WORLD ALLIANCE FOR PATIENT SAFETY

# WHO GUIDELINES ON HAND HYGIENE IN HEALTH CARE (ADVANCED DRAFT)

GLOBAL PATIENT SAFETY CHALLENGE 2005–2006:

Clean Care is Safer Care

World Health Organization

The WHO Guidelines on Hand Hygiene in Healthcare (Advanced Draft) will be issued as a final version in 2007.

At present it is important for countries and organisations to note that the Guidelines represent a consensus of international experts and up to date technical information on hand hygiene improvement within a health care context across the world.

The Guidelines are being pilot tested and it is likely that changes will be made to some of the technical content of the chapters in light of pilot test results.

The Advanced Draft status offers WHO the opportunity to review and update the literature during the life of the Global Patient Safety Challenge to ensure that evidence is as contemporaneous as possible on final publication.

It is unlikely that the fundamental principles behind the guideline recommendations will change by the time the Guidelines are finalized in 2007.

We welcome formal feedback on these guidelines. Feedback is invited using the AGREE methodology http://www.agreecollaboration.org/pdf/agreeinstrumentfinal.pdf

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# WHO GUIDELINES ON HAND HYGIENE IN HEALTH CARE (ADVANCED DRAFT)

## GLOBAL PATIENT SAFETY CHALLENGE 2005–2006: "CLEAN CARE IS SAFER CARE"

APRIL 2006

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# INTRODUCTION

The *WHO Advanced Draft Guidelines on Hand Hygiene in Health Care* provide health-care workers (HCWs), hospital administrators and health authorities with a thorough review of evidence on hand hygiene in health care and specific recommendations to improve practices and reduce transmission of pathogenic microorganisms to patients and HCWs. The present guidelines are intended to be implemented in any situation in which health care is delivered either to a patient or to a specific group in a population. Therefore, this concept applies to specific health-care facilities, to community settings and to other settings where health care is occasionally performed, such as home care by birth attendants. Definitions of health-care settings are proposed in Appendix 1.

The development of the advanced draft guidelines followed the World Health Organization (WHO) recommended process for guidelines and began in autumn 2004. This process included two international consultations (in December 2004 and April 2005) attended by experts from all over the world and technical experts from WHO. Numerous experts conducted multiple search strategies of available published information by 31 July 2005. A core group of experts coordinated the work of reviewing the available scientific evidence, writing the document, and fostering discussion among authors; more than 100 international experts contributed to preparing the document. WHO advisers and members of the WHO Consultations and Task Forces on Hand Hygiene who actively participated in the work process up to final publication are listed in the Acknowledgements at the end of the document.

At present, pilot tests of the guidelines are being conducted in each of the six WHO regions to help provide local data on the resources required to carry out the recommendations and generate information on feasibility, validity, reliability and cost–effectiveness of the interventions concerned. In addition, task forces of experts have been established to foster ongoing discussion on some crucial topics included in the guidelines – candidates for further development and practical solutions. The work of these groups is planned to continue until the analysis of the issues has been completed and practical solutions have been identified.

The *WHO Advanced Draft Guidelines on Hand Hygiene in Health Care* provide a comprehensive review of scientific data on hand hygiene rationale and practices in health care. This extensive review includes in one document sufficient technical information to support training materials and help plan implementation strategies. The document comprises five parts:

- Part I reviews scientific data on hand hygiene practices in health care and in health-care settings in particular.
- Part II provides consensus recommendations of the international panel of experts mandated by WHO to summarize the evidence and proposes guidelines that could be used worldwide.
- Part III discusses outcome and process measurements.
- Part IV addresses the issue of promoting hand hygiene on a large scale.
- Part V covers public information.

For convenience, the figures and tables are numbered to correspond to the Part and the Section in which they are discussed. The tabular presentations are grouped together after the text and the references.

# PART I. REVIEW OF SCIENTIFIC DATA RELATED TO HAND HYGIENE

## 1. DEFINITION OF TERMS

**Hand hygiene**. A general term referring to any action of hand cleansing (see "Hand hygiene practices").

### HAND HYGIENE PRODUCTS

**Alcohol-based (hand)rub**. An alcohol-containing preparation (liquid, gel or foam) designed for application to the hands to reduce the growth of microorganisms. Such preparations may contain one or more types of alcohol with excipients, other active ingredients, and humectants.

**Antimicrobial (medicated) soap**. Soap (detergent) containing an antiseptic agent at a concentration which is sufficient to reduce or inhibit the growth of microorganisms.

**Antiseptic agent**. An antimicrobial substance which reduces or inhibits the growth of microorganisms on living tissues. Examples include alcohols, chlorhexidine gluconate, chlorine derivatives, iodine, chloroxylenol (PCMX), quaternary ammonium compounds, and triclosan.

**Detergent (surfactant)**. Compounds that possess a cleaning action. They are composed of a hydrophilic and a lipophilic part and can be divided into four groups: anionic, cationic, amphoteric, and non-ionic. Although products used for handwashing or antiseptic handwash in health care represent various types of detergents, the term "soap" will be used to refer to such detergents in these guidelines.

**Plain soap**. Detergents that do not contain antimicrobial agents, or that contain very low concentrations of antimicrobial agents effective solely as preservatives.

**Waterless antiseptic agent**. An antiseptic agent that does not require the use of exogenous water. After application, the individual rubs the hands together until the agent has dried. The term includes different types of handrubs (liquid formulations, gels, foams).

### HAND HYGIENE PRACTICES

**Antiseptic handwashing**. Washing hands with water and soap or other detergents containing an antiseptic agent.

**Antiseptic handrubbing (or handrubbing)**. Applying an antiseptic handrub to reduce or inhibit the growth of microorganisms without the need for an exogenous source of water and requiring no rinsing or drying with towels or other devices.

**Hand antisepsis/decontamination/degerming**. Reducing or inhibiting the growth of microorganisms by the application of an antiseptic handrub or by performing an antiseptic handwash.

**Hand care**. Actions to reduce the risk of skin irritation.

**Handwashing**. Washing hands with plain or antimicrobial soap and water.

**Hand cleansing**. Action of performing hand hygiene for the purpose of physically or mechanically removing dirt, organic material or microorganisms.

**Hand disinfection** is extensively used as a term in some parts of the world and can refer to antiseptic handwash, antiseptic handrubbing, hand antisepsis/decontamination/degerming, handwashing with an antimicrobial soap and water, hygienic hand antisepsis, or hygienic handrub. Disinfection generally refers to inanimate surfaces, but hand disinfection is frequently used in the same sense as hand antisepsis in the literature but not in these Guidelines.

**Hygienic hand antisepsis**. Treatment of hands with either an antiseptic handrub or antiseptic handwash to reduce the transient microbial flora without necessarily affecting the resident skin flora.

**Hygienic handrub**. Treatment of hands with an antiseptic handrub to reduce the transient flora without necessarily affecting the resident skin flora. These preparations are broad spectrum and fast-acting, and persistent activity is not necessary.

**Hygienic handwash**. Treatment of hands with an antiseptic handwash to reduce the transient flora without necessarily affecting the resident skin flora. It is broad spectrum, but is usually less efficacious and acts more slowly than the hygienic handrub.

**Surgical hand antisepsis/surgical hand preparation**. Antiseptic handwash or antiseptic handrub performed pre-operatively by the surgical team to eliminate transient and reduce resident skin flora. Such antiseptics often have persistent antimicrobial activity. **Surgical handscrub(bing)**/presurgical scrub refer to surgical hand preparation with antimicrobial soap and water. **Surgical handrub(bing)** refers to surgical hand preparation with a waterless, alcohol-based handrub.

### ASSOCIATED TERMS

**Cumulative effect**. Increasing antimicrobial effect with repeated applications of a given antiseptic.

**Substantivity**. An attribute of some active ingredients that adhere to the *stratum corneum* and provide an inhibitory effect on the growth of bacteria by remaining on the skin after rinsing or drying.

**Persistent activity**. The prolonged or extended antimicrobial activity that prevents the growth or survival of microorganisms after application of a given antiseptic; also called "residual", "sustained" or "remnant" activity. Both substantive and non-substantive active ingredients can show a persistent effect significantly inhibiting the growth of microorganisms after application.

**Humectant**. Ingredient(s) added to hand hygiene products to moisturize the skin.

Excipient. Inert substance combined to the product formula to serve as a vehicle for the active substance.

**Surrogate microorganism**. A microorganism used to represent a given type or category of nosocomial pathogen when testing the antimicrobial activity of antiseptics. Surrogates are selected for their safety, ease of handling and relative resistance to antimicrobials.

**Visibly soiled hands**. Hands on which dirt or body fluids are readily visible.

**Efficacy/efficaceous**. The (possible) effect of the application of a hand hygiene formulation when tested in laboratory or *in vivo* situations.

**Effectiveness/effective**. The clinical conditions under which hand hygiene products have been tested, such as field trials, where the impact of a hand hygiene formulation is monitored on the rates of cross-transmission of infection or resistance.

## 2. HISTORICAL PERSPECTIVE ON HAND HYGIENE IN HEALTH CARE

For centuries, handwashing with soap and water has been considered a measure of personal hygiene[1,2] but the link between handwashing and the spread of disease has only been established in the last 200 years. In the mid-1800s, studies by Ignaz Semmelweis in Vienna and Oliver Wendell Holmes in Boston established that hospital-acquired diseases, now known to be caused by infectious agents, were transmitted via the hands of HCWs. In the community, hand hygiene has been acknowledged as an important measure to prevent and control infectious diseases[3] and can significantly reduce the burden of disease, in particular among children in developing countries[4,5]. In the health-care setting, a prospective controlled trial conducted in a hospital nursery[6] and investigations conducted during the past 40 years have confirmed the important role that contaminated hands of HCWs play in the transmission of health care-associated pathogens. Currently, hand hygiene is considered the most important measure for preventing the spread of pathogens in health-care settings[7].

The 1980s represented a landmark in the evolution of concepts of hand hygiene in health care. The first national hand hygiene guidelines were published in the 1980s[8,9]), followed by many others in more recent years. These guidelines were essentially issued in countries in the northern hemisphere, including the United States of America (USA), Canada and some European countries. Therefore, it can be seen that hand hygiene concepts have much evolved over the past two decades[10].

In 1961, the United States public health service produced a training film that demonstrated handwashing techniques recommended for use by HCWs[11]. At that time, it was recommended to wash hands with soap and water for 1 to 2 minutes before and after patient contact. Rinsing hands with an antiseptic agent was believed to be less effective than handwashing and was recommended only in emergencies or in areas where sinks were unavailable. Twenty years later, the United States national guidelines[9] still recommended waterless antiseptic agents (i.e. alcohol-based solutions) only in situations where sinks were not available, and handwashing with soap and water was considered the standard of care. Subsequent hand hygiene guidelines in the USA[12,13] included more detailed discussion of alcohol-based handrubs and supported their use in more clinical settings than what had previously been recommended[13]. In 1995 and 1996, the United States Centers for Disease Control and Prevention (CDC)/Healthcare Infection Control Practices Advisory Committee (HICPAC) recommended that either antimicrobial soap or a waterless antiseptic agent be used for cleansing hands upon leaving the rooms of patients with multidrug-resistant pathogens such as vancomycin-resistant enterococci (VRE) and methicillin-resistant *Staphylococcus aureus* (MRSA)[14,15]. More recently, the CDC/HICPAC guidelines issued in 2002 defined alcohol-based handrubbing as the standard of care for hand hygiene practices in health-care settings[7].

In central European countries, the use of alcohol-based rubs for hand hygiene has been the method of choice for many years[16]. However, in many other countries, handwashing is

still considered the standard of care and alcohol-based handrub is reserved for particular situations only (i.e. emergency, no sinks available)[16].

WHO publications addressing infection control measures to reduce the spread of pathogens in health-care settings have emphasized hand hygiene as a key measure[17-19]. However, the guidance referring to hand hygiene technique has so far not clearly classified handrubbing as the gold standard when compared to handwashing with soap and water. The recommendations for the control of MRSA suggest handrubbing as an alternative "in the absence of good water supply or running water"[17]. Two recent WHO infection control guidelines provide a more detailed description of the handrubbing technique, and suggest that hand hygiene be performed by either handwashing or handrubbing, but without stating any advantage of one over the other[18,19].

## 3. NORMAL BACTERIAL FLORA ON HANDS

In 1938, Price[20] established that bacteria recovered from the hands could be divided into two categories, namely transient or resident. The resident flora consists of microorganisms residing under the superficial cells of the *stratum corneum*, and can also be found on the surface of the skin[21]. *Staphylococcus epidermidis* is the dominant species[22], and oxacillin resistance is extraordinarily high, particularly among HCWs[23]. Other resident bacteria include *Staphylococcus hominis* and other coagulase-negative staphylococci, followed by coryneform bacteria (*propionibacteria*, *corynebacteria*, dermobacteria, and micrococci)[24]. Among fungi, the most common genus of the resident skin flora, when present, is *Pityrosporum* (*Malassezia*) spp.[25]. Resident flora has two main protective functions: microbial antagonism and the competition for nutrients in the ecosystem[26]. In general, resident flora is less likely to be associated with infections, but may cause infections in sterile body cavities, in the eyes, or on non-intact skin[27].

Transient flora, which colonizes the superficial layers of the skin, is more amenable to removal by routine handwashing. Transient microorganisms do not usually multiply on the skin, but they survive and sporadically multiply on skin surface[26]. They are often acquired by HCWs during direct contact with patients or contaminated environmental surfaces adjacent to the patient, and are the organisms most frequently associated with health care-associated infections (HCAIs). Some types of contact are more frequently associated with higher levels of bacterial contamination of HCWs' hands during routine neonatal care: respiratory secretions, nappy/diaper change and direct skin contact[28,29]. The transmissibility of transient flora depends on the species present, the number of microorganisms on the surface, and the skin moisture[30,31]. The hands of some HCWs may become persistently colonized by pathogenic flora such as *S. aureus*, Gram-negative bacilli, or yeast[32].

Normal human skin is colonized by bacteria, with total aerobic bacterial counts ranging from more than $1 \times 10^6$ colony forming units (CFU)/cm$^2$ on the scalp, $5 \times 10^5$ CFU/cm$^2$ in the axilla, and $4 \times 10^4$ CFU/cm$^2$ on the abdomen to $1 \times 10^4$ CFU/cm$^2$ on the forearm[33]. Total bacterial counts on the hands of HCWs have ranged from $3.9 \times 10^4$ to $4.6 \times 10^6$ CFU/cm$^2$ [20,34-36]. Fingertip contamination ranged from 0 to 300 CFU when sampled by agar contact methods[28]. Price and subsequent investigators documented that although the number of transient and resident flora varies considerably among individuals, it is often relatively constant for any given individual[20,37].

## 4. PHYSIOLOGY OF NORMAL SKIN

The primary function of the skin is to reduce water loss, provide protection against abrasive action and microorganisms, and generally act as a permeability barrier to the environment. Its basic structure is: the superficial region, termed the *stratum corneum* or horny layer, is between 10 and 20 µm thick; underlying this region are the viable epidermis (50–100 µm), dermis (1–2 mm) and hypodermis (1–2 mm). The barrier to percutaneous absorption lies within the *stratum corneum*, the thinnest and smallest compartment. The *stratum corneum* contains the corneocytes or horny cells, which are flat polyhedral-shaped non-nucleated cells, remnants of the terminally differentiated keratinocytes found in the viable epidermis. Corneocytes are composed primarily of insoluble bundled keratins surrounded by a cell envelope stabilized by cross-linked proteins and covalently bound lipids. Interconnecting the corneocytes of the *stratum corneum* are polar structures such as corneodesmosomes, which contribute to *stratum corneum* cohesion.

The intercellular region of the *stratum corneum* is composed of lipids primarily generated from the exocytosis of lamellar bodies during the terminal differentiation of the keratinocytes. The intercellular lipid is required for a competent skin barrier and forms the acontinuous tissue. Directly under the *stratum corneum* is a stratified epidermis, composed primarily of 10–20 layers of keratinizing epithelial cells, which are responsible for the synthesis of the *stratum corneum*. This layer also contains melanocytes involved in skin pigmentation; Langerhans cells, which are important for antigen presentation and immune responses; and Merkel cells whose precise role in sensory reception has yet to be fully delineated. As keratinocytes undergo terminal differentiation, they begin to flatten out and assume the dimensions characteristic of the corneocytes, i.e. their diameter changes from 10–12 µm to 20–30 µm and their volume increases 10-fold to 20-fold. The viable epidermis does not contain a vascular network, and the keratinocytes obtain their nutrients from below by passive diffusion through the interstitial fluid.

The skin is a dynamic structure. Barrier function does not simply arise from the dying, degeneration and compaction of the underlying epidermis. Rather, the processes of cornification and desquamation are intimately linked; synthesis of the *stratum corneum* occurs at the same rate as loss. There is now substantial evidence that the formation of the skin barrier is under homeostatic control. This is illustrated by the epidermal response to barrier perturbation by skin stripping or solvent extraction. There is circumstantial evidence that the rate of keratinocyte proliferation directly influences the integrity of the skin barrier. A general increase in the rate of proliferation will result in a decrease in the time available for (i) uptake of nutrients, such as essential fatty acids; (ii) synthesis of protein and lipid; and (iii) processing of the precursor molecules required for skin barrier function. It remains unclear if chronic but quantitatively smaller increases in the rate of epidermal proliferation also lead to changes in skin barrier function. Thus, equally unclear is the extent to which the decreased barrier function caused by irritants is due to an increased epidermal proliferation.

The current understanding of the formation of the *stratum corneum* has come from studies of the epidermal responses to perturbation of the skin barrier. Experimental manipulations that disrupt the skin barrier include: (i) extraction of skin lipids with apolar solvents; (ii) physical stripping of the *stratum corneum* using adhesive tape; and (iii) chemically induced irritation. All such experimental manipulations lead to a decreased skin barrier as determined by transepidermal water loss. Perhaps the most studied experimental system is the treatment of mouse skin with acetone. This leads to a marked and immediate increase in transepidermal water loss, indicating a decrease in skin barrier function. Since acetone

treatment selectively removes glycerolipids and sterols from the skin, this suggests that these lipids are necessary though perhaps not sufficient in themselves for a barrier function. Detergents (see below) act similarly to acetone on the intercellular lipid area. The return to normal barrier function is biphasic: 50–60% of barrier recovery is typically seen within 6 hours but complete normalization of barrier function requires 5–6 days.

## 5. TRANSMISSION OF PATHOGENS ON HANDS

Transmission of health care-associated pathogens from one patient to another via HCWs' hands requires five sequential elements: (i) organisms are present on the patient's skin, or have been shed onto inanimate objects immediately surrounding the patient; (ii) organisms must be transferred to the hands of HCWs; (iii) organisms must be capable of surviving for at least several minutes on HCWs' hands; (iv) handwashing or hand antisepsis by the HCW must be inadequate or entirely omitted, or the agent used for hand hygiene inappropriate; and (v) the contaminated hand or hands of the caregiver must come into direct contact with another patient or with an inanimate object that will come into direct contact with the patient. Evidence supporting each of these elements is given below.

### 5.1 ORGANISMS PRESENT ON PATIENTS' SKIN OR IN THE INANIMATE ENVIRONMENT

Health care-associated pathogens can be recovered not only from infected or draining wounds, but also from frequently colonized areas of normal, intact patient skin[38-49]. The perineal or inguinal areas tend to be most heavily colonized, but the axillae, trunk, and upper extremities (including the hands) also are frequently colonized[41,42,44,45,47,49,50]. The number of organisms such as *S. aureus*, *Proteus mirabilis*, *Klebsiella* and *Acinetobacter* spp. present on intact areas of the skin of some patients can vary from 100 to $10^6$ CFU/$cm^2$ [42,44,48,51]. Diabetics, patients undergoing dialysis for chronic renal failure, and those with chronic dermatitis are particularly likely to have areas of intact skin that are colonized with *S. aureus*[52-59]. Because nearly $10^6$ skin squames containing viable microorganisms are shed daily from normal skin[60], it is not surprising that patient gowns, bed linen, bedside furniture and other objects in the immediate environment of the patient become contaminated with patient flora[49,61-64]. Such contamination is particularly likely to be due to staphylococci or enterococci, which are more resistant to dessication. Contamination of the inanimate environment has also been detected on ward handwash station surfaces, and many of the organisms isolated were staphylococci[65]. Tap/faucet handles were more likely to be contaminated and be in excess of benchmark values than other parts of the station. This study emphasizes the potential importance of environmental contamination on microbial cross-contamination and pathogen spread[65].

### 5.2 ORGANISMS TRANSFERRED TO HEALTH-CARE WORKERS' HANDS

Relatively few data are available regarding the types of patient-care activities that result in transmission of patient flora to HCWs' hands[28,45,63,64,66-69]. In the past, attempts have been made to stratify patient-care activities into those most likely to cause hand contamination[70], but such stratification schemes were never validated by quantifying the level of bacterial contamination that occurred. Casewell & Phillips[67] demonstrated that nurses could contaminate their hands with 100 to 1000 CFU of *Klebsiella* spp. during "clean" activities such

as lifting patients, taking the patient's pulse, blood pressure or oral temperature; or touching the patient's hand, shoulder or groin. Similarly, Ehrenkranz and colleagues[44] cultured the hands of nurses who touched the groin of patients heavily colonized with *P. mirabilis* and found 10 to 600 colony forming units (CFU)/ml in glove juice samples.

