that it is present in the formulation. This is not to say that reputable manufacturers do not conduct appropriate testing, only that this testing is not required to label your product as an “antibacterial” soap. In addition, there is the possibility of selecting for biocide resistance in soaps that might be only marginally more efficacious than standard soap, if more efficacious at all (9, 10). However when this works, the resultant product can be quite good. Fuls et al. (11) found that with a particular soap containing triclosan, the use of a greater volume of soap and longer wash time resulted in a marked superiority of the antibacterial soap over the traditional formulation.

The biocides most commonly used as soap additives include triclosan, chlorhexidine, ethylenediaminetetraacetic acid (EDTA), and alcohols. Triclosan has come under intense scrutiny for potential selection of antibiotic-resistant mutant microorganisms, particularly in Europe. This prompted the European Commission (EC) to formally examine the safety of triclosan and the Scientific Steering Committee of the European Commission adopted an official opinion in 2002 that triclosan, used in biocidal concentrations, is safe and effective (12). Chlorhexidine still has a place in the surgical scrub arena but is not a major component in consumer products.

To sum up, biocides added to soap make an antibacterial soap. However, this is not a guarantee that the resultant antibacterial soaps are, in fact, antibacterial as instances of antibacterial soap suffering contamination have been reported (13, 14).

HAND JEWELRY

Hand jewelry (e.g., rings, bracelets, watches, etc.) should be removed when washing your hands. These items of jewelry make it very difficult to clean your hands effectively. Alp et al. (2006) (15) examined the hand washing practices of laboratory

workers, figuring that regular exposure to pathogenic organisms would make them aware of the dangers. Compliance was 100% for the act itself after training, but 36.7% wore a ring, 46.9% a watch, and 6.1% a bracelet, all of which harbored pathogenic organisms after hand washing. This was corrected by repeated interventions. Fagernes et al. (16), in a study of healthcare workers, examined the impact of wearing a single plain ring (rather like the wedding ring many of us are no longer able to remove). The good news is that the total bioburden after washing was not different between ring wearing and no ring subjects, although the study showed a clear increase in *Enterbacteriaceae* contamination when compared to the subjects without rings.

DRYING

Several teams have looked at paper towels vs. hot air dryer in regards to cleaning and transmission of contamination. Matthews and Newsom (17) compared hot air driers and paper towels for the potential to spread airborne microorganisms during the drying process. Their design focused on air sampling using Casella slit-to-agar sampler for airborne bacteria during drying (in the somewhat controlled environment of a biological safety cabinet). They found minor differences in airborne viable counts in a comparison between one model of dryer and paper towels, and significantly less airborne viable counts for two other models in comparison to paper towels. Blackmore expanded this comparison, conducting a study (18) on the effect of drying by air blower, by paper towel, and by cloth towel on a continuous roller. The finger tips of the left hand were sampled by touching to nutrient agar and then the hands were washed. After washing, the hands were dried by one of the three methods and sampled again. The expelled air from the air driers was sampled by blowing it onto "nutrient agar" from 6 inches for a controlled period of time (differing by cycle time of the model of air drier). The paper and cloth towels were sampled by touch plates. Blackmore reports that the air blowers tested (in public locations) harbored bacteria and could serve as a source for recontamination of hands after washing. The situation with continuous cloth

drying was not encouraging either. The cloth roller towels were very good when new but over the course of three months (the length of time studied) they became contaminated. In addition, she found (in 1989) that these continuous cloth towels are laundered and re-used, the laundered material was contaminated as well (range of 10-60 CFU/touch plate) as installed in the roller dispenser. One explanation for the apparent contradiction in the results is offered by Meers and Long (19) who did a limited study to evaluate the purchase of hot-air dryers for their hospital and sampled the air before, during, and after drying, finding an increase in counts only after drying. They concluded that it was difficult for small particles to escape from skin while moist (covered with water). What was important was that the skin be thoroughly dried.