Pittet and colleagues[28] studied contamination of HCWs' hands before and after direct patient contact, wound care, intravascular catheter care, respiratory tract care or handling patient secretions. Using agar fingertip impression plates, they found that the number of bacteria recovered from fingertips ranged from 0 to 300 CFU. Direct patient contact and respiratory tract care were most likely to contaminate the fingers of caregivers. Gram-negative bacilli accounted for 15% of isolates and *S. aureus* for 11%. Importantly, duration of patient-care activity was strongly associated with the intensity of bacterial contamination of HCWs' hands in this study. A similar study of hand contamination during routine neonatal care defined skin contact, nappy/diaper change and respiratory care as independent predictors of hand contamination[29]. In the latter study, the use of gloves did not fully protect HCWs' hands from bacterial contamination, and glove contamination was almost as high as ungloved hand contamination following patient contact. In contrast, the use of gloves during procedures such as nappy/diaper change and respiratory care almost halved the average increase of bacteria CFU/min on HCWs' hands[29].

Several other studies have documented that HCWs can contaminate their hands with Gram-negative bacilli, *S. aureus*, enterococci or *Clostridium difficile* by performing "clean procedures" or touching intact areas of skin of hospitalized patients[45,63,64,71]. A recent study that involved culturing the HCWs' hands after various activities showed that hands were contaminated following patient contact and after contact with body fluids or waste[72]. McBryde and colleagues[73] estimated the frequency of HCWs' glove contamination with MRSA after contact with a colonized patient. HCWs were intercepted after a patient-care episode and cultures were taken from their gloved hands before handwashing had occurred; 17% ($CI_{95}$ 9–25%) of contacts with patients, a patient's clothing or a patient's bed resulted in transmission of MRSA from a patient to the HCWs' gloves. Furthermore, HCWs caring for infants with respiratory syncytial virus (RSV) infections have acquired it by performing activities such as feeding infants, nappy/diaper change and playing with the infant[68]. Caregivers who had contact only with surfaces contaminated with the infants' secretions also acquired RSV. In the above studies, HCWs contaminated their hands with RSV and inoculated their oral or conjunctival mucosa. Other studies have also documented that the hands (or gloves) of HCWs may be contaminated after touching inanimate objects in patient rooms[29,64,71-77]. Similarly, laboratory-based studies have shown that touching contaminated surfaces can transfer *S. aureus* or Gram-negative bacilli to the fingers[78]. Unfortunately, none of the studies dealing with HCW hand contamination was designed to determine if the contamination resulted in the transmission of pathogens to susceptible patients.

Many other studies have reported contamination of HCWs' hands with potential pathogens, but did not relate their findings to the specific type of preceding patient contact[34,35,79-85]. For example, in studies conducted before glove use was common among HCWs, Ayliffe and colleagues[82] found that 15% of nurses working in an isolation unit carried a median of 1 x $10^4$ CFU of *S. aureus* on their hands. Twenty-nine per cent of nurses working in a general hospital had *S. aureus* on their hands (median count, 3.8 x $10^3$ CFU), while 78% of those working in a hospital for dermatology patients had the organism on their hands (median count, 14.3 x $10^6$ CFU). The same survey revealed that 17% to 30% of nurses carried Gram-negative bacilli on their hands (median counts ranged from 3.4 x $10^3$ CFU to 38 x $10^3$ CFU). Daschner[80] found that *S. aureus* could be recovered from the hands of 21% of intensive care unit (ICU) caregivers and that 21% of doctors and 5% of nurse carriers had >$10^3$ CFU

of the organism on their hands. Maki[36] found lower levels of colonization on the hands of HCWs working in a neurosurgery unit, with an average of 3 CFUs of *S. aureus* and 11 CFUs of Gram-negative bacilli. Serial cultures revealed that 100% of HCWs carried Gram-negative bacilli at least once, and 64% carried *S. aureus* at least once. A recent study conducted in two neonatal ICUs revealed that Gram-negative bacilli were recovered from the hands of 38% of nurses[84].

## 5.3 ORGANISMS CAPABLE OF SURVIVING ON HANDS

Several studies have shown the ability of microorganisms to survive on hands for differing times. Musa and colleagues demonstrated in a laboratory study that *Acinetobacter* calcoaceticus survived better than strains of *A. lwoffi* at 60 minutes after an inoculum of $10^4$ CFU/finger[86]. A similar study by Fryklund and colleagues using epidemic and non-epidemic strains of *E. coli* and *Klebsiella* spp showed a 50% killing to be achieved at 6 and 2 minutes, respectively[87]. Noskin and colleagues studied the survival of vancomycin-resistant enterococci (VRE) on hands and the environment; both *Enterococcus faecalis* and *E. faecium* survived for at least 60 minutes on gloved and ungloved fingertips[88]. Furthermore, Doring and colleagues showed that *P. aeruginosa* and *Burkholderia cepacia* were transmissible by handshaking for up to 30 minutes when the organisms were suspended in saline and up to 180 minutes when they were suspended in sputum[89]. The study by Islam and colleagues with *Shigella dysenteriae* 1 showed its capacity to survive on hands for up to 1 hour in culturable form[90]. Two studies by Ansari and colleagues using rotavirus[91] and human parainfluenza virus 3 and rhinovirus 14 in another[92] showed survival percentages for rotavirus at 20 and 60 minutes to be 16.1% and 1.8%, respectively. Viability at 1 hour for human parainfluenza virus 3 and rhinovirus 14 was <1% and 37.8%, respectively. The above-mentioned studies clearly demonstrate that contaminated hands could be vehicles for the spread of certain viruses.

## 5.4 DEFECTIVE HAND CLEANSING RESULTING IN HANDS REMAINING CONTAMINATED

Studies that prove inadequate hand cleansing are few. From these few studies one can assume that hands remain contaminated with the risk of transmitting organisms via hands. In a laboratory-based study, Larson et al.[93] found that using only 1 ml of liquid soap or alcohol-based handrub yielded lower log reductions (greater number of bacteria remaining on hands) than using 3 ml of product to clean hands. The findings have clinical relevance since some HCWs use as little as 0.4 ml of soap to clean their hands. Kac and colleagues[94] did a comparative crossover study of microbiological efficacy of handrubbing with an alcohol-based solution and handwashing with an unmedicated soap. The study's results were: 15% of HCWs' hands were contaminated with transient pathogens before hand hygiene; no transient pathogens were recovered after handrubbing while two cases were found after handwashing. Trick and colleagues[95] did a comparative study of three hand hygiene agents (62% ethyl alcohol handrub, medicated hand wipe, and handwashing with plain soap and water), in a group of surgical ICUs. They also studied the impact of ring wearing on hand contamination. Their results showed that hand contamination with transient organisms was significantly less likely after the use of an alcohol-based handrub compared with the medicated wipe or soap and water. Ring wearing increased the frequency of hand contamination with potential nosocomial pathogens. Wearing artificial acrylic fingernails can also result in hands remaining contaminated with pathogens after use of either soap or alcohol-based hand gel[96]. Sala and colleagues[97] investigating an outbreak of food poisoning attributed to norovirus genogroup 1 traced the index case to a food handler in the hospital cafeteria.

Most of the foodstuffs consumed in the outbreak were hand made, thus suggesting inadequate hand hygiene. Noskin and colleagues[88] in a study using VRE showed that a 5-second handwash with water alone produced no change in contamination, and 20% of the initial inoculum was recovered on unwashed hands. In the same study, a 5-second wash with two soaps did not remove the organisms completely, with approximately a 1% recovery; a 30-seconds wash with either soap was necessary to remove the organisms completely from the hands[88].

## 5.5 CROSS-TRANSMISSION OF ORGANISMS BY CONTAMINATED HANDS

There are several studies showing cross-transmission of organisms by hands. Factors that influence the transfer of microorganisms from surface to surface and affect cross-contamination rates are type of organism, source and destination surfaces, moisture level and size of inoculum. Harrison and colleagues[98] showed that contaminated hands could contaminate a clean paper towel dispenser and vice versa. The transfer rates ranged from 0.01% to 0.64% and 12.4% to 13.1%, respectively.

A study by Barker and colleagues[99] showed that fingers contaminated with norovirus could sequentially transfer virus to up to seven clean surfaces, and from contaminated cleaning clothes to clean hands and surfaces. Contaminated HCWs' hands have been associated with endemic HCAIs[100,101]. Sartor et al.[101] provided evidence that endemic *Serratia marcescens* was transmitted from contaminated soap to patients via the hands of HCWs. During an outbreak investigation of *Serratia liquefaciens*, bloodstream infections and pyrogenic reactions in a hemodialysis centre, pathogens were isolated from extrinsically contaminated vials of medication resulting from multiple dose usage, antibacterial soap, and hand lotion[102]. Duckro and colleagues[103] showed that VRE could be transferred from contaminated environment or patients' intact skin to clean sites via hands.

Several HCAI outbreaks have been associated with contaminated HCWs' hands[104-106]. El Shafie and colleagues[106] investigated an outbreak of multidrug-resistant *A. baumannii* and documented identical strains from patients, hands of staff and the environment. The outbreak was terminated when remedial measures were taken. Contaminated HCWs' hands were clearly related to outbreaks among surgical[104] and neonatal[105] patients.

Finally, several studies have shown that pathogens can be transmitted from out-of-hospital sources to patients via the hands of personnel. For example, an outbreak of postoperative *S. marcescens* wound infections was traced to a contaminated jar of exfoliant cream in a nurse's home. An investigation suggested that the organism was transmitted to patients via the hands of the nurse, who wore artificial fingernails[107]. In another outbreak, *Malassezia pachydermatis* was probably transmitted from a nurse's pet dogs to infants in an intensive care nursery via the hands of the nurse[108].

# 6. MODELS OF HAND TRANSMISSION

## 6.1 EXPERIMENTAL MODELS

Several investigators have studied the transmission of infectious agents using different experimental models. Ehrenkranz and colleagues[44] asked nurses to touch a patient's groin for 15 seconds as though they were taking a femoral pulse. The patient was known to be heavily colonized with Gram-negative bacilli. Nurses then cleaned their hands by washing with plain soap and water, or by using an alcohol handrub. After cleansing their hands, they touched a piece of urinary catheter material with their fingers and the catheter segment was cultured. The study revealed that touching intact areas of moist skin transferred enough organisms to the nurses' hands to allow subsequent transmission to catheter material despite handwashing with plain soap and water.

Marples and colleagues[30] studied transmission of organisms from artificially contaminated "donor" fabrics to clean "recipient" fabrics via hand contact and found that the number of organisms transmitted was greater if the donor fabric or the hands were wet. Overall, only 0.06% of the organisms obtained from the contaminated donor fabric were transferred to the recipient fabric via hand contact. Using the same experimental model, Mackintosh and colleagues[109] found that *S. saprophyticus*, *Pseudomonas aeruginosa* and *Serratia* spp. were transferred in greater numbers than was *Escherichia coli* from a contaminated to a clean fabric following hand contact. Patrick and colleagues[31] found that organisms were transferred to various types of surfaces in much larger numbers ($>10^4$) from wet hands than from hands that had been dried carefully. Sattar and colleagues[110] demonstrated that the transfer of *S. aureus* from fabrics commonly used for clothing and bed linen to fingerpads occurred more frequently when fingerpads were moist.

## 6.2 MATHEMATICAL MODELS

Recently, mathematical modelling has been used to examine the relationships between the multiple factors that influence the transmission of pathogens in health-care facilities. These factors include hand hygiene compliance, nurse staffing levels, frequency of introduction of colonized or infected patients onto a ward, whether or not cohorting is practised, characteristics of patients and antibiotic use practices, to name but a few[111]. Most reports describing mathematical modelling of health care-associated pathogens have attempted to quantify the influence of various factors on a single ward, such as an ICU[112-115]. Given that such units tend to house a relatively small number of patients at any time, random variations (stochastic events) such as the number of patients admitted with a particular pathogen during a short time period can have significant impact on transmission dynamics. As a result, stochastic models appear to be the most appropriate for estimating the impact of various infection control measures, including hand hygiene compliance, on colonization and infection rates.

In a mathematical model of MRSA infection in an ICU, Sebille and colleagues[112] found that the number of patients who became colonized by strains transmitted from HCWs was one of the most important determinants of transmission rates. Of interest, they found that increasing hand hygiene compliance rates had only a modest effect on the prevelance of MRSA colonization. Their model estimated that if the prevalence of MRSA colonization was 30% without any hand hygiene, it would decrease to only 22% if hand hygiene compliance

increased to 40% and to 20% if hand hygiene compliance increased to 60%. Antibiotic policies have relatively little impact in this model.

Austin and colleagues[113] used daily surveillance cultures of patients, molecular typing of isolates, and monitoring of compliance with infection control practices to study the transmission dynamics of VRE in an ICU. The study found that hand hygiene and staff cohorting were predicted to be the most effective control measures. The model predicted that for a given level of hand hygiene compliance, adding staff cohorting would lead to better control of VRE transmission. The rate at which new VRE cases were admitted to the ICU played an important role in the level of transmission of VRE in the unit.

In a study that used a stochastic model of transmission dynamics, Cooper and colleagues[116] predicted that improving hand hygiene compliance from very low levels to 20% or 40% significantly reduced transmission, but that improving compliance to levels above 40% would have relatively little impact on the prevalence of *S. aureus*. Grundmann and colleagues[115] conducted an investigation that included cultures of patients at the time of ICU admission and twice weekly, observations of the frequency of contact between HCWs and patients, cultures of HCWs' hands, and molecular typing of MRSA isolates. A stochastic model predicted that a 12% improvement in adherence to hand hygiene policies or in cohorting levels might have compensated for staff shortages and prevented transmission during periods of overcrowding and high workloads.

While the above studies have provided new insights into the relative contribution of various infection control measures, all have been based on assumptions that may not be valid in all situations. For example, most studies assumed that transmission of pathogens occurred only via the hands of HCWs and that contaminated environmental surfaces played no role in transmission. The latter may not be true for some pathogens that can remain viable in the inanimate environment for prolonged periods. Also, most if not all mathematical models were based on the assumption that when HCWs did clean their hands,100% of the pathogen of interest was eliminated from the hands, which is unlikely to be true in many instances[116]. Importantly, all the mathematical models described above predicted that improvements in hand hygiene compliance could reduce pathogen transmission. However, the models did not agree on the level of hand hygiene compliance that is necessary to halt transmission of health care-associated pathogens. In reality, the level may not be the same for all pathogens and in all clinical situations. Further use of mathematical models of transmission of health care-associated pathogens is warranted. Potential benefits of such studies include evaluating the benefits of various infection control interventions, and understanding the impact of random variations in the incidence and prevalence of various pathogens[111].

## 7. RELATIONSHIP BETWEEN HAND HYGIENE AND THE ACQUISITION OF HEALTH CARE-ASSOCIATED PATHOGENS

Despite a paucity of appropriate randomized, controlled trials, there is substantial evidence that hand antisepsis reduces the incidence of HCAI[7,117,118]. In what would be considered an intervention trial using historical controls, Semmelweis[117] demonstrated in 1847 that the mortality rate among mothers delivering at the First Obstetrics Clinic at the General Hospital of Vienna was significantly lower when hospital staff cleaned their hands with an antiseptic agent than when they washed their hands with plain soap and water.

In the 1960s, a prospective, controlled trial sponsored by the United States National Institutes of Health and the Office of the Surgeon General compared the impact of no handwashing versus antiseptic handwashing on the acquisition of *S. aureus* among infants in a hospital nursery[6]. The investigators demonstrated that infants cared for by nurses who did not wash their hands after handling an index infant colonized with *S. aureus* acquired the organism significantly more often, and more rapidly, than did infants cared for by nurses who used hexachlorophene to clean their hands between infant contacts. This trial provided compelling evidence that when compared with no handwashing, hand cleansing with an antiseptic agent between patient contacts reduces transmission of health care-associated pathogens.

Several investigators have found that health care-associated acquisition of MRSA was reduced when the antimicrobial soap used for hygienic hand antisepsis was changed[119,120]. In one of these studies, endemic MRSA in a neonatal ICU was eliminated seven months after introduction of a new hand antiseptic agent (1% triclosan) while continuing all other infection control measures, including weekly active surveillance cultures[119]. Another study reported an MRSA outbreak involving 22 infants in a neonatal unit[120]. Despite intensive efforts, the outbreak could not be controlled until a new antiseptic agent was added (0.3% triclosan) while continuing all previous control measures, which included the use of gloves and gowns, cohorting and surveillance cultures. Casewell & Phillips[67] reported that increased handwashing frequency among hospital staff was associated with a decrease in transmission of *Klebsiella* spp. among patients, but they did not quantify the level of handwashing among HCWs.

In addition to these studies, outbreak investigations have suggested an association between infection and understaffing or overcrowding that was consistently linked with poor adherence to hand hygiene. During an outbreak, Fridkin[121] investigated risk factors for central venous catheter-associated bloodstream infections. After adjustment for confounding factors, the patient-to-nurse ratio remained an independent risk factor for bloodstream infection, suggesting that nursing staff reduction below a critical threshold may have contributed to this outbreak by jeopardizing adequate catheter care. Vicca[122] demonstrated the relationship between understaffing and the spread of MRSA in intensive care. These findings show indirectly that an imbalance between workload and staffing leads to relaxed attention to basic control measures, such as hand hygiene, and spread of microorganisms. Harbarth and colleagues[123] investigated an outbreak of *Enterobacter cloacae* in a neonatal ICU and showed that the daily number of hospitalized children was above the maximal capacity of the unit, resulting in an available space per child well below current recommendations. In parallel, the number of staff on duty was significantly below that required by the workload, and this also resulted in relaxed attention to basic infection control measures. Adherence to hand hygiene practices before device contact was only 25% during the workload peak, but increased to 70% after the end of the understaffing and overcrowding period. Continuous surveillance showed that being hospitalized during this period carried a fourfold increased risk of acquiring an HCAI. This study not only shows the association between workload and infections, but also highlights the intermediate step – poor adherence to hand hygiene practices. Robert and colleagues suggested that suboptimal nurse staffing composition for the three days before bloodstream infection (ie, lower regular-nurse-to-patient and higher pool-nurse-to-patient ratios) was an independent risk factor for infection[124].

Overcrowding and understaffing are commonly observed in health-care settings and have been associated throughout the world, particularly in developing countries where limited personnel and facility resources contribute to the perpetuation of this problem[121-127]. Overcrowding and understaffing were documented in the largest nosocomial outbreak

attributable to *Salmonella* spp. ever reported[128]; in this outbreak in Brazil, there was a clear relationship between understaffing and the quality of health care, including hand hygiene.

## 8. METHODS TO EVALUATE THE ANTIMICROBIAL EFFICACY OF HANDRUB AND HANDWASH AGENTS AND FORMULATIONS FOR SURGICAL HAND PREPARATION

With the exception of non-medicated soaps, every new formulation for hand antisepsis should be tested for its antimicrobial efficacy to demonstrate that: (i) it has superior efficacy over normal soap; or (ii) it meets an agreed performance standard. The formulation with all its ingredients should be evaluated to ensure that humectants or rehydrating chemicals added to ensure better skin tolerance do not in any way compromise its antimicrobial action.

Many methods are currently available for this purpose, but some are more useful and relevant than others. For example, determination of the minimum inhibitory concentration (MIC) of such formulations against bacteria has no direct bearing on the "killing effect" expected of such products in the field. Conditions in suspension, and *in vitro*[129] or ex vivo[130] testing do not reflect those on human skin. Even simulated-use tests with volunteers are considered by some as "too controlled", prompting testing under in praxi or field conditions. Such field-testing is difficult to control for extraneous influences. Besides, and quite importantly, the findings of field tests do not tell us much about a given formulation's ability to cause a measurable reduction in hand-transmitted nosocomial infections. While the ultimate approach in this context would be clinical trials, they are generally quite cumbersome and expensive. For instance, power analysis reveals that for demonstrating a reduction in hand-transmitted infections from 2% to 1% by changing to a presumably better hand antiseptic agent, almost 2500 patients would be required in each of two experimental arms at the statistical pre-settings of $\alpha$ (unidirectional) = 0.05 and a power of 1-ß = 0.9[131]. This is why the number of such trials remains quite limited[132-134]. To achieve a reduction from 7% to 5% would require 3100 patients per arm (courtesy of Michael Kundi). This reinforces the utility of well-controlled, *in vivo* laboratory-based tests to give enough information economically to assess a given formulation's potential benefits under field use.

### 8.1 CURRENT METHODS

Direct comparisons of the results of *in vivo* efficacy testing of handwashing, antiseptic handwash, antiseptic handrub and surgical hand antisepsis are not possible because of wide variations in test protocols. Such variations include: (i) whether hands are purposely contaminated with bacteria before use of the test agent; (ii) the method used to contaminate fingers or hands; (iii) the volume of hand hygiene product applied; (iv) the time the product is in contact with the skin; and (v) the method used to recover bacteria from the skin after the test formulation has been used.

Despite the differences noted above, most testing falls into one of two major categories. One category is designed to evaluate handwash or handrub agents to eliminate transient pathogens from HCWs' hands. In most of such studies, the volunteer's hands are artificially contaminated with the test organism before applying the test formulation. In the second category, which applies to pre-surgical scrubs, the objective is to evaluate the test formulation

for its ability to reduce the release of naturally present resident flora from the hands. The basic experimental design of these methods is summarized below.

In Europe, the most commonly used methods to test hand antiseptics are those of the European Committee for Standardization (CEN). In the USA, such formulations are regulated by the Food and Drug Administration (FDA)[135], which refers to the standards of the American Society for Testing and Materials (ASTM) in its Tentative Final Monograph (TFM).

It should be noted that the current group of experts recommend using the term efficacy to refer to the (possible) effect of the application of a hand hygiene formulation when tested in laboratory or *in vivo* situations. In contrast, they would recommend using the term effectiveness to refer to the clinical conditions under which hand hygiene products have been tested, such as field trials, where the impact of a hand hygiene formulation is monitored on the rates of cross-transmission of infection or resistance[136].

### 8.1.1 METHODS TO TEST ACTIVITY OF HYGIENIC HANDWASH AND HANDRUB AGENTS (SEE TABLE I.8.1.)

The following *in vivo* methods use artificial contamination to test the capacity of a formulation to reduce the level of transient microflora on the hands without regard to the resident flora. The formulations to be tested are hand antiseptic agents intended for use by HCWs except in the surgical area.

#### CEN STANDARDS

In Europe, the most common methods for testing hygienic hand antiseptic agents are EN 1499[137] and EN 1500[138]. Briefly, these methods require 12–15 volunteers and a culture of *E. coli*. Volunteers are assigned randomly to two groups where one applies the test formulation and the other a standardized reference solution. In a consecutive run, the two groups reverse roles (cross-over design).

If an antiseptic soap has been tested according to EN 1499[137], the mean $\log_{10}$ reduction by the product must be significantly higher than that obtained with the control (soft soap). For handrubs (EN 1500), the mean acceptable reduction with a test formulation shall not be significantly lower than that with the reference alcohol-based rub (isopropyl alcohol or isopropanol 60% volume).

#### ASTM STANDARDS

ASTM E-1174[139]

Currently, handwash or handrub agents are evaluated using this method in the USA. The TFM criteria for efficacy are a 2-$\log_{10}$ reduction of the indicator organism on each hand within 5 minutes after the first use, and a 3-$\log_{10}$ reduction of the indicator organism on each hand within 5 minutes after the tenth use[135].

The performance criteria in EN 1500 and in the TFM for alcohol-based handrubs are not the same[1,135,138]. Therefore, a formulation may pass the TFM criterion but may not meet that of EN 1500 or vice versa[140]. It should be emphasized here that the level of reduction in microbial counts needed to produce a meaningful drop in the hand-borne spread of nosocomial pathogens is not yet known[1,13].

ASTM E-1838 (fingerpad method for viruses)[141]

The fingerpad method can be applied with equal ease to handwash or handrub agents. When testing handwash agents, it can also measure reductions in virus infectivity after exposure to the test formulation alone, after post-treatment water rinsing and post-rinse drying of hands. This method also presents a lower risk to volunteers because it entails con-

tamination of smaller and well-defined areas on the skin in contrast to using whole hands. The method can be applied to traditional as well as "new" viruses such as caliciviruses[142].

ASTM E-2276 (fingerpad method for bacteria)[143]

This method is for testing handwash or handrub against bacteria. It is similar in design and application to the method (E-1838)[141] described above for working with viruses.

ASTM E-2011 (whole hand method for viruses)[144]

In this method, the entire surface of both hands is contaminated with the test virus and the test handwash or handrub formulation is rubbed on them. The surface of both hands is eluted and the eluates assayed for viable virus.

### 8.1.2 SURGICAL HAND PREPARATION (SEE TABLE I.8.1)

In contrast to hygienic handwash or handrub, surgical hand preparation is directed against the resident hand flora. No artificial contamination of hands is used in any existing methods.

CEN prEN 12791 (surgical hand preparation)[145]

This European prenorm is comparable with that described in EN 1500 except that the bactericidal effect of a product is tested: (i) on clean, not artificially contaminated hands; (ii) with 18–20 volunteers; (iii) using the split-hands model by Michaud, McGrath & Goss[146] to assess the immediate effect on one hand and a 3-hour effect (to detect a possible sustained effect) on the other, meanwhile gloved hand; (iv) in addition, a cross-over design is used; but contrary to hygienic hand antisepsis, the two experimental runs are separated by one week in order to enable regrowth of the resident flora; (v) the reference antisepsis procedure uses as many as 3-ml portions of n-propanol 60% (*V/V*) as are necessary to keep hands wet for 3 minutes; (vi) the product is used according to manufacturer's instructions with a maximum duration of 5 minutes; (vii) the requirements are that the immediate and 3-hour effects of a product must not be significantly inferior to those of the reference hand antisepsis; and (viii) if there is a claim for sustained activity, the product must demonstrate a significantly lower bacterial release than the reference at 3 hours.

ASTM E-1115 (surgical hand scrub)[147]

This test method is designed to measure the reduction of microbial flora on the skin. It is intended for determining immediate and persistent microbial reductions, after single or repetitive treatments, or both. It may also be used to measure cumulative antimicrobial activity after repetitive treatments.

In the USA, this method is required to assess the activity of surgical scrubs[135]. The TFM requires that formulations: (i) reduce the number of bacteria 1-$\log_{10}$ on each hand within 1 minute of product use and that the bacterial cell count on each hand does not subsequently exceed baseline within 6 hours on day 1; (ii) produce a 2-$\log_{10}$ reduction in microbial flora on each hand within 1 minute of product use by the end of the second day of enumeration; and (iii) accomplish a 3-$\log_{10}$ reduction of microbial flora on each hand within 1 minute of product use by the end of the fifth day when compared to the established baseline[135].

## 8.2 SHORTCOMINGS OF TRADITIONAL TEST METHODS

### 8.2.1 HYGIENIC HANDWASH AND HANDRUB; HCW HANDWASH AND HANDRUB

A major obstacle for testing hand hygiene products to meet regulatory requirements is the cost, which can be prohibitive even for large multinational companies. Cases in point are the extensive and varied evaluations as specified in the TFM[135]. The TFM requires *in vitro* determination of the antimicrobial spectrum of the active agent, of the vehicle and of the final formulation by assessing the MIC with approximately 1000 microbial strains, half of which must be freshly recovered clinical strains. Furthermore, time-kill curves have to be established and studies on the development of resistance have to be done. *In vivo*, at least 54 volunteers are necessary in each arm to test the product and a positive control, hence a minimum of 2 x 54 subjects. The immense expenditure would, however, be much smaller if the same subjects were used to test both formulations concurrently in two runs in a cross-over fashion, as described in EN 1499 and EN 1500[137,138]. The results could then be intra-individually compared, thus allowing a considerable reduction in sample size at the same statistical power.

Another shortcoming of existing test methods is the duration of hand treatments which require volunteers to treat their hands with the hand hygiene product or a positive control for 30 seconds[135] or 1 minute[137] despite the fact that the average duration of hand cleansing by HCWs has been observed to be less than 15 seconds in most studies[70,148-153]. A few investigators have used 15-second handwashing or hygienic hand antisepsis protocols[93,154-157]. Therefore, almost no data exist regarding the efficacy of antimicrobial soaps under conditions in which they are actually used. Similarly, some accepted methods for evaluating waterless antiseptic agents for use as antiseptic handrubs such as the reference hand antisepsis in EN 1500[138], require that 3 ml of alcohol be rubbed into the hands for 30 seconds, followed by a repeat application of the same type. Again, this type of protocol does not reflect actual usage patterns among HCWs. However, it could be argued that equivalence in the efficacy of a test product with the reference is easier to prove with longer skin contact because, if a difference in the efficacy exists, it is greater after longer application times and therefore easier to detect. Or, inversely, to prove a difference between two treatments of very short duration, such as 15 seconds, under valid statistical settings is difficult and requires large sample sizes, i.e. numbers of volunteers. Therefore, a reference treatment which has usually been chosen for its comparatively high efficacy may include longer skin contact than is usual in real practice if the aim is to demonstrate the equivalence of a test product with economically justifiable sample sizes.

A further shortcoming relates to the requirements for efficacy. The TFM[135] for instance, requires a hand hygiene product for an HCW handwash *in vivo* to reduce the number of the indicator organisms on each hand by 2 log within 5 minutes after the first wash and by 3 log after the tenth wash. This requirement is inappropriate to the needs of working in a health-care setting for two reasons. First, to allow a preparation to reduce the bacterial release by only 2 log within a maximum time span of 5 minutes seems an unrealistically low requirement, as even with unmedicated soap and water a reduction of 3 log is achievable within 1 minute[1,158]. Furthermore, 5 minutes is much too long to wait between two patients. Second, the necessity for residual action of a hand disinfectant in the non-surgical area has been challenged[159-161]. The current group of experts does not believe that for the aforementioned purpose a residual antimicrobial activity is necessary in the health-care setting. Rather, a fast and strong immediate effect against a broad spectrum of transient flora is required to render hands safe, not only in a very short time, but also already after the first application of the

formulation. Therefore, the requirement that a product must demonstrate a stronger activity after the tenth wash than after the first seems illogical.

The statistical analysis as suggested by EN 1500 is not optimal because in the case of an inferior efficacy of the product, the difference from the mean reduction achieved by the reference is tested for significance as for a comparative trial rather than for an equivalence trial which would be more appropriate.

### 8.2.2 SURGICAL HANDWASH AND HANDRUB; SURGICAL HAND SCRUB; SURGICAL HAND PREPARATION

As with hygienic hand antisepsis, a major shortcoming for testing surgical scrubs is the resource expenditure associated with the use of the TFM model. The required *in vitro* tests are the same as described under 8.2.1 (see also Table I.8.1). According to TFM, the *in vivo* tests require a large number of volunteers corresponding to:

$$n \leq 2\ s2\ [za/2 + zb]2 / D2$$

where s2 is an estimate of the variance (e.g. 1.01), $z_{a/2}$ = level of significance (e.g. for p = 5% → 1.96), $z_b$ = power of the test (e.g. for 80% → 0.82), and D = the clinical difference of significance to be ruled out (e.g. 20% of the active control's mean reduction from baseline at a specific time)[135]. For the above example of estimates and with the statistical settings therein, a sample size of 64 subjects per arm of a trial is required if, for example, the comparative active control hand scrub produces a mean reduction at a specific time of 2.5 log-steps and the result of the test product is to be within 20% of this (D = 0.5)[135]. Hence, at least a total of approximately 130 subjects is necessary to test a product together with an active control in the suggested parallel arm design. For some products, this number will even have to be multiplied for concomitant testing of the vehicle and perhaps of a placebo to demonstrate efficacy[135]. This would add up to a total of 520 or even more subjects, in the event that the variance is larger than that mentioned above[135]. As mentioned with the test model for HCW handwashes (see Part I, Section 8.2.1) and described in prEN 12791[145], this enormous number of volunteers can be much reduced if the tests are not made with different populations of subjects for each arm, but if the same volunteers participate in each arm, being randomly allocated to the various components of a Latin square design, the experiments of which can be carried out at weekly intervals. The results are then treated as related samples with intra-individual comparison. Additionally, it is not clear why the vehicle or a placebo needs to be tested in parallel, if a product is shown to be equivalent in its antimicrobial efficacy to an active control scrub. For the patient and for the surgeon, it is of no interest whether the product is sufficiently efficacious because of the active ingredient only or, perhaps, additionally by a synergistic or even antimicrobial effect of the vehicle. In any case, it is to be hoped that a test product, the efficacy of which can be shown to be equivalent to that of an active control scrub, is superior to a placebo. If not, the active control has been badly chosen.

In contrast to the requirement of prEN 12791 where a sustained (or persistent) effect of the surgical scrub is optional, the TFM model requires a product to possess this feature (see above). Whether a sustained (or persistent) effect is necessary or not is a matter for discussion. It is, however, difficult to understand why the efficacy of a scrub is required to increase from the first to the fifth day of permanent use. Ethical considerations would suggest that the first patient on a Monday, when the required immediate bacterial reduction from baseline is only 1 log, should be treated under the same safety precautions as patients operated on the following Friday when, according to the TFM requirement, the log reduction has to be 3.0. Indeed, an immediate effect comparable to the latter reduction is achievable at the first surgical hand scrub after a period of non-use with handrubs containing high concentra-

tions of short-chain aliphatic alcohols such as ethanol, iso-propanol and n-propanol[1]. With their strong antibacterial efficacy, the importance of a sustained effect is questionable, as regrowth of the skin flora takes several hours even without the explicitly sustained effect of the alcohols.

With regard to the statistical analysis of prEN 12791, the currently suggested model of a comparative trial is no longer up to date. It should be exchanged for an equivalence trial. The latest CDC/HICPAC guideline for hand hygiene in health-care settings[7] considers it as a shortcoming that *in vivo* laboratory test models use volunteers as surrogates for HCWs, as their hand flora may not reflect the microbial flora on the hands of caregivers working in health-care settings. This argument is only valid for testing surgical scrubs, however, because for evaluating hygienic handwash or rub preparations, protocols include artificial hand contamination. Furthermore, the antimicrobial spectrum of a product should be known from the results of preceding *in vitro* tests.

## 8.3 NEW METHODS FOR THE FUTURE

Further studies will be needed to identify necessary amendments to the existing test methods and to evaluate amended protocols, to devise standardized protocols for obtaining more realistic views of microbial colonization, and to better estimate the risk of bacterial transfer and cross-transmission[28].

To summarize, the following amendments to traditional test methods are needed:

- The few existing protocols should be adapted so that they lead to comparable conclusions about the efficacy of hand hygiene products.
- Protocols should be updated so that they can be performed with economically justifiable expenditure.
- To be plausible, results of *in vivo* test models should show that they are realistic under practical conditions such as the duration of application, the choice of test organism, or the use of volunteers.
- Requirements for efficacy should not be formulated with a view to the efficacy of products available on the market, but in consideration of objectively identified needs.
- *In vivo* studies in the laboratory should be organized like clinical studies, i.e. as equivalence rather than as comparative studies.
- Protocols for controlled field trials should help to ensure that hand hygiene products are evaluated under more plausible, if not more realistic, conditions.

There is no doubt that results from well-controlled clinical studies are urgently needed to generate epidemiological data on the influence of various groups of hand hygiene products on the frequency of hand-transmitted hospital infections and antimicrobial-resistant pathogen cross-transmission, i.e. proof of clinical effectiveness.

# 9. REVIEW OF PREPARATIONS USED FOR HAND HYGIENE

## 9.1 WATER

Routine handwashing is the removal of dirt, organic material and transient microorganisms. The purpose of handwashing for routine patient care is to remove microbial contamination acquired by recent contact with infected or colonized patients or with environmental sources and to remove organic matter from the hands.

Water is a good solvent for a large number of substances and is often called the universal solvent. It is stable, has a high boiling point and has very high surface tension, an important characteristic for cleansing soiled hands. Because of its properties, water cannot directly remove soils such as fats, oils and proteins which are common components of organic soil. For efficacious cleansing of soiled hands, it is essential that soils dissolve or are suspended in water to allow them to be flushed away. Soaps and detergents are able to dissolve fats and oils: they loosen them and disperse them into the water. Soaps also ensure that soils are kept in suspension so that they can be flushed away with the water. Thus water alone is not suitable for cleaning soiled hands; soap or detergent is required to be applied along with water. This is followed by flushing with water. During handwashing, friction and thorough rinsing are the most important factors for clean hands. Use of medicated or plain soap seems to have roughly the same effect in preventing diarrhoeal disease, upper respiratory tract infection or impetigo among children in the community setting [4,5]. The cleansing effect is probably the result of the friction while spreading the product over the hands and rinsing afterwards.

### 9.1.1 ASSOCIATION OF WATER CONTAMINATION WITH INFECTIONS

Drinking-water may be contaminated by any kind of microorganism: bacteria, viruses, helminths and pathogenic protozoa. Table I.9.1 lists microorganisms that have been documented as causing or are suspected of causing outbreaks of waterborne diseases, and indicates their health significance, their persistence in water supplies, and relative infectivity[162].

### 9.1.2 WATER CONTAMINATION AND HEALTH CARE-ASSOCIATED INFECTIONS

Contamination of a healthcare institution water supply can occur, and there is a body of evidence that links nosocomial infections to hospital water or point-of-use water. Attention should be paid to guaranteeing that sewage is segregated from the water supply of the hospital. By a Medline search, investigators identified 43 outbreaks associated with health care where organisms were waterborne, of which 29 had epidemiological and molecular evidence linking the outbreak to the hospital water system[163]. Sources of the organisms were hospital water storage tanks, tap water and showers[164-166]. The cause of poor water quality is the build-up of biofilm, corrosion of distribution systems and tanks or water stagnation. Biofilms are microbial growths adhering to surfaces through the slime they secrete; they can build up on any surface exposed to water and bacteria. Among organisms identified in hospital water and associated with nosocomial infections were *Legionella* spp., *P. aeruginosa*[167,168], *Stenotrophomonas maltophilia*[169], *Mycobacterium avium*[170], *M. fortuitum*[171], *M. chelonae*[172], *Fusarium* spp.[173] and *Aspergillus fumigatus*[174]. One of the routes of transmission of these organisms from water to patient could be through HCWs' hands if contaminated water is used to wash them.

### 9.1.3 WATER QUALITY

The physical, chemical and bacteriological characteristics of water used in health-care institutions must meet local regulations[162]. The institution is responsible for the quality of water once it enters the building. In Europe, requirements for water quality in public buildings are regulated by the European Council Directive 98/83/EC of 3 November 1998 "Water for human consumption". In France, national guidelines for health-care settings have recently proposed microbiological standards for water quality (Table I.9.2).

If the water is non-drinkable or suspected of being contaminated, steps can be taken to treat it for medical use through physical or chemical treatments[162]. These include a filtration process to remove particles including protozoa and a disinfection stage to reduce the number of pathogens. Disinfectants include chlorine, monochloramine, chlorine dioxide, ozone and ultraviolet irradiation[162]. Chlorine is the most practical disinfectant to use. Ozone has high installation costs, and monochloramine acts more slowly against bacteria, protozoa and viruses than does chlorine. It is usual to apply a residual disinfectant following primary treatment: first, to prevent or limit regrowth of microorganisms in the distribution system; and second, to inactivate any microorganisms that may enter the system through contamination. Materials that come into contact with drinking-water are known to stimulate microbial growth. Microorganisms may enter the distribution system through cross-connections, breaks in the pipes or faulty backflow prevention devices. However, conventional disinfectant residuals are ineffective against massive contamination[175]. Ultraviolet radiation is one potential alternative to chlorine for disinfecting small water systems. It is suitable for the disinfection of water which is free of suspended matter, turbidity and colour. However, the disadvantage of this method is that it does not leave a residue[176].

Many developing countries do not have drinkable water at the health-care facility for handwashing. Even if water used for handwashing should ideally be drinkable, it is important to highlight that there is no evidence to date that washing hands with non-potable water leads to higher hand contamination. A study was conducted in a rural area of Bangladesh where, for reasons of limited resources, supplying safer water and improving sanitation were not possible[177]. In this community setting, education and promotion of handwashing with plain soap and water significantly reduced the spread of diarrhoeal diseases across all age groups[177]. In Pakistan, hand hygiene promotion in the community setting also reduced the infectious disease burden[4].

Nevertheless, if soap applied on the hands has to be rinsed by flushing with water which may be contaminated, antibacterial soap alone may not be adequate. Steps may be taken to reduce the risk of infection caused by washing hands with non-drinkable water. These include use of antiseptic handrubs, treating the water by filtration or disinfection, and restricting the use of tap water in high-risk populations[178]. In areas of the world where water supply is intermittent, water contamination is a greater problem than in areas where supply is sufficient through piped distribution systems. In these situations, water is usually stored in containers at the health-care facility. Improperly stored and dispensed water may become contaminated by a number of human pathogens, including enteric bacteria, staphylococci, yeasts and parasites, in addition to free-living aquatic organisms. Practical methods to ensure microbiological safety of water supplied in containers include point-of-use filtration and disinfection[179].

In addition, water storage containers should be emptied and cleaned frequently and inverted to dry. The frequency of cleaning will depend on the size of the container, but no specific recommendations are available to date. Direct or indirect hand contact with the stored water should be avoided at all times, and containers should always be covered.

Ideally, narrow-topped containers should be used and dispensing from the container should be done through a tap/faucet that can be turned on and off.

### 9.1.4 WATER TEMPERATURE

Does water temperature affect handwashing? A report to determine the impact of different temperatures ranging from 5°C (40°F) to 50°C (120°F) on removal of different types of bacteria showed that temperature had no effect in reducing transient or residual flora 180. Volunteer subjects were tested for resident and transient flora, and washed their hands at different temperatures levels using a specific amount of liquid plain soap. They lathered their hands for 15 seconds and rinsed for 10 seconds. Neither the use of medicated soap nor the water temperature had any significant effect on bacteria removal. Apparently, contact time and friction are more important aspects than temperature. Even if warm water helps in dissolving dirt and suspension of oily residues, a quick wash with medicated soap is less effective than a 30-second wash with cool water and no soap[181].

Since the reported data are not included in peer-reviewed publications, the consequent considerations are based on limited evidence. Water temperature does not, however, seem to be a critical issue for handwashing.

### 9.1.5 HAND DRYING

Hand drying is an essential step in hand cleansing and should be done in such a way that hand recontamination does not occur. Wet hands, as a wet environment compared with a dry environment, provide better conditions for the transmission of microorganisms[31]. Careful hand drying is a critical factor determining the level of bacterial transfer associated with touch-contact after hand cleansing. Recognition of this could make a significant contribution towards improving hand hygiene practices in clinical and public health sectors[31].

Common hand drying methods include paper towels, cloth towels and hot air dryers. One report compared four methods of hand drying: cloth towels from a roller; paper towels left on a sink; hot air dryer; and letting hands dry by evaporation[182]; no significant difference in the efficacy of the methods was noted in this study. However, reusing or sharing towels should be avoided because of the risk of cross-infection[183]. In a comparison of methods to test efficiency of hand drying for removing bacteria from washed hands, warm air drying performed worse than drying with paper towels[184]. Furthermore, air dryers may be less practical because of longer time needed to achieve dry hands[184], with a possible negative impact on hand hygiene compliance, and because of the aerosolization of waterborne pathogens[185]. Ideally, drying of hands should be done by using individual paper towels. Nevertheless, the bacteria counts on palm and fingers after handwashing may not significantly differ after drying with a paper towel[184].