Harrison et al. (20) took a closer look at transmission of bacteria between hands and paper towels. They looked at both directions of transmission, reasoning that the concern over a contaminated towel transmitting to the hand is clear, but there is also a possibility for a contaminated hand to transfer bacteria to the dispenser while freeing jammed towels. Using a wall-mounted paper towel dispenser and a range of paper towels, volunteers (with either clean or contaminated hands) were asked to clear jammed towels from the dispenser (the dispenser either clean or contaminated). They found that while the contaminated hands only marginally contaminated the dispenser (0.01%-0.64%) the dispenser was fairly effective at contaminating hands (12.4-13.1%).

In looking at the potential for dirty hands to contaminate surfaces we should also consider dryness. Patrick et al. (21), in studying this issue, concluded that "...bacterial numbers translocating on touch contact decreased progressively as drying with an air or cloth towel system removed residual moisture from the hands . . . Careful hand drying is a critical factor determining the level of touch-contact-associated bacterial transfer after hand washing and its recognition could make a significant contribution towards improving hand care practices in clinical and public health sectors."

Reinforcing this consideration is the recent study of Yamamoto et al. (22) who looked at drying by

paper towel, by hot air, and by hot air supplemented with ultraviolet (UV) light. In addition, the hot air drying was performed either by holding the hands stationary or by rubbing the hands together. After looking at all variables they concluded that the hot air dryer is effective if the hands were held motionless (i.e., not rubbed) until dry. The UV light also seemed to help in decreasing residual viable cells for the hot air dryer. Paper towels were shown to be more effective when measured by fingertip sampling, but equivalent by other measures.

TRAINING AND MONITORING

All budgetary resources spent on a personnel hygiene program will be ineffective if training and management attention is incomplete or indifferent. Compliance is universally the major problem in hand washing programs (23). The first problem to address is to determine a suitable procedure for hand washing. Several are available, although none are specifically directed to the pharmaceutical worker.

Training becomes the next issue. Training by rote is always an option, but this is not a particularly effective one as “everyone knows” how to wash their hands and any changes made solely to meet standard operating procedure (SOP) requirements will be transitory at best. There are several tools available for assistance in training, particularly in the evaluation of cleaning efficacy. A common method is to apply a fluorescent gel as a marker prior to washing. After washing, the hands are held under UV light to determine efficacy of cleaning. One such activity is available on the Internet at http://www.bam.gov/teachers/activities/epi_4_hand_wash.pdf (downloaded 9/27/09). This activity guide is useful in supplying a teaching resource for hand washing that includes a lesson outline and three separate sources of the fluorescent gel to use as a marker.

The final issue is monitoring compliance. This is particularly difficult as self-assessment is notoriously inaccurate, at least among healthcare workers who consistently self-report more conscientious hygiene behavior than what is observed independently (24-27). On the other hand, Stevenson et al. (28) report a tool for self-reporting that is directed at the

general population that might have use as a monitoring method, perhaps coupled with observation. Observation of behavior should be included in any evaluation, however else compliance is measured in your facility.

A SUGGESTED HAND WASHING PROTOCOL

The following stepwise procedure is recommended for hand washing in the pharmaceutical environment. The following protocol is based on a CDC (Centers for Disease Control) hand washing protocol:

- Remove jewelry from hands and wrists.
- Consider the sink, including the faucet controls, contaminated. Avoid touching the sink and faucet controls with your hands.
- Turn water on using elbow controls (or foot control). If these are not available, use a paper towel and then wet your hands and wrists.
- Apply soap from a dispenser (do not use bar soap which will certainly be contaminated with microbes). Assume the control lever for the soap is contaminated. Work soap into a lather.
- Vigorously rub together all surfaces of the lathered hands for at least 20 seconds. Friction helps remove dirt and microorganisms. Wash around cuticles, in the finger webbing, the back of the hands, and under fingernails in addition to rubbing the palms together.
- Rinse hands thoroughly under a stream of water. Running water carries away dirt and debris. Point fingers down so water and contamination won't drip toward elbows.
- Dry hands completely (leave water running).
- Use a clean dry paper towel. Be aware that if the towel jams and you need to work to release it you should re-wash your hands if you touch the dispenser.
- Use a hot-air blower (preferably one that has an integral UV light). Start the unit with your elbow (not your wet hands). Do not rub your hands together while drying them completely under the hot air flow.
- Use elbow or foot to turn faucet off. If appropriate faucet controls are not available, use a clean paper towel to turn off the faucet.