When clean or disposable towels are used, it is important to pat the skin, rather than rub it, to avoid cracking. Skin excoriation may lead to bacteria colonizing the skin and possible spread of bloodborne viruses as well as other microorganisms[35]. Sore hands may also lead to decreased compliance with hand hygiene practices (see also Part I, Section 13).

***Case study: experience of Egypt***

*The national infection control programme started in Egypt in 2000. One of the important initiatives was promoting hand hygiene in hospitals. Routine handwashing was encouraged and required the availability of critical supplies such as soap and hand drying materials. The high consumption of hand drying materials stimulated hospital infection control teams to search for cost-effective alternatives. Many hospitals started by purchasing cheap disposable paper towels. The low quality of paper discouraged HCWs from using it, as it lacked the required thickness and strength to achieve effective hand drying. Another option was the use of single-use cloth towels where old hospital linen was divided into small-sized towels and reprocessed after single use. Although this was considered as cost-saving from the perspective of the hospital administration, not all hospital staff liked this option. Some HCWs refused to dry hands with previously used linen, even after reprocessing. A better option identified was the purchasing of cheap cloth material (in metres) that was cut into small-sized towels and used the same way as the old linen. The use of single-use cloth towels was welcomed by almost all hospitals; the price of the material was acceptable for the hospital administration and there were plenty of towels for HCWs to use in all required opportunities.*

### 9.2 PLAIN (NON-ANTIMICROBIAL) SOAP

Soaps are detergent-based products that contain esterified fatty acids and sodium or potassium hydroxide. They are available in various forms including bar soap, tissue, leaf and liquid preparations. Their cleansing activity can be attributed to their detergent properties, which result in removal of lipid and adhering dirt, soil and various organic substances from the hands. Plain soaps have minimal, if any, antimicrobial activity. However, handwashing with plain soap can remove loosely adherent transient flora. For example, handwashing with plain soap and water for 15 seconds reduces bacterial counts on the skin by 0.6–1.1 $\log_{10}$, whereas washing for 30 seconds reduces counts by 1.8–2.8 $\log_{10}$[1]. In several studies, however, handwashing with plain soap failed to remove pathogens from the hands of HCWs[44,63,186]. Handwashing with plain soap can result in a paradoxical increase in bacterial counts on the skin[155,187-189]. Since soaps may be associated with considerable skin irritation and dryness[155,188,190], adding humectants to soap preparations may reduce their propensity to cause irritation. Occasionally, plain soaps have become contaminated, which may lead to the colonization of hands of HCWs with Gram-negative bacilli[101]. Still, there is some evidence that the actual hazard of transmitting microorganisms through handwashing with previously used soap bars is negligible[191,192].

## 9.3 ALCOHOLS

Most alcohol-based hand antiseptics contain either ethanol, isopropanol or n-propanol, or a combination of two of these products. Concentrations are given as either percentage of volume (= ml/100 ml), abbreviated % *V/V*; percentage of weight (= g/100 g), abbr. % m/m; or percentage of weight/volume (= g/100 ml), abbr. % m/V. Studies of alcohols have evaluated either individual alcohols in varying concentrations (a majority of studies), combinations of two alcohols, or alcohol solutions containing small amounts of hexachlorophene, quaternary ammonium compounds, povidone-iodine, triclosan or chlorhexidine gluconate[82,156,193-212].

The antimicrobial activity of alcohols results from their ability to denature proteins[213]. Alcohol solutions containing 60–80% alcohol are most effective, with higher concentrations being less potent[214,215]. This paradox results from the fact that proteins are not denatured

easily in the absence of water[213]. The alcohol content of solutions may be expressed as a percentage by weight (m/m), which is not affected by temperature or other variables, or as a percentage by volume (*V/V*), which may be affected by temperature, specific gravity and reaction concentration[216]. For example, 70% alcohol by weight is equivalent to 76.8% by volume if prepared at 15ºC, or 80.5% if prepared at 25ºC[216]. Alcohol concentrations in antiseptic handrubs are often expressed as a percentage by volume[135].

Alcohols have excellent *in vitro* germicidal activity against Gram-positive and Gram-negative vegetative bacteria (including multidrug-resistant pathogens such as MRSA and VRE), *M. tuberculosis*, and a variety of fungi[213-215,217-222]. However, they have virtually no activity against bacterial spores or protozoan oocysts, and very poor activity against some non-enveloped (non-lipophilic) viruses. In tropical settings, the lack of activity against parasites is a matter of concern about the opportunity to promote the extensive use of alcohol-based handrubs, instead of handwashing, which may at least guarantee a mechanical removal effect.

Some enveloped (lipophilic) viruses such as herpes simplex virus, human immunodeficiency virus (HIV), influenza virus, RSV and vaccinia virus are susceptible to alcohols when tested *in vitro* (Table I.9.3)[213,223,224]. For ethical reasons, *in vivo* tests have not been conducted with HIV. Other enveloped viruses that are somewhat less susceptible, but are killed by 60–70% alcohol, include hepatitis B virus and probably hepatitis C virus[225]. In a porcine tissue carrier model used to study antiseptic activity, 70% ethanol and 70% isopropanol were found to reduce titres of an enveloped bacteriophage more effectively than an antimicrobial soap containing 4% chlorhexidine gluconate[129].

Numerous studies have documented the *in vivo* antimicrobial activity of alcohols. Early quantitative studies of the effects of antiseptic handrubs established that alcohols effectively reduce bacterial counts on hands[20,214,218,226]. Typically, log reductions of the release of test bacteria from artificially contaminated hands average 3.5 $\log_{10}$ after a 30-second application, and 4.0–5.0 $\log_{10}$ after a 1-minute application[1]. In 1994, the FDA TFM classified ethanol 60–95% as a generally safe and effective active agent for use in antiseptic hand hygiene or HCW handwash products[135]. Although the TFM considered that there were insufficient data to classify isopropanol 70–91.3% as effective, 60% isopropanol has subsequently been adopted in Europe as the reference standard against which alcohol-based handrub products are compared[138]. Alcohols are rapidly germicidal when applied to the skin, but have no appreciable persistent (residual) activity. However, re-growth of bacteria on the skin occurs slowly after use of alcohol-based hand antiseptics, presumably because of the sub-lethal effect alcohols have on some of the skin bacteria[227,228]. Addition of chlorhexidine, quaternary ammonium compounds, octenidine or triclosan to alcohol-based formulations can result in persistent activity[1]. A synergistic combination of a humectant (octoxyglycerine) and preservatives has resulted in prolonged activity against transient pathogens[229].

Alcohols, when used in concentrations present in alcohol-based handrubs, also have *in vivo* activity against a number of non-enveloped viruses (Table I.9.3). For example, *in vivo* studies using a fingerpad model have demonstrated that 70% isopropanol and 70% ethanol were more effective than medicated soap or non-medicated soap in reducing rotavirus titres on finger-pads[183,230]. A more recent study using the same test methods evaluated a commercially available product containing 60% ethanol, and found that the product reduced the infectivity titres of three non-enveloped viruses (rotavirus, adenovirus and rhinovirus) by 3 to 4 logs[231]. Other non-enveloped viruses such as hepatitis A and enteroviruses (e.g. poliovirus) may require 70–80% alcohol to be reliably inactivated[232,233]. However, it is worth noting that both 70% ethanol and a 62% ethanol foam product with humectants reduced hepatitis A virus titres on whole hands or fingertips to a greater degree than non-medicated soap,

and both reduced viral counts on hands to about the same extent as antimicrobial soap containing 4% chlorhexidine gluconate[234]. The same study found that both 70% ethanol and the 62% ethanol foam product demonstrated greater virucidal activity against poliovirus than either non-antimicrobial soap or a 4% chlorhexidine gluconate-containing soap[234]. However, depending on the alcohol concentration, time and viral variant, alcohol may not be effective against hepatitis A and other non-lipophilic viruses. Schurmann concluded that the inactivation of naked (non-enveloped) viruses is influenced by temperature, the ratio of disinfectant to virus volume, and protein load[235]. Various 70% alcohol solutions (ethanol, propan-1-ol, propan-2-ol) were tested against a surrogate of norovirus and ethanol with 30-minute exposure and demonstrated virucidal activity superior to the others[236]. In a recent experimental study, ethyl alcohol-based products showed significant reductions of the tested surrogate for a non-enveloped human virus; however, activity was not superior to non-antimicrobial or tap water controls[237]. In general, ethanol has greater activity against viruses than isopropanol. Further *in vitro* and *in vivo* studies of both alcohol-based formulations and antimicrobial soaps are warranted to establish the minimal level of virucidal activity that is required to interrupt direct contact transmission of viruses in health-care settings.

Alcohols are not good cleansing agents, and their use is not recommended when hands are dirty or visibly contaminated with proteinaceous materials. However, when relatively small amounts of proteinaceous material (e.g. blood) are present, ethanol and isopropanol may reduce viable bacterial counts on hands[238], but do not obviate the need for handwashing with water and soap whenever such contamination occurs[117]. A few studies have examined the ability of alcohols to prevent the transfer of health care-associated pathogens by using experimental models of pathogen transmission[30,44,109]. Ehrenkranz and colleagues[44] found that Gram-negative bacilli were transferred from a colonized patient's skin to a piece of catheter material via the hands of nurses in only 17% of experiments following antiseptic handrub with an alcohol-based hand rinse. In contrast, transfer of the organisms occurred in 92% of experiments following handwashing with plain soap and water. This experimental model suggests that when the hands of HCWs are heavily contaminated, alcohol-based handrubbing can prevent pathogen transmission more effectively than handwashing with plain soap and water.

Table I.9.4 summarizes a number of studies that have compared alcohol-based products with plain or antimicrobial soaps to determine which was more effective for standard handwashing or hand antisepsis by HCWs (for details see Part I, Section 9.13)[44,71,82,156,158,199-205,212,239-247].

The efficacy of alcohol-based hand hygiene products is affected by a number of factors, including the type of alcohol used, the concentration of alcohol, the contact time, the volume of alcohol used, and whether the hands are wet when the alcohol is applied. Small volumes (0.2–0.5 ml) of alcohol applied to the hands are not more effective than washing hands with plain soap and water[30,109]. Larson and colleagues[93] documented that 1 ml of alcohol was significantly less effective than 3 ml. The ideal volume of product to apply to the hands is not known, and may vary for different formulations. In general, however, if hands feel dry after being rubbed together for less than 10–15 seconds, it is likely that an insufficient volume of product was applied. Alcohol-impregnated towelettes contain only a small amount of alcohol and are not much more effective than washing with soap and water[30,248,249].

Alcohol-based handrubs intended for use in hospitals are available as solutions (with low viscosity), gels and foams. Few data are available regarding the relative efficacy of various formulations. One small field trial found that an ethanol gel was somewhat less effective than a comparable ethanol solution at reducing bacterial counts on the hands of HCWs 250.

Recent studies found similar results demonstrating that solutions reduced bacterial counts on the hands to a significantly greater extent than the tested gels[140,251]. Most gels showed results closer to a 1-minute simple handwash than to a 1-minute reference antisepsis[252]. New generations of gel formulations with higher antibacterial efficacy than previous editions have since been proposed[252]. Further studies are warranted to determine the relative efficacy of alcohol-based solutions and gels in reducing transmission of health care-associated pathogens. Furthermore, it is worth considering that compliance is probably of higher importance, thus if a gel with lower *in vitro* activity is more frequently used, the overall outcome is still expected to be better.

Frequent use of alcohol-based formulations for hand antisepsis tends to cause drying of the skin unless humectants or other skin conditioning agents are added to the formulations. For example, the drying effect of alcohol can be reduced or eliminated by adding 1–3% glycerol or other skin conditioning agents[154,156,193,194,199,227,239,253,254]. Moreover, in prospective trials, alcohol-based solutions or gels containing humectants caused significantly less skin irritation and dryness than the soaps or antimicrobial detergents tested[188,190,255,256]. These studies, which were conducted in clinical settings, used a variety of subjective and objective methods for assessing skin irritation and dryness. Further studies of this type are warranted to establish if products with different formulations yield similar results.

Even well-tolerated alcohol-based handrubs containing humectants may cause a transient stinging sensation at the site of any broken skin (cuts, abrasions). Alcohol-based handrub preparations with strong fragrances may be poorly tolerated by a few HCWs with respiratory allergies. Allergic contact dermatitis or contact urticaria syndrome caused by hypersensitivity to alcohol, or to various additives present in some alcohol-based handrubs, occurs rarely (see also Part I, Section 11)[257-259].

A recent systematic review of publications between 1992 and 2002 with an adequate methodological quality on the effectiveness of alcohol-based solutions for hand hygiene showed that alcohol-based handrubs remove organisms more effectively, require less time and irritate skin less often than handwashing with soap or other antiseptic agents and water[260]. The availability of bedside alcohol-based solutions increased compliance with hand hygiene among HCWs[260-263].

Alcohols are flammable, and HCWs handling alcohol-based preparations should respect safety standards (see Part I, Section 9.14). Because alcohols are volatile, containers should be designed so that evaporation is minimized and initial concentration is preserved. Contamination of alcohol-based solutions has seldom been reported. One report documented a pseudo-epidemic of infections resulting from contamination of ethyl alcohol by *Bacillus cereus* spores[264] and in-use contamination by *Bacillus* spp. has been reported[265] .

## 9.4 CHLORHEXIDINE

Chlorhexidine gluconate, a cationic bisbiguanide, was developed in the United Kingdom in the early 1950s and introduced into the USA in the 1970s[13,266]. Chlorhexidine base is barely soluble in water, but the digluconate form is water-soluble. The antimicrobial activity of chlorhexidine appears to be attributable to the attachment to, and subsequent disruption of cytoplasmic membranes, resulting in precipitation of cellular contents 1,13. Chlorhexidine's immediate antimicrobial activity is slower than that of alcohols. It has good activity against Gram-positive bacteria, somewhat less activity against Gram-negative bacteria and fungi, and minimal activity against mycobacteria[1,13,266]. Chlorhexidine is not sporicidal[1,266]. It has *in vitro* activity against enveloped viruses such as herpes simplex virus, HIV, cytomegalovirus, influenza and RSV, but significantly less activity against non-enveloped viruses such as rotavirus, adenovirus and enteroviruses[223,224,267]. The antimicrobial

activity of chlorhexidine is not seriously affected by the presence of organic material, including blood. Because chlorhexidine is a cationic molecule, its activity can be reduced by natural soaps, various inorganic anions, non-ionic surfactants, and hand creams containing anionic emulsifying agents[13,266,268]. Chlorhexidine gluconate has been incorporated into a number of hand hygiene preparations. Aqueous or detergent formulations containing 0.5%, 0.75% , or 1% chlorhexidine are more effective than plain soap, but are less effective than antiseptic detergent preparations containing 4% chlorhexidine gluconate[227,269]. Preparations with 2% chlorhexidine gluconate are slightly less effective than those containing 4% chlorhexidine[270].

Chlorhexidine has significant residual activity[199,207-209,211,227,241,269]. Addition of low concentrations (0.5–1%) of chlorhexidine to alcohol-based preparations results in significantly greater residual activity than alcohol alone[209,227]. When used as recommended, chlorhexidine has a good safety record[266]. Little, if any, absorption of the compound occurs through the skin. Care must be taken to avoid contact with the eyes when using preparations with 1% chlorhexidine or greater as the agent can cause conjunctivitis or serious corneal damage. Ototoxicity precludes its use in surgery involving the inner or middle ear. Direct contact with brain tissue and the meninges should be avoided. The frequency of skin irritation is concentration-dependent, with products containing 4% most likely to cause dermatitis when used frequently for antiseptic handwashing[271]. True allergic reactions to chlorhexidine gluconate are very uncommon (see also Part I, Section 11)[211,266]. Occasional outbreaks of nosocomial infections have been traced to contaminated solutions of chlorhexidine[272-275]. Resistance to chlorhexidine has also been reported[276].

## 9.5 CHLOROXYLENOL

Chloroxylenol, also known as para-chloro-meta-xylenol (PCMX), is a halogen-substituted phenolic compound that has been used widely as a preservative in cosmetics and other products and as an active agent in antimicrobial soaps. It was developed in Europe in the late 1920s and has been used in the USA since the 1950s[277].

The antimicrobial activity of chloroxylenol is apparently attributable to the inactivation of bacterial enzymes and alteration of cell walls 1. It has good *in vitro* activity against Gram-positive organisms and fair activity against Gram-negative bacteria, mycobacteria and some viruses[1,12,277]. Chloroxylenol is less active against *P. aeruginosa*, but the addition of ethylenediaminetetraacetic acid (EDTA) increases its activity against *Pseudomonas* spp. and other pathogens.

Relatively few articles dealing with the efficacy of chloroxylenol-containing preparations intended for use by HCWs have been published in the last 25 years, and the results of studies have sometimes been contradictory. For example, in experiments where antiseptics were applied to abdominal skin, Davies and colleagues found that chloroxylenol had the weakest immediate and residual activity of any of the agents studied[278]. However, when 30-second handwashes were performed using 0.6% chloroxylenol, 2% chlorhexidine gluconate or 0.3% triclosan, the immediate effect of chloroxylenol was similar to that of the other agents. When used 18 times/day for five days, chloroxylenol had less cumulative activity than did chlorhexidine gluconate[279]. When chloroxylenol was used as a surgical scrub, Soulsby and colleagues[280] reported that 3% chloroxylenol had immediate and residual activity comparable to 4% chlorhexidine gluconate, while two other studies found that the immediate and residual activity of chloroxylenol was inferior to both chlorhexidine gluconate and povidone-iodine[270,281]. The disparity between published studies may result in part from the various concentrations of chloroxylenol included in the preparations evaluated, and to other aspects of the formulations tested, including the presence or absence of EDTA[12,277]. Larson

concluded that chloroxylenol is not as rapidly active as chlorhexidine gluconate or iodophors, and that its residual activity is less pronounced than that observed with chlorhexidine gluconate[12,277]. In 1994, the FDA TFM tentatively classified chloroxylenol as a Category IIISE active agent (insufficient data to classify as safe and effective)[135]. Further evaluation of this agent by the FDA is ongoing.

The antimicrobial activity of chloroxylenol is minimally affected by the presence of organic matter, but is neutralized by non-ionic surfactants. Chloroxylenol is absorbed through the skin[12,277]. Chloroxylenol is generally well tolerated, and allergic reactions are relatively uncommon. Chloroxylenol is available in concentrations ranging from 0.3% to 3.75%. In-use contamination of a chloroxylenol-containing preparation has been reported[282].

## 9.6 HEXACHLOROPHENE

Hexachlorophene is a bisphenol composed of two phenolic groups and three chlorine moieties. In the 1950s and early 1960s, emulsions containing 3% hexachlorophene were widely used for hygienic handwashing, as surgical scrubs, and for routine bathing of infants in hospital nurseries. The antimicrobial activity of hexachlorophene is related to its ability to inactivate essential enzyme systems in microorganisms. Hexachlorophene is bacteriostatic, with good activity against *S. aureus*, and relatively weak activity against Gram-negative bacteria, fungi and mycobacteria[12].

Studies of hexachlorophene as a hygienic handwash or surgical scrub demonstrated only modest efficacy after a single handwash[71,239,283]. Hexachlorophene has residual activity for several hours after use and gradually reduces bacterial counts on hands after multiple uses (cumulative effect)[1,194,283,284]. In fact, with repeated use of 3% hexachlorophene preparations, the drug is absorbed through the skin. Infants bathed with hexachlorophene and caregivers regularly using a 3% hexachlorophene preparation for handwashing have blood levels of 0.1–0.6 parts per million (ppm) hexachlorophene[285]. In the early 1970s, infants bathed with hexachlorophene sometimes developed neurotoxicity (vacuolar degeneration)[286]. As a result, in 1972, the FDA warned that hexachlorophene should no longer be used routinely for bathing infants. After routine use of hexachlorophene for bathing infants in nurseries was discontinued, a number of investigators noted that the incidence of *S. aureus* infections associated with health care in hospital nurseries increased substantially[287,288]. In several instances, the frequency of infections decreased when hexachlorophene bathing of infants was reinstituted. However, current guidelines recommend against routine bathing of neonates with hexachlorophene because of its potential neurotoxic effects[289]. The agent is classified by the FDA TFM as not generally recognized as safe and effective for use as an antiseptic handwash[135]. Hexachlorophene should not be used to bathe patients with burns or extensive areas of abnormal, sensitive skin. Soaps containing 3% hexachlorophene are available by prescription only[12]. Because of its high rate of dermal absorption and subsequent toxic effects[26,290], hexachlorophene-containing products should be avoided.

Hexachlorohene has been banned worldwide because of its high rates of dermal absorption and subsequent toxic effects[26,290].

## 9.7 IODINE AND IODOPHORS

Iodine has been recognized as an effective antiseptic since the 1800s. However, because iodine often causes irritation and discolouring of skin, iodophors have largely replaced iodine as the active ingredient in antiseptics.

Iodine molecules rapidly penetrate the cell wall of microorganisms and inactivate cells by forming complexes with amino acids and unsaturated fatty acids, resulting in impaired

protein synthesis and alteration of cell membranes[291]. Iodophors are composed of elemental iodine, iodide or triiodide, and a polymer carrier (complexing agent) of high molecular weight. The amount of molecular iodine present (so-called "free" iodine), determines the level of antimicrobial activity of iodophors. "Available" iodine refers to the total amount of iodine that can be titrated with sodium thiosulfate[292]. Typical 10% povidone-iodine formulations contain 1% available iodine and yield free iodine concentrations of 1 ppm[292]. Combining iodine with various polymers increases the solubility of iodine, promotes sustained-release of iodine and reduces skin irritation. The most common polymers incorporated into iodophors are polyvinyl pyrrolidone (povidone) and ethoxylated nonionic detergents (poloxamers)[291,292]. The antimicrobial activity of iodophors also can be affected by pH, temperature, exposure time, concentration of total available iodine and the amount and type of organic and inorganic compounds present (e.g. alcohols and detergents).

Iodine and iodophors have bactericidal activity against Gram-positive, Gram-negative and some spore-forming bacteria (clostridia, *Bacillus* spp.) and are active against mycobacteria, viruses and fungi[13,291,293-296]. However, in concentrations used in antiseptics, iodophors are not usually sporicidal[297]. *In vivo* studies have demonstrated that iodophors reduce the number of viable organisms that may be recovered from HCWs' hands[206,240,243,246,298]. Povidone-iodine 5–10% has been tentatively classified by the FDA TFM as a safe and effective (Category I) active agent for use as an antiseptic handwash and HCW handwash[135]. The extent to which iodophors exhibit persistent antimicrobial activity once they have been washed off the skin is a matter of some controversy. In a study by Paulson and colleagues[270], persistent activity was noted for six hours, but several other studies demonstrated persistent activity for 30–60 minutes after washing hands with an iodophor[82,210,299]. However, in studies where bacterial counts were obtained after individuals wore gloves for 1–4 hours after washing, iodophors demonstrated poor persistent activity[1,197,208,284,300-305]. The *in vivo* antimicrobial activity of iodophors is significantly reduced in the presence of organic substances such as blood or sputum[13].

Most iodophor preparations used for hand hygiene contain 7.5–10% povidone-iodine. Formulations with lower concentrations also have good antimicrobial activity because dilution tends to increase free iodine concentrations[306]. As the amount of free iodine increases, however, the degree of skin irritation also may increase[306]. Iodophors cause less skin irritation and fewer allergic reactions than iodine, but more irritant contact dermatitis than other antiseptics commonly used for hand hygiene[155]. Occasionally, iodophor antiseptics have become contaminated with Gram-negative bacilli as a result of poor manufacturing processes and have caused outbreaks or pseudo-outbreaks of infection[292,307]. An outbreak of P. cepacia pseudobacteremia involving[52] patients in four hospitals in New York over six months was attributed to the contamination of a 10% povidone-iodine solution used as an antiseptic and disinfectant solution[307].

## 9.8 QUATERNARY AMMONIUM COMPOUNDS

Quaternary ammonium compounds are composed of a nitrogen atom linked directly to four alkyl groups, which may vary considerably in their structure and complexity[308]. Of this large group of compounds, alkyl benzalkonium chlorides have been the most widely used as antiseptics. Other compounds that have been used as antiseptics include benzethonium chloride, cetrimide, and cetylpyridium chloride[1]. The antimicrobial activity of these compounds was first studied in the early 1900s, and a quaternary ammonium compound for pre-operative cleaning of surgeons' hands was used as early as 1935[308]. The antimicrobial activity of this group of compounds appears to be attributable to adsorption to

the cytoplasmic membrane, with subsequent leakage of low molecular weight cytoplasmic constituents[308].

Quaternary ammonium compounds are primarily bacteriostatic and fungistatic, although they are microbicidal against some organisms at high concentrations[1]. They are more active against Gram-positive bacteria than against Gram-negative bacilli. Quaternary ammonium compounds have relatively weak activity against mycobacteria and fungi and have greater activity against lipophilic viruses. Their antimicrobial activity is adversely affected by the presence of organic material, and they are not compatible with anionic detergents[1,308]. In 1994, the FDA TFM tentatively classified benzalkonium chloride and benzethonium chloride as Category IIISE active agents (insufficient data to classify as safe and effective for use as a antiseptic handwash)[135]. Further evaluation of these agents by the FDA is in progress.

In general, quaternary ammonium compounds are relatively well tolerated. Unfortunately, because of weak activity against Gram-negative bacteria, benzalkonium chloride is prone to contamination by these organisms. A number of outbreaks of infection or pseudo-infection have been traced to quaternary ammonium compounds contaminated with Gram-negative bacilli[309-311]. For this reason, in the USA these compounds have seldom been used for hand antisepsis during the last 15–20 years. However, newer handwashing products containing benzalkonium chloride or benzethonium chloride have recently been introduced for use by HCWs. A recent clinical study performed among surgical ICU HCWs found that cleaning hands with antimicrobial wipes containing a quaternary ammonium compound was about as effective as plain soap and water handwashing, and that both were significantly less effective than decontaminating hands with an alcohol-based handrub[312]. One laboratory-based study reported that an alcohol-free handrub product containing a quaternary ammonium compound was efficacious in reducing microbial counts on the hands of volunteers[313]. Further studies of such products are needed to determine if newer formulations are effective in health-care settings.

## 9.9 TRICLOSAN

Triclosan (chemical name 2,4,4′–trichloro-2′-hydroxydiphenyl ether) is a nonionic, colourless substance that was developed in the 1960s. It has been incorporated into soaps for use by HCWs and the public and into a variety of other consumer products. Concentrations ranging from 0.2% to 2% have antimicrobial activity. Triclosan enters bacterial cells and affects the cytoplasmic membrane and synthesis of RNA, fatty acids, and proteins[314]. Recent studies suggest that this agent's antibacterial activity is attributable in large part to binding to the active site of enoyl-acyl carrier protein reductase[315,316].

Triclosan has a fairly broad range of antimicrobial activity, but tends to be bacteriostatic[1]. MICs range from 0.1 to 10 µg/ml, while minimum bactericidal concentrations are 25–500 µg/ml. Triclosan's activity against Gram-positive organisms (including MRSA) is greater than against Gram-negative bacilli, particularly *P. aeruginosa*[1,314]. The agent possesses reasonable activity against mycobacterial and *Candida* spp., but has little activity against filamentous fungi. Triclosan (0.1%) reduces bacterial counts on hands by 2.8 $\log_{10}$ after a 1-minute hygienic handwash[1]. In a number of studies, log reductions achieved have been lower than with chlorhexidine, iodophors or alcohol-based products[1,82,158,279,317]. In 1994, the FDA TFM tentatively classified triclosan up to 1% as a Category IIISE active agent (insufficient data to classify as safe and effective for use as an antiseptic handwash)[135]. Further evaluation of this agent by the FDA is under way. Like chlorhexidine, triclosan has persistent activity on the skin. Its activity in hand-care products is affected by pH, the presence of surfactants or humectants, and the ionic nature of the particular formulation[1,314]. Triclosan's activity is not substantially affected by organic matter, but may be inhibited by sequestration of the agent

in micelle structures formed by surfactants present in some formulations. Most formulations containing less than 2% triclosan are well tolerated and seldom cause allergic reactions. A few reports suggest that providing HCWs with a triclosan-containing preparation for hand antisepsis has led to decreased infections caused by MRSA[119,120]. Triclosan's lack of potent activity against Gram-negative bacilli has resulted in occasional reports of contaminated triclosan[318].

## 9.10 OTHER AGENTS

More than 100 years after Semmelweis demonstrated the impact of rinsing hands with a hypochlorite solution on maternal mortality related to puerperal fever, Lowbury and colleagues[319] studied the efficacy of rubbing hands for 30 seconds with an aqueous hypochlorite solution. They found that the solution was not more effective than rinsing with distilled water. Rotter[320] subsequently studied the regimen used by Semmelweis which called for rubbing hands with a 4%[321] hypochlorite solution until the hands were slippery (approximately 5 minutes). He found that the regimen was 30 times more effective than a 1-minute rub using 60% isopropanol. However, because hypochlorite solutions tend to be very irritating to the skin when used repeatedly and have a strong odour, they are seldom used for hand hygiene today.

A number of other agents are being evaluated by the FDA for use in antiseptics related to health care[135]. However, the efficacy of these agents has not been evaluated adequately for use in hand hygiene preparations intended for use by HCWs. Further evaluation of some of these agents may be warranted. Products that utilize different concentrations of traditional antiseptics (e.g. low concentrations of iodophor) or contain novel compounds with antiseptic properties are likely to be introduced for use by HCWs. For example, preliminary studies have demonstrated that adding silver-containing polymers to an ethanol carrier (Surfacine) results in a preparation that has persistent antimicrobial activity on animal and human skin[322]. New compounds with good *in vitro* activity must be tested *in vivo* to determine their abilities to reduce transient and resident skin flora on the hands of caregivers.

## 9.11 ACTIVITY OF ANTISEPTIC AGENTS AGAINST SPORE-FORMING BACTERIA

The widespread prevalence of diarrhoea associated with health care attributable to *C. difficile*, and the recent occurrence in the USA of human *Bacillus anthracis* infections related to contaminated items sent through the postal system have raised concerns about the activity of antiseptic agents against spore-forming bacteria. None of the agents (including alcohols, chlorhexidine, hexachlorophene, iodophors, chloroxylenol, triclosan) used in antiseptic handwash or antiseptic handrub preparations is reliably sporicidal against *Clostridium* spp. or *Bacillus* spp.[213,266,323,324]. Washing hands with non-antimicrobial or antimicrobial soap and water may help physically remove spores from the surface of contaminated hands[325]. HCWs should be encouraged to wear gloves when caring for patients with *C. difficile*-associated diarrhoea[326]. After glove removal, hands should be washed with a non-antimicrobial or antimicrobial soap and water, or cleansed with an alcohol-based handrub[325]. During outbreaks of *C. difficile*-related infections, it may be preferable to wash hands with a non-antimicrobial or antimicrobial soap and water after glove removal. A recent study demonstrated that washing hands with either non-antimicrobial soap or antimicrobial soap and water reduced the amount of *Bacillus atrophaeus* (a surrogate for *B. anthracis*) on hands, whereas an alcohol-based handrub was not effective[327]. Accordingly, HCWs with suspected

or documented exposure to *B. anthracis*-contaminated items should wash their hands with a non-antimicrobial or antimicrobial soap and water.

## 9.12 REDUCED SUSCEPTIBILITY OF MICROORGANISMS TO ANTISEPTICS

Reduced susceptibility of bacteria to antiseptic agents can be an intrinsic characteristic of a species, or can be an acquired trait[328]. A number of reports have described strains of bacteria that appear to have acquired reduced susceptibility, when defined by minimum inhibitory concentrations (MICs) established *in vitro*, to antiseptics such as chlorhexidine, quaternary ammonium compounds, or triclosan[328-331]. However, since "in-use" concentrations of antiseptics are often substantially higher than the MICs of strains with reduced antiseptic susceptibility, the clinical relevance of the *in vitro* findings is in question. For example, some strains of MRSA have chlorhexidine and quaternary ammonium compound MICs that are several-fold higher than methicillin-susceptible strains, and some strains of *S. aureus* have elevated MICs to triclosan[328,329,332]. However, such strains were readily inhibited by in-use concentrations of these antiseptics[328,329]. Very high MIC for triclosan were reported by Sasatsu et al.[333], and the description of a triclosan-resistant bacterial enzyme has raised the question of whether resistance may develop more readily to this agent than to other antiseptic agents[316]. Under laboratory conditions, bacteria with reduced susceptibility to triclosan carry cross-resistance to antibiotics[334,335]. Reduced triclosan susceptibility or resistance was detected in clinical isolates of methicillin-resistant *S. epidermidis* and in MRSA, respectively[336,337]. Of additional concern, exposing *Pseudomonas* strains containing the MexAB-OprM efflux system to triclosan may select for mutants that are resistant to multiple antibiotics, including fluoroquinolones[331,334,335]. Nevertheless, a recent study failed to demonstrate a statistically significant association between elevated triclosan MICs and reduced antibiotic susceptibility among staphylococci and several species of Gram-negative bacteria[338]. Clearly, further studies are necessary to determine if reduced susceptibility to antiseptic agents is of epidemiological importance, and whether or not resistance to antiseptics may influence the prevalence of antibiotic-resistant strains[328]. Periodic surveillance may be needed to ensure that this situation has not changed[339].

## 9.13 RELATIVE EFFICACY OF PLAIN SOAP, ANTISEPTIC SOAPS AND DETERGENTS, AND ALCOHOLS

Comparing the results of studies dealing with the *in vivo* efficacy of plain soap, antimicrobial soaps and alcohol-based handrubs may be problematic for various reasons. First, different test methods produce different results, especially if a bacteriostatic effect of a formulation is not (or not sufficiently) abolished – either by dilution or chemical neutralizers – prior to quantitative cultivation of post-treatment samples. This leads to results too favourable for the formulation. Second, the antimicrobial efficacy of a hand antiseptic agent is significantly different amongst a given population of individuals[241]. Therefore the average reductions of bacterial release by the same formulation will be different in different laboratories or in one laboratory with different test populations. Inter-laboratory results will be comparable only if they are linked up with those of a reference procedure performed in parallel by the same individuals in a cross-over designed test and compared intraindividually. However, summarizing the relative efficacy of agents in each study can provide a useful overview of the *in vivo* activity of various formulations (Tables I.9.4 and I.9.5). From there it can be seen that antiseptic soaps and detergents are more efficacious than plain soap and that alcohol-based rubs are more efficacious than antiseptic detergents. A few studies show that chlorhexidine may be as effective as plain soap against MRSA but not as effective as alcohol and povidone iodine[340].

In all the studies that included plain soap, alcohols were more effective than soap. In all but two of the trials comparing alcohol-based solutions with antimicrobial soaps or detergents, alcohol reduced bacterial counts on hands to a greater extent than washing hands with soaps or detergents containing hexachlorophene, povidone-iodine, 4% chlorhexidine, or triclosan. A cross-over study comparing plain soap with one containing 4% chlorhexidine gluconate showed higher final CFU counts after chlorhexidine as compared with plain soap, but the comparative CFU log reduction was not provided to permit conclusions concerning relative efficacy[341]. However, a recent randomized clinical trial comparing the efficacy of handrubbing versus conventional handwashing with antiseptic soap showed that the median percentage reduction in bacterial contamination was significantly higher with handrubbing than with hand antisepsis with medicated soap (chlorhexidine gluconate 4%) and water[342]. In another trial to compare microbiological efficacy of handrubbing with alcohol-based solution and handwashing with water and unmedicated soap in HCWs from different wards, with particular emphasis on transient flora, handrubbing was more efficacious than handwashing for the decontamination of HCWs' hands[94]. In studies dealing with antimicrobial-resistant organisms, alcohol-based products reduced the number of multidrug-resistant pathogens recovered from the hands of HCWs more effectively than handwashing with soap and water[160,298,343]. An observational study was conducted to assess the effect of alcohol-gel hand antiseptic on infection rates attributable to the three most common multidrug-resistant bacteria (*S. aureus*, *K. pneumoniae* and *P. aeruginosa*) in Argentina[344]. Two periods were compared, 12 months before (handwashing with water and soap) and 12 months after starting alcohol gel use. The second period (alcohol gel use) showed a significant reduction in incidence rates of *K. pneumoniae* with extended spectrum beta-lactamase (ESBL) overall infections and particularly bacteremias. Nevertheless, on the basis of this study, the authors could not conclude whether the result was a result of alcohol gel itself or of an increase in hand hygiene compliance.

The efficacy of alcohols for surgical hand antisepsis has been addressed in numerous studies[1,194,197,206-212,227,239,242,345-348]. In many of these studies, bacterial counts on the hands were determined immediately after using the product and again 1–3 hours later. The delayed testing is performed to determine if regrowth of bacteria on the hands is inhibited during operative procedures. The relative efficacy of plain soap, antimicrobial soaps, and alcohol-based solutions to reduce the number of bacteria recovered from hands immediately after use of products for surgical hand preparation is shown in Table I.9.6. A comparison of five surgical hand antisepsis products – two alcohol-based handrubs and three handwashes (active ingredient triclosan, chlorhexidine or povidone-iodine) – by prEN 12791, an *in vivo* test, showed that preparations containing povidone-iodine and triclosan failed the test although all products passed the *in vitro* suspension test prEN 12054. Better results were achieved with the alcohol-based handrubs[349]. Alcohol-based solutions were more effective than washing hands with plain soap in all studies, and reduced bacterial counts on hands to a greater extent than antimicrobial soaps or detergents in most experiments[194,197,206-212,227,239,242,346-348]. Table I.9.7 shows the $\log_{10}$ reductions in the release of resident skin flora from clean hands immediately and three hours after use of surgical handrub products. Alcohol-based preparations proved more efficacious than plain soap and water and, with most formulations, were superior to povidone-iodine or chlorhexidine. Among the alcohols, a clear positive correlation with their concentration is noticeable and, when tested at the same concentration, the range of order in terms of efficacy is ethanol < isopropanol < n-propanol.

## 9.14 SAFETY ISSUES RELATED TO ALCOHOL-BASED PREPARATIONS

### 9.14.1 FIRE HAZARD ISSUES

Alcohols are flammable. Flash points of alcohol-based handrubs range from 21°C to 24°C, depending on the type and concentration of alcohol present[350,351]. As a result, alcohol-based handrubs should be stored away from high temperatures or flames, in accordance with National Fire Protection Agency recommendations in the USA. In Europe, where alcohol-based handrubs have been used extensively for many years, the incidence of fires related to such products has been extremely low[350]. One recent report from the USA described a flash fire that occurred as a result of an unusual series of events, which included an HCW applying an alcohol gel to her hands, then immediately removing a polyester isolation gown and touching a metal door before the alcohol had evaporated[352]. Removing the polyester gown created a large amount of static electricity that generated an audible static spark when she touched the metal door, igniting the unevaporated alcohol on her hands[352]. This incident underscores the fact that following application of alcohol-based handrubs, hands should be rubbed together until all the alcohol has evaporated.

In the USA, shortly after publication of the 2002 CDC/HICPAC hand hygiene guideline, fire marshals in a number of states prohibited the placement of alcohol-based handrub dispensers in egress corridors because of a concern that they may represent a fire hazard. On 25 March 2005, the Center for Medicare and Medicaid Services adopted a revised version of the United States National Fire Protection Agency's Life Safety Code, which allows such dispensers to be placed in egress corridors. The International Fire Code recently agreed to accept alcohol-based handrubs in corridors. In addition, the CMS 3145-IFC (Fire Safety Requirement for Certain Health Care Facilities; Alcohol-Based Hand Sanitizer & Smoke Detector Amendment) was published in March 2005, addressing this issue[353].

### 9.14.2 OTHER SAFETY-RELATED ISSUES

Accidental ingestion and dermal absorption of alcohol-based preparations used for hand hygiene have been reported[354,355]. Acute, severe alcohol intoxication resulting from accidental ingestion of an unknown quantity of alcohol-based handrub gel was recently alleged in the United Kingdom, resulting in the unconsciousness of an adult male patient (Glasgow Coma Scale 3)[354]. This unusual complication of hand hygiene may become more common in the future, and security measures are needed. These may involve: placing the preparation in secure wall dispensers; labelling dispensers to make the alcohol content less clear at a casual glance and adding a warning against consumption; and the inclusion of an additive in the product formula to reduce its palatability. In the meantime, medical and nursing staff should be aware of this potential risk.

Alcohol toxicity usually occurs after ingestion. It is primarily metabolized by an alcohol dehydrogenase in the liver to acetone. Symptoms and signs of alcohol intoxication include headache, dizziness, lack of coordination, hypoglycaemia, abdominal pain, nausea, vomiting, and haematemesis. Signs of severe toxicity include respiratory depression, hypotension, and coma. Among alcohols, isopropyl alcohol appears to be more toxic than ethanol, but less so than methanol. Blood isopropyl alcohol levels of 50 mg/dl are associated with mild intoxication and 150 mg/dl with deep coma. Apparently, isopropyl alcohol has no adverse effects on reproduction and is not genotoxic, teratogenic or carcinogenic[356].

In addition to accidental ingestion, alcohols can be absorbed through intact skin and result in toxicity in animals[357] and humans[358]. Turner et al. evaluated the dermal absorption through intact HCWs' skin. Three ml of isopropyl alcohol-containing handrub (52.6% (w/w)

isopropyl alcohol) were applied to HCWs' hands every 10 minutes over a 4-hour period. A blood sample was taken 5 minutes after the final application of handrub and blood isopropyl alcohol levels were measured. In 9 out of 10 participants, a rise in the blood isopropyl alcohol level was noted at very low levels (the highest observed level was 0.18 mg/dl), much less than the levels achieved with mild intoxication (50 mg/dl). In addition, reliable investigations demonstrate that the amount of alcohol absorbed is negligible on the toxic level for human beings (A. Kramer, personal communication 2005). Studies to measure both alcohol and acetone levels in subjects chronically exposed to topical alcohols are required to investigate further this issue.

# 10. A WHO ALCOHOL-BASED FORMULATION

## 10.1 GENERAL REMARKS

The design of a product to be used worldwide has to take logistic, economic and cultural (including religious) factors into consideration (see also Part I, Section 14).

At present, alcohol-based handrubs are the only products to reduce or inhibit the growth of microorganisms with maximum efficacy[156,256,262,350,359-361].

WHO recommends an alcohol-based formulation for the following reasons:

- to benefit from its evidence-based intrinsic advantages: fast acting and broad-spectrum activity, excellent microbicidal characteristics, lack of potential emergence of resistance;
- to overcome the lack of accessibility to sinks or other facilities (including clean running water or towels in some poor and remote areas) to perform hand cleansing actions that require the use of water (handwashing and hand antisepsis using a formulation different from a waterless agent);
- to improve compliance with hand hygiene by reducing the time required to perform it and the convenience of the method;
- to reduce costs: the annual cost of hand hygiene promotion including recourse to an alcohol-based handrub may not exceed 1% of HCAI costs (see also Part III, Section 3)[362-364].