- Do not top off the soap dispenser. This leads to contaminated reservoirs in addition to the contamination in the nozzle. If possible, use a soap dispenser that is refilled in a sealed container that includes the soap in a plastic bag and a fresh nozzle.
- Do not assume antibacterial soaps are efficacious. Treat all soaps as potentially contaminated and exercise sanitary practices in regularly cleaning dispensers.

IMPLICATIONS FOR COMPLIANCE

Personnel properly trained in routine cleanliness are an obvious need for all manufacturing and testing. This need is heightened in high risk manufacturing such as in aseptic processing. This need is also heightened in situations wherein microbial testing is part of validation testing but is not usually conducted in routine manufacturing. For example, preparation of granulating liquids for solid products does not usually include microbial testing. Preparation of aqueous coating liquids does not usually include microbial testing. Clean equipment storage does not usually include microbial testing. All of these examples would likely include microbial testing for process validation or cleaning validation. The two aforementioned formulation examples likely do not contain preservatives in their respective formulations. Depending on the formulation, microbial growth could be easily supported in these situations. Clean equipment hold time validation should include microbial testing. Drug dispensing practices may not routinely include microbial testing even though liquid materials that support microbial growth may be routinely dispensed for use in manufacturing commercial product. Validation personnel should carefully evaluate personnel practices when microbial testing is required in validation protocols. It is likely that simple processes, such as hand washing, are generally assumed to be under control when they may be an undetected source of product contamination.

HAND SCRUBS

The product category of “antibacterial hand scrubs” should be considered. Even though antibacterial hand scrubs are not covered in the CFR, their enor-

mous popularity has made them a common fixture in many companies. Recent literature studies would suggest that they can be very useful. Suchomel, M, et al. (29) looked at three commercial products with alcohols (propanols or ethanol) at 73% - 78% and found propanol preparations more effective, passing the requirements of EN 12791 after a 90-second rub. An earlier study by Rotter, ML et al. (30) evaluated a series of alcohol-based sanitizing rubs and found several that performed suitably (under EN 12791) when applied for 90 seconds. They made the strong recommendation, however, that their results not be generalized to all alcohol-based rubs as they did see differences among those tested. Each rub needs to be qualified for its application. Finally, Witt (31) argues that the use of hand sanitizers as an adjunct to hand washing can be extremely effective, particularly if coupled with effective technique and attention to those portions of the hands most commonly overlooked on hand washing.

What we are left with then is that it would be prudent to include a hand sanitizer in the hygiene practice. This can be used with a 90-second rub as a sanitization step between hand washings or after hand washing once the skin is completely dry. The sanitizing rub should cover the entire hand, but provide particular attention to the fingertips, back of the thumbs (to the base), and webbing of the fingers (areas sometimes neglected during hand washing).

SUMMARY

Hand washing is an activity that is frequently taken for granted. Every pharmaceutical process that includes some aspect of human intervention is subject to contamination and the integrity of well-designed and controlled pharmaceutical processes may be compromised by careless hand washing. Employee awareness of this potential coupled with effective training will minimize inadvertent contamination due to careless hand washing techniques.

There are several key points to ensure effective hand washing. It is important to use proper technique in storing the soap in a clean manner (to prevent excessive contamination), remove all jewelry, to use enough soap to do the job, wash thoroughly (time and applica-

tion), and to completely dry your hands while preventing recontamination.

As for drying method, there does not seem to be strong, unambiguous data showing superiority for either paper towel drying or hot air drying (although UV irradiation when used with hot air seems preferable).

Technique and procedure are paramount in minimizing transmission. Once trained, ongoing compliance with the hand washing procedure should be monitored as part of an ongoing contamination control program for the facility, and an aid to minimize employee absence due to illness.

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ARTICLE ACRONYM LISTING

ASTM	American Society for Testing and Materials
CDC	Centers for Disease Control
CFR	Code of Federal Regulations
CGMP	Current Good Manufacturing Practice
EC	European Commission
EDTA	Ethylendiaminetetraacetic Acid
GMP	Good Manufacturing Practice
prEN	Preliminary European Norm
SOP	Standard Operating Procedure
UV	Ultraviolet

ABOUT THE AUTHOR

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