To achieve a maximum effect and optimal compliance of HCWs with hand hygiene, products should be easily available, either through dispensers placed close to the point of care or in small individual bottles for pocket carriage[263,359].

Health-care settings currently using commercially-available handrubs, liquid soaps and skin care products sold in disposable containers should continue this practice, provided that the handrubs meet recognised standards for microbiological efficacy (ASTM or EN standards) and are well accepted by the HCWs. In health-care settings where these products are not available or too costly, production of the WHO handrub according to the formulation/s and methodology suggested below is an alternative.

### 10.1.1 SUGGESTED COMPOSITION OF ALCOHOL-BASED FORMULATIONS FOR IN-HOUSE/LOCAL PRODUCTION

The choice of components for the WHO handrub formulations takes into account cost constraints and microbiological efficacy. Where commercially-available and validated (ASTM or EN) products are already used and well accepted by HCWs, they should obviously be regarded as acceptable even if their contents differ from those of the WHO formulations described below. The following two formulations are recommended for preparation in-house or in a local production facility up to a maximum of 50 litres:

#### FORMULATION I

To produce final concentrations of ethanol 80% *v/v*, glycerol 1.45% *v/v*, hydrogen peroxide 0.125% *v/v*.

Pour into a 1000 ml graduated flask:

a) ethanol 96% *v/v*, 833.3 ml

b) hydrogen peroxide 3%, 41.7 ml

c) glycerol 98% ,14.5 ml

Top up the flask to 1000 ml with distilled or boiled and cooled water and shake the flask gently to mix the content.

#### FORMULATION II

To produce final concentrations of isopropyl alcohol 75% *v/v*, glycerol 1.45% *v/v*, hydrogen peroxide 0.125% *v/v*:

Pour into a 1000 ml graduated flask:

a) isopropyl alcohol (with a purity of 99.8%), 751.5 ml

b) hydrogen peroxide 3%, 41.7 ml

c) glycerol 98%, 14.5 ml

Top up the flask to 1000 ml with distilled or boiled and cooled water and shake the flask gently to mix the content.

### 10.1.2 METHOD FOR IN-HOUSE/LOCAL PRODUCTION

**10 litre** preparations: glass or plastic bottles with screw-threaded stoppers can be used.

**50 litre** preparations: large plastic (preferably polypropylene, translucent enough to see the liquid level) or stainless steel tanks with an 80 to 100 litre capacity should be used to allow for mixing without overflowing.

The tanks should be calibrated for the ethanol/isopropyl alcohol volumes and for the final volumes of either 10 or 50 litres. It is best to mark plastic tanks on the outside and stainless steel ones on the inside.

Mixing should be carried out using wooden, plastic or metallic paddles. Electric mixers should not be used unless "EX" protected because of the danger of explosion.

#### PREPARATION

1) The alcohol for the chosen formulation is poured into the large bottle or tank up to the graduated mark.

2) Hydrogen peroxide is added using the measuring cylinder.

3) Glycerol is added using a measuring cylinder. As the glycerol is very viscous and sticks to the walls of the measuring cylinder, it can be rinsed with some of the water to be added and emptied into the tank.
4) The tank is then topped up to the corresponding mark of the volume to be prepared with the remainder of the distilled or cooled, boiled water.
5) The solution is mixed by gently shaking the recipient where appropriate (small quantities), or by using a paddle.
6) The lid or the screw cap is placed on the tank/bottle immediately after mixing to prevent evaporation.

For a more detailed production guideline for 10 and 50 litres of both formulations see the "Guide to in-house/local manufacturing" at www.who.int/patientsafety

After dividing the solution into smaller containers (e.g., 1000, 500 or 100 ml plastic bottles), the bottles should be kept in quarantine for 72 hours. This allows time for any spores present in the alcohol or the (re-used) bottles to be destroyed by the hydrogen peroxide.

Note: If concentrated alcohol is obtained from local production, verify the alcohol concentration and make the necessary adjustments in volume to obtain the final recommended concentration.

**Labelling of the bottles** should be in accordance with national guidelines, but should include the mention:

- antiseptic handrub solution
- for external use only
- keep out of reach of children
- avoid contact with eyes
- use: apply about 2 ml to the palm of the hand and rub both hands and fingers, front and back until dry
- formula contents:

FORMULATION I

Ethanol 80% (*v/v*), glycerol 1.45% and hydrogen peroxide 0.125%

or

FORMULATION II

Isopropyl alcohol 75% (*v/v*), glycerol 1.45% and hydrogen peroxide 0.125%

- flammable liquid: keep away from heat and flame.

Special requirements are applicable for the production and storage of the formulations, as well as the storage of the primary products. The quantity of locally-produced WHO handrub should not exceed 50 litres, or possibly less if regulated by local and/or national guidelines and regulations.

Alcohol is the active component and some aspects concerning other components should be respected. All components should be free of spores [i.e., by treatment with hydrogen peroxide ($H_2O_2$) or commercially by filtering]. While the use of $H_2O_2$ autosterilizes the solution, thus eliminating spores originating from components or reused bottles and thereby adding an important safety aspect, the use of 3–6% of $H_2O_2$ for the production might be complicated by its corrosive nature and difficult procurement in some countries. Further investigation is needed to assess $H_2O_2$ availability in different countries as well as the possibility of using a stock solution with a lower concentration.

While the chance of ingestion should be reduced by using a bad taste additive such as methylethylketone (1% in 96% ethanol), this would increase the toxicity of the product in cases of accidental ingestion, as well as adding costs and problems of availability. For this reason, no bad taste additive is included in the above formulations. Any further additive to both formulations should be clearly labelled and non-toxic in case of accidental ingestion. A colorant may be added to allow differentiation from other fluids, but should not add to toxicity, promote allergy or interfere with the antimicrobial properties (see also Part I, Section 11). Formulations should be labelled adequately in accordance with national guidelines.

To reduce further the risk of abuse and to promote the product in regions where even external alcohol use is problematic because of cultural or religious reasons (see Part I, Section 14.4), the product name should avoid the term "alcohol" and should be referred to as a handrub with antimicrobial properties. Both recommended formulations should be produced in liquid form. Addition of gelling agents may increase production costs and, in some cases, reduce antimicrobial efficacy[140,251].

While sterile distilled water is the preferable component for production of the formulations, cooled, boiled water may also be used.

Glycerol is added to the formulation as a humectant to increase the acceptability of the product. Other humectants or emollients may be used as long as they are non-toxic, cheap, widely available, do not cause allergies, and miscible (mixable) in water and alcohol. Glycerol was chosen because of its historical safety record. The possibility of a lower percentage of glycerol should be investigated to reduce further the risk of stickiness.

The WHO handrub formulations can be used for hygienic hand antisepsis and for surgical hand preparation. According to EN standards, the efficacy of the formulations is equivalent to the reference substance for hygienic hand antisepsis, whereas for surgical hand preparation, it is slightly lower. Further results according to both the EN and ASTM standards will be available in the near future. Substances such as chlorhexidine could be added to achieve a sustained effect (see Part I, Sections 9.4 and 9.13 for advantages), but this would complicate production and increase costs. For hygienic hand antisepsis, a sustained effect is not required.

Within the implementation strategy, the use of the WHO formulations at country level should undergo a pilot phase in a limited number of sites to evaluate feasibility and acceptability.

### 10.1.3 PRODUCTION FACILITIES AND COST ISSUES

Manufacture of the WHO handrub formulation should be possible in production units such as central pharmacies or dispensaries. According to local policies, governments should make every effort to encourage local production, support the quality assessment process and keep production costs as low as possible. Since undiluted ethanol is highly flammable and may ignite at temperatures as low as 10°C, production facilities should directly dilute it to the above-mentioned concentration. The flash points of ethanol 80% (*v/v*) and isopropyl alcohol 75% (*v/v*) are 24°C and 18°C, respectively[351], and special attention should be given to proper storage in tropical climates (see also Part I, Section 9.14.1). National safety guidelines and local legal requirements have to be considered in the storage of ingredients and the final product. The WHO handrub formulations should not be produced in quantities above 50 litres locally or in central pharmacies lacking specialised air conditioning and ventilation. There should be no smoking or naked flames in production and storage areas.

The costs of the WHO handrub formulation may vary according to country, resources and labour costs; studies to evaluate costs and resource use are necessary. As an example,

in 2005 the costs of an alcohol-based hand rinse developed by a Swiss hospital pharmacy were (Euros) € 0.57 for a 100 ml pocket bottle, € 1.74 for a 500 ml bottle, and € 3.01 for a 1000 ml bottle. The solution contains chlorhexidine gluconate (0.5%) and isopropyl alcohol (68.5 g). In Brazil, the prices of a commercially-available alcohol-based formulation based on ethanol (70% m/m) and glycerine (2%) are US$ 0.45 for a 100 ml disposable bottle and US$ 3 for a 1000 ml bottle. Nevertheless, the prices of some other commercially-available products may be much higher.

#### 10.1.4 SAFETY STANDARDS

The recommended handrub formulations have been tested for efficacy according to international norms (see also Part I, Section 8) in WHO-designated independent laboratories. With regard to skin reactions, handrubbing with alcohol-based solutions is better tolerated than handwashing with soap and water (see also Part I, Section 11). Any additive should be as non-toxic as possible in case of accidental or intentional ingestion.

#### 10.1.5DISTRIBUTION

To avoid contamination with spore-forming organisms[265], disposable bottles should preferably be used although reusable sterilizable bottles may reduce production costs and waste management. To prevent evaporation, containers should have a maximum capacity of 500 ml on wards, and 1 litre in operating theatres, and possibly fit into a wall dispenser. Leakage-free pocket bottles with a capacity of no more than 100 ml should also be available and distributed individually to HCWs, but it should be emphasized that the use of these products should be confined to health care only. The production or re-filling unit should follow norms on how to clean and disinfect the bottles (e.g., autoclaving, boiling, or chemical disinfection with chlorine). Autoclaving is considered the most suitable procedure. Reusable bottles should never be refilled until they have been completely emptied and then cleansed and disinfected.

Cleansing and disinfection process for reusable handrub bottles: empty bottles should be brought to a central point to be reprocessed using standard operational protocols. Bottles should be thoroughly washed with detergent and tap water to eliminate any residual liquid. If heat-resistant, bottles should be thermally disinfected by boiling in water. Whenever possible, thermal disinfection should be chosen in preference to chemical disinfection, since chemical disinfection not only might increase costs but also needs an extra step to flush out the remains of the disinfectant. Chemical disinfection should include soaking the bottles in a solution containing 1000 ppm of chlorine for a minimum of 15 minutes and then rinsing with sterile/cooled boiled water[365]. After thermal or chemical disinfection, bottles should be left to dry completely upside-down in a bottle rack. Dry bottles should be closed with a lid and stored, protected from dust, until use.

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## 11. SURGICAL HAND PREPARATION

### 11.1 EVIDENCE FOR SURGICAL HAND PREPARATION

Historically, Joseph Lister (1827–1912) demonstrated the effect of hand antisepsis on the reduction of surgical site infections[366]. Surgical gloves were not available at the time, so appropriate antisepsis of the surgical site of the patient and hand antisepsis by the surgeon

were required[367]. For several decades of the 19th century, surgical hand preparation consisted of washing the hands with antimicrobial soap and warm water, frequently with the use of a brush[368]. In 1894, three steps were suggested: (i) wash hands with hot water, medicated soap and a brush for 5 minutes; (ii) apply 90% ethanol for 3–5 minutes with a brush; and (iii) rinse the hands with an aseptic liquid[368]. In 1939, Price suggested a 7-minute handwash with soap, water and a brush, followed by 70% ethanol for 3 minutes after drying the hands with a towel[20]. The recommended time for surgical hand preparation decreased from over 10 minutes to 5 minutes[369,370]. Even today, 5-minute protocols are common[134]. A comparison of different countries' practices revealed almost as many protocols as listed countries[371].

The introduction of sterile gloves does not render surgical hand preparation unnecessary. Sterile gloves contribute to preventing surgical site contamination[372] and reduce the risk of bloodborne pathogen transmission from patients to the surgical team[373]. However, 18% (range: 5–82%) of gloves have tiny punctures after surgery, and more than 80% of such cases go unnoticed by the surgeon. After two hours of surgery, 35% of all gloves demonstrate puncture, thus allowing water (hence also body fluids) to penetrate the gloves without using pressure[374]. Double gloving decreases the risk of puncture during surgery, but punctures are nevertheless still observed in 4% after the procedure[375,376]. In addition, even unused gloves do not fully prevent bacterial contamination of hands[377]. Not surprisingly, multiple outbreaks have been reported that have been traced to contaminated hands in the surgical team, despite the wearing of sterile gloves[27,378]. In addition, one outbreak of surgical site infections occurred when surgeons who normally used an antiseptic surgical scrub preparation switched to a non-antimicrobial product[379]. Despite this indirect evidence of the need for surgical hand antisepsis, its requirement before surgical interventions has never been proven by a randomized, controlled clinical trial. A randomized trial clearly showing an *in vitro* benefit of an alcohol-based handrub versus a chlorhexidine hand scrub failed to demonstrate a reduction of surgical site infections[134]. In all probability, such a study would not be acceptable to an ethics committee and will never be performed again.

Gloves reduce the risk of exposure of the HCW to bloodborne pathogens. In orthopaedic surgery, double gloving has been a common practice that significantly reduces, but does not eliminate the risk of punctures during surgery[380]. Given the high percentage of punctures found after surgery, it would be desirable for the operating team to benefit from a product with a prolonged antiseptic effect on the skin and capable of inactivating bloodborne viruses such as HIV or hepatitis viruses, in particular, in cases where gloves are torn and an exposure to such viruses occurs during surgery[373].

## 11.2 OBJECTIVES OF SURGICAL HAND PREPARATION

Surgical hand preparation is a critical element of safe surgical care[381]; it aims to reduce the release of skin bacteria from the hands of the surgical team for the duration of the procedure in the event of an unnoticed puncture of the surgical glove and potential release of bacteria to the open wound[382]. In contrast to the hygienic handwash or handrub, surgical hand preparation must eliminate the transient and reduce the resident flora[350,383]. It should also inhibit growth of bacteria under the gloved hand. Rapid multiplication of skin bacteria occurs under surgical gloves if hands are washed with a non-antimicrobial soap, whereas it occurs more slowly following preoperative scrubbing with a medicated soap. The skin flora, mainly coagulase-negative staphylococci, *Propionibacterium* spp. and *Corynebacteria* spp., are rarely responsible for surgical site infections, but in the presence of a foreign body or necrotic tissue even inocula as low as 100 CFU can trigger such infections[384]. The virulence of the microorganisms, extent of microbial exposure, presence of foreign material (e.g. implants), and host defence mechanisms are key factors in the pathogenesis of postoperative

infection, risk factors that are largely beyond the influence of the surgical team. Therefore, products for surgical hand preparation must eliminate the transient and significantly reduce the resident flora at the beginning of an operation and maintain the microbial release from the hands below baseline until the end of an operation.

The spectrum of antimicrobial activity for surgical hand preparation should be as broad as possible against bacteria and fungi[385]. Viruses are rarely involved in surgical site infection and are not part of surgical hand antisepsis test procedures for licensing in any country. Similarly, activity against spore-producing bacteria is not part of international testing procedures. In an outbreak of antibiotic-associated diarrhoea, the hands of 59% of 35 HCWs were *C. difficile*-positive after direct contact with culture-positive patients; colonization was found in 43% of HCWs in the subungual area 63. In another study, 14% of 73 HCWs were culture positive for *C. difficile*[64]. The potential for transmission of spores by contaminated hands cannot be ruled out. Transmission of *Clostridium* spp., especially *C. perfringens*, during the intervention might theoretically induce life-threatening infections that might be responsible for unexplained deaths after orthopaedic implant and allograft surgery[386]. A case of osteosynthesis-associated bone infection caused by a *Clostridium botulinum*-like strain was reported following the repair of a supracondylar fracture of the humerus[387].

## 11.3 SELECTION OF PRODUCTS FOR SURGICAL HAND PREPARATION

Antiseptic preparations intended for use as surgical hand preparation are evaluated for their ability to reduce the number of bacteria released from hands (i) immediately after scrubbing; (ii) after wearing surgical gloves for six hours (persistent activity); and (iii) after multiple applications over five days (cumulative activity). Immediate and persistent activities are considered the most important. Guidelines in the USA recommend that agents used for surgical hand preparation should significantly reduce microorganisms on intact skin, contain a non-irritating antimicrobial preparation, have broad-spectrum activity, and be fast acting and persistent[388] (see Part I, Section 8).

Most guidelines prohibit any jewellery or watches on the hands of the surgical team[7,389]. Artificial fingernails are an additional important risk factor that should be prohibited for the surgical team and in the operating theatre[96,390]. They are associated with changes in the normal flora and impede proper hand hygiene[96].

## 11.4 SURGICAL HAND ANTISEPSIS USING MEDICATED SOAP

The different active compounds included in commercially available handrub formulations have been described in Part I, Section 9. The most commonly used products for surgical hand antisepsis are soaps containing chlorhexidine gluconate or povidone-iodine. The most active agents (in order of decreasing activity) are chlorhexidine gluconate, iodophors, triclosan, and plain soap[208,281,302,391-393]. Products containing triclosan have also been tested for surgical hand antisepsis, but triclosan is mainly bacteriostatic, inactive against *P. aeruginosa* and has been associated with water pollution[394,395]. Application of chlorhexidine or povidone-iodine result in similar initial reductions of bacterial counts (70–80%), increasing to 99% after repeated application. Rapid regrowth occurs after application of povidone-iodine, but not after use of chlorhexidine[351]. Hexachlorophene and triclosan detergents show a lower immediate reduction, but a good residual effect. These agents are not further discussed because chlorhexidine or povidone-iodine provide similar efficacy at lower levels of toxicity, faster mode of action, or broader spectrum of activity. Povidone-iodine remains one of the most widely used products for surgical hand antisepsis, despite both *in vitro* and *in vivo* studies demonstrating that it is less efficacious than chlorhexidine, induces more allergic reactions, and does not show similar residual effects[197,348]. Hexachlorophene has

been banned worldwide because of its high rate of dermal absorption and subsequent toxic effects[26,290]. At the end of a surgical intervention, iodophor-treated hands can have even more microorganisms than before surgical scrubbing. Warm water makes antiseptics and soap work more effectively, while very hot water removes more of the protective fatty acids from the skin. Therefore, washing with very hot water should be avoided.

### 11.4.1 REQUIRED TIME FOR THE PROCEDURE

Hingst and colleagues compared hand bacterial counts after 3-minute and 5-minute scrubs with seven different products[302]. Results showed that the 3-minute scrub could be as effective as the 5-minute scrub, depending on the formula of the scrub agent.

Immediate and postoperative hand bacterial counts after 5-minute and 10-minute scrubs with 4% chlorhexidine gluconate were compared by O'Farrell and colleagues before total hip arthroplasty procedures[396]. The 10-minute scrub reduced the immediate colony count more than the 5-minute scrub. The postoperative mean log CFU count was slightly higher for the 5-minute scrub than for the 10-minute scrub but the difference between post-scrub and post-operative means CFU counts were higher for the 10-minute scrub than for the 5 minute-scrub in longer procedures (>90 minutes). The study recommended a 5-minute scrub before total hip arthroplasty.

A study by O'Shaughnessy and colleagues used 4% chlorhexidine gluconate in 2, 4 and 6-minute scrubs. A reduction in post-scrub bacterial counts was found in all three groups. Scrubbing for longer than two minutes did not confer any advantage. This study recommended a 4-minute scrub for the surgical team's first procedure and a 2-minute scrub for subsequent procedures[397]. Bacterial counts on hands after 2-minute and 3-minute scrubs with 4% chlorhexidine gluconate were compared[398]. A statistically significant difference in mean CFU counts was found between groups, with the higher mean log reduction in the 2-minute group. The investigators recommended a 2-minute procedure.

Poon and colleagues applied different scrub techniques with a 10% povidone-iodine solution[399]. Investigators found that a 30-second handwash can be as effective as a 20-minute contact with an antiseptic in reducing bacterial flora and that vigorous friction scrub is not necessarily advantageous.

### 11.4.2 USE OF BRUSHES

Almost all studies discourage the use of brushes. Early in the 1980s, Mitchell and colleagues suggested a brushless surgical hand scrub[400]. Scrubbing with a disposable sponge or combination sponge-brush has been shown to reduce bacterial counts on the hands as effectively as scrubbing with a brush[401-403]. Today, almost all studies discourage the use of brushes. Recently, even a randomized controlled clinical trial failed to demonstrate an additional antimicrobial effect by using a brush[404]. It is conceivable that a brush may be beneficial on visibly dirty hands before entering the operating theatre. Members of the surgical team who have contaminated their hands before entering the hospital may wish to use a sponge or brush to render their hands visibly clean before entering the operating theatre area.

### 11.4.3 DRYING OF HANDS

Sterile cloth towels are most frequently used in operating theatres to dry wet hands after surgical hand antisepsis. Several methods of drying have been tested without significant differences between techniques[182].

### 11.4.4 SIDE-EFFECTS OF THE SURGICAL HAND SCRUB

Skin irritation and dermatitis are more frequently observed after surgical hand scrub with chlorhexidine than after the use of surgical hand antisepsis with an alcohol-based hand rinse[134].

### 11.4.5 POTENTIAL FOR RECONTAMINATION

Surgical hand antisepsis with medicated soap requires clean water (see also Part I, Section 9.1) to rinse the hands after application of the medicated soap. However, *Pseudomonas* spp., specifically *P. aeruginosa*, are frequently isolated from tap/faucet water in hospitals [405]. Tap/faucet water is a common source of *P. aeruginosa* and has even been linked to infections in an ICU[406]. It is therefore prudent to remove tap aerators from sinks designated for surgical hand antisepsis[406-408]. Even automated sensor-operated taps have been linked to *P. aeruginosa* contamination[409]. Outbreaks or cases clearly linked to contaminated hands of surgeons after proper surgical hand scrub have not yet been observed. However, in countries lacking continuous monitoring of drinking-water and improper tap maintenance, recontamination may be a real risk even after correct surgical hand scrub.

## 11.5 SURGICAL HAND PREPARATION WITH WATERLESS, ALCOHOL-BASED HANDRUB

Several alcohol-based handrubs have been licensed for the commercial market[385,410,411], frequently with additional, long acting compounds (e.g. chlorhexidine gluconate) limiting regrowth of bacteria under the gloved hand[301,412-416]. The antimicrobial activity of alcohol-based rubs is superior to that of all other currently available methods of preoperative surgical hand preparation. Numerous studies have demonstrated that formulations containing 60–95% alcohol alone, or 50–95% when combined with small amounts of a quaternary ammonium compound, hexachlorophene or chlorhexidine gluconate, lower bacterial counts on the skin immediately post-scrub more effectively than do other agents (Table I.9.6). Grabsch and colleagues conducted a crossover study to compare chlorhexidine gluconate (0.5%) in isopropyl alcohol (76% *v/v*) with povidine iodine (0.75%) for surgical hand preparation[416]; the chlorhexidine in alcohol regimen was markedly superior in terms of reductions in bacterial hand counts with persistent antibacterial efficacy between surgical procedures. The next most active agents (in order of decreasing activity) are chlorhexidine gluconate, iodophors, triclosan, and plain soap[197,212,281,283,300,301,303,305,417]. Because studies of chloroxylenol (PCMX) as a surgical scrub have yielded contradictory results, further studies are needed to establish how the efficacy of this compound compares with that of the above agents[270,280,281].

Hand-care products should not decrease the antimicrobial activity of the handrub. A study by Heeg[418] failed to demonstrate such an interaction, but manufacturers of a handrub should provide good evidence of non-interaction.

It is not necessary to wash hands before using handrub unless they are visibly soiled[418,419]. The hands of the surgical team should be clean upon entering the operating theatre by washing with a non-medicated soap. Experimental and epidemiological data failed to demonstrate an additional effect of washing hands before applying handrub in the overall reduction of the resident skin flora[385]. The activity of hand disinfectant may even be impaired if hands are not completely dry before applying the handrub or by the washing phase itself[418-420]. In addition, alcohol is not active against spores; therefore, a simple handwash with soap and water before entering the operating theatre area is highly recommended to eliminate any risk of colonization with bacterial spores[325]. Non-medicated soaps are sufficient[421]. This proce-

dure is necessary only upon entering the operating theatre; repeating handrubbing without prior handwash or scrub is recommended before switching to the next procedure.

### 11.5.1 TECHNIQUE FOR SURGICAL HAND PREPARATION USING ALCOHOL-BASED HANDRUB

This simple procedure appears not to require training. However, expert opinion strongly recommends training[385,422]. The hands should be wet from the alcoholic rub during the whole procedure, requiring usually >6 ml. One study demonstrated that keeping the hands wet with the rub is more important than the volume used[423].

### 11.5.2 REQUIRED TIME FOR THE PROCEDURE

For many years, surgical staff commonly scrubbed their hands for 10 minutes pre-operatively, which frequently led to skin damage. Several studies have demonstrated that scrubbing for five minutes reduces bacterial counts as effectively as a 10-minute scrub[210,396,402]. In other studies, scrubbing for two or three minutes reduced bacterial counts to acceptable levels[302,304,345,350,397,398]. Very recently, even 90 seconds of rub have been shown to be equivalent to a 3-minute rub with a product containing a mixture of alcohols and mecetronium acetate[411]. Cumulative observational data are abundant for more than three minutes of applying the alcohol-based solutions. Alcohol-based hand gels should not yet be used unless they pass the test prEN 12791 or an equivalent standard required for solutions[389]. Many of the currently available gels for hygienic handrub do not meet the European standard EN 1500[140]. However, at least one gel on the market has been tested and introduced in a hospital for hygienic and surgical handrub[424].

## 11.6 STEPS FOR SURGICAL HAND PREPARATION

#### STEPS BEFORE STARTING SURGICAL HAND PREPARATION

- Keep nails short and pay attention to them when washing your hands – most microbes on hands come from beneath the fingernails.
- Do not wear artificial nails or nail polish.
- Remove all jewellery (rings, watches, bracelets) before entering the operating room suite.
- Wash hands and arms up to elbows with a non-medicated soap before entering the operating room area or if hands are visibly soiled.
- Clean subungual areas with a nail file. Nailbrushes should not be used as they may damage the skin and encourage shedding of cells. Nailbrushes, if used, must be sterile and used only once. Reusable autoclavable nail brushes are available commercially.

#### PROTOCOL FOR SURGICAL SCRUB WITH A MEDICATED SOAP

- Start timing. Scrub each side of each finger, between the fingers, and the back and front of the hand for two minutes.
- Proceed to scrub the arms, keeping the hand higher than the arm at all times. This helps to avoid recontamination of the hands by water from the elbows and prevents bacteria-laden soap and water from contaminating the hands.
- Wash each side of the arm from wrist to the elbow for one minute.

- Repeat the process on the other hand and arm, keeping hands above elbows at all times. If the hand touches anything except the brush at any time, the scrub must be lengthened by one minute for the area that has been contaminated.
- Rinse hands and arms by passing them through the water in one direction only, from fingertips to elbow. Do not move the arm back and forth through the water.
- Proceed to the operating room suite holding hands above elbows.
- At all times during the scrub procedure, care should be taken not to splash water onto surgical attire.
- Once in the operating room suite, hands and arms should be dried using a sterile towel and aseptic technique before putting on gown and gloves.

#### PROTOCOL FOR SURGICAL SCRUB WITH AN ALCOHOL-BASED PREPARATION

- Start timing. Use sufficient product to keep hands and forearms wet with the handrub throughout the procedure.
- After application of the alcohol-based product, allow hands and forearms to dry thoroughly before donning sterile gloves.
- Proceed to the operating room suite holding hands above elbows.

### 11.7 SURGICAL HAND SCRUB WITH MEDICATED SOAP OR SURGICAL HANDRUB WITH ALCOHOL-BASED FORMULATIONS

Either method is suitable for the prevention of surgical site infection. In terms of antimicrobial efficacy, surgical handrubs and surgical hand scrubs that contain chlorhexidine pass the test outlined in the European norm prEN 12791. However, the combined effect – rapid action at the beginning and inhibition of regrowth of bacteria under the gloved hands – is best achieved by using an alcohol-based compound containing chlorhexidine, or with the addition of a quaternary ammonium compound such as mecetronium sulfate or N-duopropenide[252,301,411,412,415,424]. Several factors, including, in particular, rapid action, time savings, lower side-effects, and no risk of recontamination by rinsing the hands with water, clearly favour the use of surgical handrubbing. Some surgeons nevertheless consider the time taken for the surgical hand antisepsis with the hand scrub as a ritual for the preparation of the intervention[425]. Therefore, a switch from the hand scrub to the handrub must be prepared with caution. In countries with limited resources, in particular when availability, quantity or quality of water is doubtful, the current panel of experts clearly favours the use of alcohol-based handrub for surgical hand preparation.

## 12.SKIN REACTIONS RELATED TO HAND HYGIENE

There are two major types of skin reactions associated with hand hygiene. The first and most common type includes symptoms which can vary from quite mild to debilitating, including dryness, irritation, itching, and even cracking and bleeding. This array of symptoms is referred to as irritant contact dermatitis. The second type of skin reaction, allergic contact dermatitis, is rare and represents an allergy to some ingredient in a hand hygiene product. Symptoms of allergic contact dermatitis can also range from mild and localized to severe and generalized. In its most serious form, allergic contact dermatitis may be associ-

ated with respiratory distress and other symptoms of anaphylaxis. Therefore it is sometimes difficult to differentiate between the two conditions.

## 12.1 FREQUENCY AND PATHOPHYSIOLOGY OF IRRITANT CONTACT DERMATITIS

In some surveys, about 25% of nurses have reported symptoms or signs of dermatitis involving their hands, and as many as 85% give a history of having skin problems[426]. Frequent and repeated use of hand hygiene products, particularly soaps and other detergents, is an important cause of chronic irritant contact dermatitis among HCWs[427]. Cutaneous adverse reaction were infrequent among HCWs (13/2750 exposed HCWs ) exposed to an alcohol-based preparation containing chlorhexidine gluconate and skin emollient during a hand hygiene culture change, multimodal programme 428; it represented one cutaneous adverse event per 72 years of HCW exposure. The potential of detergents to cause skin irritation varies considerably and can be reduced by the addition of humectants. Irritation associated with antimicrobial soaps may be attributable to the antimicrobial agent or to other ingredients of the formulation. Affected HCWs often complain of a feeling of dryness or burning, skin that feels "rough", and erythema, scaling or fissures. An example of a hand skin self-assessment tool is given in Appendix 2.

Hand hygiene products damage the skin by causing denaturation of *stratum corneum* proteins, changes in intercellular lipids (either depletion or reorganization of lipid moieties), decreased corneocyte cohesion and decreased *stratum corneum* water-binding capacity[427,429]. Among these, the main concern is the depletion of the lipid barrier that may be consequent to contact with lipid-emulsifying detergents and lipid-dissolving alcohols[430]. Frequent handwashing leads to progressive depletion of surface lipids with resulting deeper action of detergents into the superficial skin layers. During dry seasons and in individuals with dry skin this lipid depletion occurs more quickly[430]. Damage to the skin also changes skin flora, resulting in more frequent colonization by staphylococci and Gram-negative bacilli[35,154].

Although alcohols are safer than detergents[188], they can cause dryness and skin irritation[1,431]. The lipid-dissolving effect of alcohols is inversely related to their concentration[430], and ethanol tends to be less irritating than n-propanol or isopropanol[431].

In general, irritant contact dermatitis is more commonly reported with iodophors[155] (see Part I, Section 9.7). Other antiseptic agents that may cause irritant contact dermatitis, in order of decreasing frequency, include chlorhexidine, chloroxylenol, triclosan and alcohol-based products. Skin that is damaged by repeated exposure to detergents may be more susceptible to irritation by all types of hand antisepsis formulations, including alcohol-based preparations[432]. Graham and colleagues reported low rates of cutaneous adverse reactions to an alcohol-based handrub (isopropyl alcohol 70%) formulation containing chlorhexidine (0.5%) with emollient[428].

Information regarding the irritancy potential of commercially prepared hand hygiene products, which is often determined by measuring transepidermal water loss of persons using the preparation, may be available from the manufacturer. Other factors that may contribute to dermatitis associated with frequent hand cleansing include using hot water for handwashing, low relative humidity (most common in winter months in the northern hemisphere), failure to use supplementary hand lotion or cream, and perhaps the quality of paper towels[433,434]. Shear forces associated with wearing or removing gloves and allergy to latex proteins may also contribute to dermatitis of the hands of HCWs[430].

## 12.2 ALLERGIC CONTACT DERMATITIS RELATED TO HAND HYGIENE PRODUCTS

Allergic reactions to products applied to the skin (contact allergy) may present as delayed type reactions (allergic contact dermatitis) or less commonly as immediate reactions (contact urticaria). The most common causes of contact allergies are fragrances and preservatives, with emulsifiers being less common[435-438]. Liquid soaps, hand lotion, ointments or creams used by HCWs may contain ingredients that cause contact allergies[436,437].

Allergic reactions to antiseptic agents including quaternary ammonium compounds, iodine or iodophors, chlorhexidine, triclosan, chloroxylenol and alcohols[211,257,259,266,435,439-444] as well as possible toxicity in relation to dermal absorption of products[355,445] have been reported. Allergic contact dermatitis attributable to alcohol-based handrubs is very uncommon. Surveillance at a large hospital in Switzerland where a commercial alcohol-based handrub has been used for more than 10 years failed to identify a single case of documented allergy to the product[350]. In late 2001, a Freedom of Information Request for data in the FDA's Adverse Event Reporting System regarding adverse reactions to popular alcohol-based handrubs in the USA yielded only one reported case of an erythematous rash reaction attributed to such a product (J. M. Boyce, personal communication). However, with the increasing use of such products by HCWs, it is likely that true allergic reactions to such products will occasionally be encountered. There are a few reports of allergic dermatitis resulting from contact with ethyl alcohol[446-448] and one report of ethanol-related contact urticaria syndrome[258]. More recently, Cimiotti and colleagues reported adverse reactions associated with an alcohol-based handrub preparation. In most cases, nurses who had symptoms were able to resume use of the product after a brief hiatus[259]. This study raises the alert for possible skin reactions to alcohol-based handrub preparations.

Allergic reactions to alcohol-based formulations may represent true allergy to the alcohol, or allergy to an impurity or aldehyde metabolite, or allergy to another product constituent[257]. Allergic contact dermatitis or immediate contact urticarial reactions may be caused by ethanol or isopropanol[257]. Allergic reactions may be caused by compounds that may be present as inactive ingredients in alcohol-based handrubs, including fragrances, benzyl alcohol, stearyl or isostearyl alcohol, phenoxyethanol, myristyl alcohol, propylene glycol, parabens, or benzalkonium chloride[257,435,449-453].

## 12.3 METHODS TO REDUCE ADVERSE EFFECTS OF AGENTS

There are two primary strategies for minimizing hand hygiene-related irritant contact dermatitis among HCWs: selecting less irritating hand hygiene products and using moisturizing skin care products following hand cleansing.

### 12.3.1 SELECTING LESS IRRITATING PRODUCTS

Because HCWs must clean hands frequently, it is important for health-care facilities to provide products that are both efficacious and as safe as possible for the skin. The tendency of products to cause skin irritation and dryness is a major factor influencing their acceptance and ultimate use by HCWs[82,190,454-457]. For example, concern about the drying effects of alcohol was a major cause of poor acceptance of alcohol-based handrubs in hospitals[239,458]. Although many hospitals have provided HCWs with plain soaps in the hope of minimizing dermatitis, frequent use of such products has been associated with even greater skin damage, dryness and irritation than some antiseptic preparations[155,188,190]. One strategy for reducing exposure of HCWs to irritating soaps and detergents is to promote the use of alcohol-based handrubs containing humectants. Several studies have demonstrated that such

products are tolerated better by HCWs and are associated with a better skin condition when compared with either plain or antiseptic hand products[188,190,253,256,262,360,430,459,460]. With rubs, the shorter time required for hand antisepsis may increase acceptability and compliance[461]. In settings where the water supply is unsafe, waterless hand antisepsis presents additional advantages over soap and water[462].

### 12.3.2 REDUCING SKIN IRRITATION

Certain hand hygiene practices can also increase the risk of skin irritation and should be avoided. For example, routinely washing hands with soap and water immediately before or after using an alcohol-based product is not only unnecessary but may lead to dermatitis[463]. Additionally, donning gloves while hands are still wet from either washing or applying alcohol increases the risk of skin irritation. For these reasons, HCWs should be reminded not to wash their hands before or after applying alcohol and to allow their hands to dry completely before putting on gloves. A recent study demonstrated that HCW education regarding proper skin care management was effective in preventing occupational skin disorders[464]. No product, however, is free of potential risk. Hence, it is usually necessary to provide an alternative for use by individuals with sensitivity or reactions to the hand hygiene product available in the institution.

### 12.3.3 USE OF MOISTURIZING SKIN CARE PRODUCTS

The effects of hand hygiene products on skin vary considerably, depending upon factors such as the weather and environmental conditions. For example, in tropical countries and during the summer months in temperate climates, the skin remains more moisturized than in cold, dry environments. The effects of products also vary by skin type. In one recent study, nurses with darker skin were rated as having significantly healthier skin and less skin irritation than nurses with light skin, both by their own self-assessment as well as by observer rating[465]. Results of a prevalence survey of 282 Chinese hospital nurses suggested that hand dermatitis was less common among this group when compared with those in other parts of the world[466]. Hence, the need for moisturizing products will vary across health-care settings, geographical locations and respective climate conditions, and individuals.

For HCWs who are at risk of irritant contact dermatitis or other adverse reactions to hand hygiene products, additional skin moisturizing may be needed. Hand lotions and creams often contain humectants, fats and oils that increase skin hydration and replace altered or depleted skin lipids that contribute to the barrier function of the skin[429,467]. Several controlled trials have shown that regular use of such products can help prevent and treat irritant contact dermatitis caused by hand hygiene products[468-470]. Importantly, in the trial by McCormick and colleagues[469], improved skin condition resulting from frequent and scheduled use of an oil-containing lotion led to a 50% increase in hand cleansing frequency among HCWs. These investigators emphasized the need to educate HCWs regarding the value of regular, frequent use of hand-care products. However, most of the hand moisturizing agents are not sterile so may easily become contaminated, and have been associated with outbreaks in the neonatal ICU setting[471]. In particular, if the lotion is poured from a large bottle into smaller bottles, the smaller containers should be washed and disinfected between uses and not topped up.

Recently, barrier creams have been marketed for the prevention of hand hygiene-related irritant contact dermatitis. Such products are absorbed into the superficial layers of the epidermis and are designed to form a protective layer that is not removed by standard hand cleansing. Evidence of the efficacy of such products, however, is equivocal[468,469,472]. Furthermore, such products are expensive. Therefore, their use in health-care settings,

particularly when resources are limited, cannot be recommended at present. Whether the use of basic, oil-containing products, not specifically manufactured for hand skin protection, would have similar efficacy as currently available manufactured agents remains to be determined.

Frequent wearing of gloves can increase the risk of skin problems. In a study among healthy volunteers, when a moisturizer was applied prior to wearing occlusive gloves there was a statistically significant improvement in skin hydration[473]. More recently, an examination glove coated with aloe vera resulted in improved skin integrity and decreased erythema in 30 women with occupational dry skin[474]. Nevertheless, such products cannot yet be recommended because field trials, larger sample sizes and cost analyses are needed.

In addition to evaluating the efficacy and acceptability of hand-care products, product selection committees should inquire about potential deleterious effects that oil-containing products may have on the integrity of rubber gloves and on the efficacy of antiseptic agents used in the facility[13,417], as well as the fact that, as previously mentioned, most of these products are not sterile and can easily become contaminated.

## 13. FACTORS TO CONSIDER WHEN SELECTING HAND HYGIENE PRODUCTS

To achieve a high rate of hand hygiene adherence, HCWs need education, clear guidelines, and some understanding of infectious disease risk, and acceptable hand hygiene products[134,262,454,455,459,475-477]. The selection of hand cleansing agents is a key component of hand hygiene promotion, and at the same time a difficult task. The selection strategy requires the presence of a multidisciplinary team (e.g. infection control professionals, administrative staff, pharmacists and behavioural scientists) and efforts to evaluate factors related to hand cleansing agents and to conduct clinical pilot projects to test these factors[1,7,16,277,456,478] The major determinants for product selection are antimicrobial profile and user acceptance. The antimicrobial efficacy of hand hygiene agents is provided by *in vitro* and *in vivo* studies (see Part I, Section 8) which are reproducible and can be generalized. Pilot studies aiming to help select products at the local level should mainly concentrate on user acceptability issues. Other aspects such as tolerance, availability, storage and costs should also be addressed on a local basis to guarantee feasibility and sustainability.

### 13.1 PILOT TESTING

Pilot testing to assess acceptability is strongly recommended before final selection. Characteristics that can affect HCWs' acceptance of a hand hygiene product include dermal tolerance and skin reactions to the product, and its fragrance, consistency and colour[155,445,456]. Structured self-administered questionnaires may be useful tools to assess HCWs' acceptability of hand hygiene products. Such tools should be adapted to the local setting because of differences in sociocultural backgrounds, climate and environmental conditions, and clinical practices among users. For an efficient comparison, each product should be tested by different users for at least two to three weeks. Skin reactions to hand hygiene products may be increased by low relative humidity. Therefore, dry weather, e.g. during winter months in the northern hemisphere, should be taken into account during pilot testing; the introduction of new products during dry periods, with low relative humidity, should be avoided. Dryness and irritation should be assessed with sufficient numbers of HCWs to ensure that the results

can be generalized. Test products should be compared with products already in use. If more than one new product is to be tested, a period with the routine product should be observed between test periods. When considering the replacement of a product, the new product should be at least as good as the previous one. An inferior product could be responsible for a decrease in hand hygiene compliance. After careful evaluation of suitable hand hygiene agents, HCWs should be given the option to choose themselves the product for use at their institution. Freedom of choice at an institutional level was rated the second most important feature reported by HCWs to improve hand hygiene compliance in the audit of a successful promotion programme in Victoria, Australia.

Prior to product pilot testing, the appropriate administrative decision-makers in the institution should determine which products have demonstrated efficacy and which ones can be purchased at the best cost. Only products that have already been identified as efficacious and affordable should be tested by HCWs.

## 13.2 SELECTION FACTORS

Factors to be taken into consideration during user acceptability testing include:

- dermal tolerance and skin reactions;
- aesthetic preferences of HCWs and patients such as fragrance, colour, texture and ease of use;
- practical considerations such as availability, convenience and functioning of dispenser, and ability to prevent contamination;
- cost issues;
- global policy for the use of soap and alcohol-based handrubs;
- relative efficacy of antiseptic agents (Part I, Section 9.13) and consideration for selection of products for hygienic hand antisepsis and surgical hand preparation;
- freedom of choice by HCWs at an institutional level after consideration of the above-mentioned factors.

### 13.2.1 DERMAL TOLERANCE AND SKIN REACTIONS

Several studies have published methods to evaluate dermal tolerance such as dryness or irritation[155,430], either by self-assessment or by expert clinical evaluation[134,156,190,253,254,256,321,454,456,459,478,479]. Some studies have confirmed that these assessment techniques correlate well with other physiological measures such as transepidermal water loss or desquamation, tests which are not practical to use in clinical settings[190,253,321,430,459,478,479]. An example of a self-assessment tool for use in the clinical setting is included in Appendix 2[155,426].

### 13.2.2 AESTHETIC PREFERENCES

#### FRAGRANCE

Products with a strong fragrance may occasionally lead to discomfort and respiratory symptoms in some HCWs allergic to perfume or fragrances. Many patients complain about perfumed products, especially in oncology. Therefore, consideration should be given to selecting a product with mild or no added fragrances.

#### CONSISTENCY (TEXTURE)

Handrubs are available as gels, solutions or foams. Dermal tolerance and efficacy are not affected by consistency[140,479]. Although more expensive than solutions, gels have recently become the most popular type of alcohol-based handrub preparation in many countries. Gels have a better consistency than solutions and some may produce a feeling of humectant "build-up" with repeated use or may feel slippery or oily. This difference in consistency has not been associated with better objective tolerance or higher compliance with hand cleansing in a controlled study. First generations of gel formulation have reduced antimicrobial efficacy compared with solutions[141,153].

Solutions have a consistency similar to water; a few are more viscous. They often dry more quickly than gels or foams (a potential advantage) and may be less likely to produce a feeling of humectant "build-up". They are more likely to drip from the hands onto to the floor during use and these drips have created spots on the floor under the dispensers in some hospitals. Solutions often have a stronger smell of alcohol than gels, but dermal tolerance is similar for both[478,479].

Foams are used less frequently and are more expensive. They are less likely to drip from the hands onto the floor during application, but may produce stronger "build-up" feeling with repeated use. The manufacturer's instructions for use for some of the foam products recommend a fairly large amount of product, and HCWs should be reminded to follow the manufacturer's recommendation.

### 13.2.3 PRACTICAL CONSIDERATIONS

#### PRODUCT ACCESSIBILITY

Several studies suggest that the frequency of hand cleansing is determined by the accessibility of hand hygiene facilities[263,360,476,480-484]. A reliable supplier (industrial or local, at the health-care facility) is essential to ensure a continuous supply of products. If industrial products are not available or are too expensive, products may be produced within the local setting (see also Part I, Section 10). It is, however, difficult to regulate the quality control of locally made products, and methods to monitor quality are needed.

For handrubbing, dispensers should be available near to the point of care. The time required for an HCW to leave a patient's bedside, go to a sink, and wash and dry his/her hands before attending to the next patient is a deterrent to frequent hand cleansing[461,485]. In contrast to sinks used for handwashing, dispensers for alcohol-based handrubs do not require plumbing. They can be available next to each patient's bed and at many other points of patient care, such as in the hall between patients' rooms, at nurses' stations or near the medication preparation area. To avoid any confusion between soap and alcohol-based handrubs, alcohol dispensers should preferably not be placed adjacent to sinks. Alcohol-based handrub solutions carried in the pocket, together with bedside dispensers, have been associated with significant improvement in HCWs' adherence to hand cleansing protocols[262,263,486]. For handwashing, the soap dispenser should be placed next to the sink. Soap dispensers may become contaminated[487], and their design should allow easy decontamination. In some health-care facilities, only one sink is available in rooms housing several patients, or sinks are located far away from the entrance to the room or from the patient's bedside, and this situation may discourage hand cleansing by HCWs leaving the room[488]. In ICUs, access to sinks may be blocked by bedside equipment such as ventilators, intravenous infusion pumps, or other medical devices that take up space.

Automated handwashing machines have been tested by several investigators, usually for the purpose of improving the quality and the frequency of hand cleansing, but they have not demonstrated a sustainable improvement in hand hygiene practices[152,482]. Although technologically advanced automated devices and monitoring systems have recently been developed[489], there is no published evidence demonstrating that the use of such devices results in sustained improvements in hand hygiene. In addition, these machines are quite expensive.

#### DISPENSER SYSTEMS

Dispenser systems provided by manufacturers or vendors also need to be considered when evaluating hand hygiene products. Dispensers that become blocked or partially blocked may discourage use if they do not deliver the product when accessed by HCWs or do not deliver it accurately. In one hospital where a viscous alcohol-based handrub was available, only 65% of functioning dispensers delivered the product at one press of the dispenser lever, and 9% of dispensers were totally occluded[490]. In addition, the volume delivered was often sub-optimal, and the product sometimes squirted onto the wall instead of into the HCWs' hands. Dispensers that are inconveniently located are unlikely to be used.

#### RISK OF CONTAMINATION

Alcohol-based rubs have a low risk of contamination[265], but soap contamination is very frequent[101,491-495]. Multiple-use bar soap should be avoided because it is difficult to store bar soap dry at a sink, with subsequent increase in the risk of contamination[491-493]. Although liquid soaps are generally preferred over bar soaps for handwash, the risk for either intrinsic[494] or extrinsic[101,495] microbial contamination still exists.

### 13.2.4 COST

The promotion of hand hygiene is highly cost effective (see Part III, Section 3), and the introduction of a waterless system for hand cleansing is a cost-effective measure[256,496,497]. While the cost of hand hygiene products will continue to be an important issue for departments responsible for purchasing such products, the level of acceptance of products by HCWs is even more important. An inexpensive product with undesirable characteristics may discourage hand hygiene among HCWs and the resulting poor compliance will not be cost effective.

Financial strategies to support programmes designed to improve hand hygiene across a nation may benefit from a centralized design and production of supporting materials. This strategy may be more cost effective to the overall health economy (see also Part III, Section 3).

# 14. HAND HYGIENE PRACTICES AMONG HEALTH-CARE WORKERS AND ADHERENCE TO RECOMMENDED PRACTICES

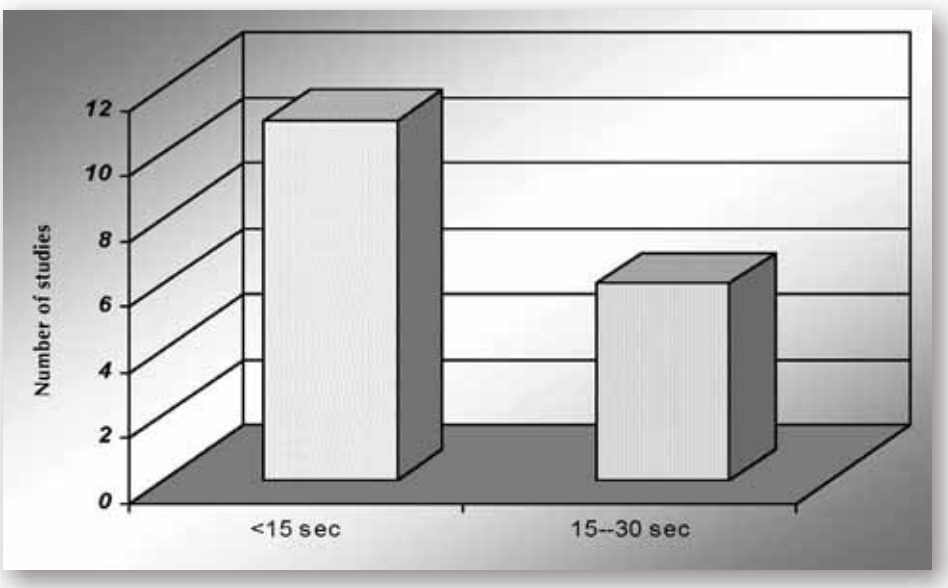
## 14.1 HAND HYGIENE PRACTICES AMONG HEALTH-CARE WORKERS

Understanding hand hygiene practices among HCWs is essential in planning interventions in health care. In observational studies conducted in hospitals, HCWs cleaned their hands on average from five times to as many as 30 times per shift (Table I.14.1)[35,82,154,190,454,498]. The average frequency of hand hygiene episodes fluctuates with the observed compliance and the setting where the observations were made, and ranges from 0.7 to 12 episodes per hour (Table I.14.1). On the other hand, the average number of opportunities for hand hygiene per HCW varies markedly between hospital wards; nurses in paediatric wards, for example, had an average of eight opportunities for hand hygiene per hour of patient care, compared with an average of 22 opportunities for nurses in ICUs[485]. In some acute clinical situations, the patient is cared for at the same time and, on average, as many as 82 hand hygiene opportunities per patient per hour of care have been observed at post-anaesthesia care unit admission[499]. The number of opportunities for hand hygiene depends largely on the process of care provided: revision of protocols for patient care may reduce unnecessary contacts and, consequently, hand hygiene opportunities.

In 17 observational studies, the duration of hand cleansing episodes by HCWs ranged on average between as little as 6.6 seconds and 30 seconds. In 16 of these studies, the hand hygiene technique used was handwashing[35,70,80,148-151,153,426,457], and handrubbing was used in one study[342] (Figure I.14.1). In addition to washing their hands for very short time periods, HCWs often failed to cover all surfaces of their hands and fingers[498].

In summary, the frequency of hand hygiene opportunities per hour of care may be very high, and despite the hand hygiene compliance rate, the applied technique may fail.

***Figure I.14.1 Average duration of hand cleansing by health-care workers***




Sources: [35,70,80,148-151,153,342,426,457].

## 14.2 OBSERVED ADHERENCE TO HAND CLEANSING

Adherence of HCWs to recommended hand hygiene procedures has been unacceptably poor, with mean baseline rates ranging from 5% to 81%, with an overall average of about 40% (Table I.14.2)[150,151,261-263,359,360,459,475,476,480,482,500-534]. It should be pointed out that the methods for defining adherence (or non-adherence) and the methods for conducting observations varied considerably in the reported studies, and many articles did not include detailed information about the methods and criteria used. Some studies assessed compliance with hand hygiene concerning the same patient[261,262,499,507,508,525,527-529,531], and few evaluated hand hygiene compliance after contact with the environment related to the patient[261,262,499,511,524,525,528,529,531]. A number of investigators reported improved adherence after implementing various interventions, but most studies had short follow-up periods and did not establish if improvements were of long duration. Few studies[262,535,536] proved that sustained improvements occurred during a long-term programme to improve adherence to hand hygiene policies.

## 14.3 FACTORS AFFECTING ADHERENCE

Factors that may influence hand hygiene include risk factors for non-adherence identified in epidemiological studies and reasons reported by HCWs for lack of adherence to hand hygiene recommendations.

Risk factors for poor adherence to hand hygiene have been determined objectively in several observational studies or interventions to improve adherence[454,485,504,507,537-542]. Among these, being a doctor or a nursing assistant, rather than a nurse, was consistently associated with reduced adherence. In addition, compliance with hand cleansing may vary among doctors from different specialties[263]. Table I.14.3 lists the major factors identified in observational studies of hand hygiene behaviour in health care.

In the largest survey conducted so far[485], the investigators identified hospital-wide predictors of poor adherence to recommended hand hygiene measures during routine patient care. Predicting variables included professional category, hospital ward, time of day/week, and type and intensity of patient care, defined as the number of opportunities for hand hygiene per hour of patient care. In 2834 observed opportunities for hand hygiene, average adherence was 48%. In multivariate analysis, non-adherence was the lowest among nurses compared with other HCWs and during weekends. Non-adherence was higher in ICUs compared with internal medicine, during procedures that carried a high risk of bacterial contamination, and when intensity of patient care was high. In other words, the higher the demand for hand hygiene, the lower the adherence. The lowest adherence rate (36%) was found in ICUs, where indications for hand hygiene were typically more frequent (on average, 20 opportunities per patient-hour). The highest adherence rate (59%) was observed in paediatrics, where the average intensity of patient care was lower than elsewhere (on average, eight opportunities per patient-hour). The results of this study suggest that full adherence to previous guidelines may be unrealistic and that easy access to hand hygiene could help improve adherence[461,485,537]. Recent studies have confirmed an inverse relation between intensity of patient care and adherence to hand hygiene[263,499,543].

Perceived barriers to adherence with hand hygiene practice recommendations include skin irritation caused by hand hygiene agents, inaccessible hand hygiene supplies, interference with HCW–patient relationships, patient needs perceived as a priority over hand hygiene, wearing of gloves, forgetfulness, lack of knowledge of guidelines, insufficient time for hand hygiene, high workload and understaffing, and the lack of scientific information showing a definitive impact of improved hand hygiene on HCAI rates[454,485,504,507,539-541,544]. Some of the perceived barriers to adherence with hand hygiene guidelines have been assessed or

quantified in observational studies[454,504,507,537,539-541]. Table I.14.3 lists the most frequently reported reasons that are possibly, or effectively, associated with poor adherence. Some of these barriers are discussed in Part I, Section 13 (i.e. skin irritation, easy access to hand hygiene supplies), and in Part I, Section 20.1 (i.e. impact of use of gloves on hand hygiene practices).

Lack of knowledge of guidelines for hand hygiene, lack of recognition of hand hygiene opportunities during patient care, and lack of awareness of the risk of cross-transmission of pathogens are barriers to good hand hygiene practices. Furthermore, some HCWs believed that they washed their hands when necessary even when observations indicated that they did not[153,155,507,508,518,545].

Additional perceived barriers to hand hygiene behaviour are listed in Table I.14.3. These are relevant not only to the institution but also to the HCW's own particular group. Therefore, both institutional and small group dynamics need to be considered when implementing a system change to secure an improvement in HCWs' hand hygiene practices.

## 15. RELIGIOUS AND CULTURAL ASPECTS OF HAND HYGIENE

There are several reasons why religious and cultural issues should be considered when dealing with the topic of hand hygiene and planning a strategy to promote it in health-care settings. The most important reason is that these guidelines, as a WHO document, are intended to be disseminated all over the world and in settings where very different cultural and religious beliefs may strongly influence their implementation. Well-known examples already exist of health interventions where the religious point of view had a critical impact on, if not interfered with, their implementation. The topic is so vast that this section cannot be considered exhaustive. This is also the reason why, intentionally, only the main religions have been considered. These include Christianity, which counts almost 2.2 billion followers in 238 countries around the world, Islam with almost 1.3 billion followers in 232 countries, Hinduism with 851 million in 166 countries and Buddhism with 375 million in 130 countries. Ethno-religion, which is made up of the followers of local, tribal, animistic or shamanistic religions, with members restricted to one ethnic group, has 253 million adherents worldwide spread over 144 countries. Other religions considered include Sikhism which has almost 25 million adherents worldwide in 34 countries, and Judaism with 15 million adherents in 134 countries[546].

These reflections should be considered to be very much as a work in progress, particularly since they will undoubtedly be revisited during the implementation phase of the guidelines at country level. The aim of this section is to explore and propose comments on this innovative topic, in order to suggest considerations and possible solutions to health-care providers dealing with hand hygiene in settings where the practice may be strongly influenced by religious and cultural factors. As regards hand hygiene in health care, this is an entirely unexplored speculative area; it has been difficult to find information about cultures in which hand hygiene has a particular meaning or impact, whereas the investigation has been more fruitful concerning religious aspects.

Philanthropy, generally inherent in any faith, has often been the motivation for establishing a relationship between the mystery of life and death, medicine and health care. This predisposition has often led to the establishment of health-care institutions under religious affiliations. Faith and medicine have always been integrated into the healing process as many

priests, monks, theologians and others inspired by religious motivations studied, researched and practised medicine. In general, religious faith has often represented an outstanding contribution to highlighting the ethical implications of health care and to focusing the attention of health-care providers on both the physical and spiritual natures of human beings.

References to the importance of physical health exist in several holy texts, prayers and prophets' teachings. For instance, one of the most authoritative Jewish rabbis was an excellent champion of personal hygiene and taught his disciples "to take a lot of care of their body". Similarly, Hindu worship services commonly end with the prayer "may all be free from disease" (*sarve santu niramayah*).

The effects of religion on health are also being investigated by a specific branch of research[547] which implies several methodological issues but, to the best of our knowledge, the topic of hand hygiene has never been considered until now.

In the increasingly multicultural, globalized community that is health-care provision today, cultural awareness has never been more crucial for implementing good clinical practice in keeping with scientific developments. Immigration and travel are more common and extensive than ever before, as a result of the geopolitically active forces of migration, asylum-seeking and, in Europe, the existence of a broad, borderless multistate Union. With the increasingly diverse populations accompanying these changes, very diverse cultural beliefs are also more prevalent than ever. This evolving cultural topography demands new, rapidly acquired knowledge and highly sensitive, informed insights of these differences, not only among patients but also among HCWs who are subject to the same global forces.

It is clear that cultural – and to some extent, religious – factors strongly influence attitudes to inherent community handwashing which, according to behavioural theories (see Part I, Section 16), are likely to have an impact on compliance with hand cleansing during health care.

In general, the degree of HCWs' compliance with hand hygiene as a fundamental infection control measure in a public health perspective may depend on their belonging to a community, rather than to an individual-oriented society. The existence of a wide awareness of everyone's contribution to the common good, such as health of the community, may certainly foster HCWs' propensity to adopt good hand hygiene habits. For instance, hand cleansing as a measure of preventing the spread of disease is clearly in harmony with the fundamental Hindu value of non-injury to others (*ahimsa*) and care for their well-being (*daya*).

Another interesting aspect may be to evaluate optional methods of hand cleansing which exist in some cultures according to deep-seated beliefs or available resources. As an example, in the Hindu culture, hands are rubbed vigorously with ash or mud and then rinsed with water. The belief behind this practice is that soap should not be used as it contains animal fat. If water is not available, other substances such as sand are used to rub the hands. In a scientific study performed in Bangladesh to assess faecal coliform counts from post-cleansing hand samples, hand cleansing with mud and ash was demonstrated to be as efficient as with soap[548].

In addition to these general considerations, some specific issues to be investigated in a transcultural and transreligious context are discussed.

## 15.1 HAND HYGIENE IN DIFFERENT RELIGIONS

Personal hygiene is a key component of human well-being regardless of religion, culture or place of origin. Human health-related behaviour, however, results from the influence of multiple factors affected by the environment, education and culture.

According to behavioural theories (see Part I, Section 16), hand cleansing patterns are most likely to be established in the first ten years of life. This imprinting subsequently affects the attitude to hand cleansing throughout life, in particular regarding the practice called "inherent hand hygiene"[542] which reflects the instinctive need to remove dirt from the skin. The attitude to handwashing in more specific opportunities is called "elective handwashing practice"[542] and may much more frequently correspond to some of the indications for hand hygiene during health-care delivery.

In some populations, both inherent and elective hand hygiene practices are deeply influenced by cultural and religious factors. Even though it is very difficult to establish whether a strong inherent attitude towards hand hygiene directly determines an increased elective behaviour, the potential impact of some religious habits is worth considering.

When considering behaviour related to personal hygiene, religious affiliations can be classified into three categories: (i) those where norms governing hand hygiene are detailed precisely in several moments throughout daily and ritual life; (ii) those where hand aspersion is indicated only on the occasion of ritual events; and (iii) those where no explicit attention is paid to personal or hand hygiene. Hand hygiene can therefore be practised for hygienic reasons, regardless of whether dirt is actually present or visible; for ritual reasons, as part of the gestures during religious ceremonies; and for symbolic reasons, in specific everyday life situations.This kind of classification is identified in Table I.15.1. Judaism, Islam and Sikhism, for example, have precise rules for handwashing included in the holy texts and this practice punctuates several crucial moments of the day. Therefore, a serious practising believer is a careful observer of these indications. Nevertheless, it is well known that in some cases, such as with Judaism, religion underlies the very culture of the population in such a way that the two concepts become almost indistinguishable. As a consequence of this, even those who do not consider themselves strong believers behave according to religious principles in everyday life. However, it is very difficult to establish if inherent[542] and elective[542] behaviour in hand hygiene, deep-seated in some communities, may influence HCWs' attitude towards hand cleansing during health-care delivery. It is likely that those who are used to caring about hand hygiene in their personal lives are more likely to be careful in their professional lives as well, and to consider hand hygiene as a duty to guarantee patient safety. In the Sikh culture for instance, hand hygiene, besides being a holy act, is also an essential element of daily life. Sikh people would always wash their hands properly with soap and water before dressing a cut or a wound. This behaviour is obviously expected to be adopted by HCWs during patient care. A natural expectation, such as this one, could also facilitate patients' ability to remind the HCW to clean their hands without creating the risk of compromising their mutual relationship.

Of the five basic tenets of Islam, observing regular prayer five times daily is one of the most important. Personal cleanliness is paramount to worship in Islam. Muslims must perform methodical ablutions before praying and explicit instructions are given in the Qu'ran as to precisely how washing should be carried out. Ablutions must be made in freely running (not stagnant) water and involve washing the hands, face, forearms, ears, nose, mouth and feet, three times each. Additionally, hair must be dampened with water. Thus, every observant Muslim is required to maintain scrupulous personal hygiene at five intervals throughout the day, aside from his/her usual routine of bathing as specified in the Qu'ran. These habits transcend Muslims of all races, cultures and ages, emphasizing the importance ascribed to correct ablutions.

*"O you, who believe! When you intend to offer As-salat (the prayer), wash your face and your hands (forearm) up to the elbows, rub (by passing wet hands over) your heads*

*and (wash) your feet up to the ankles … then make ablution at the time of each prayer" (chapter 6, Almaidah, verse 6).*

Apart from the Qu'ran, other references also exist to guide Muslims. The way in which the Prophet Mohammed conducted his life is documented in a body of literature, the ***Hadith*** and the ***Sunna***, and provide additional observations regarding both the emphasis given to personal hygiene within Islam, and the specific prominence of hand hygiene. The Prophet Mohammed always urged Muslims to wash hands frequently and especially after some clearly defined tasks (Table I.15.1)[549]. Hence, from the dawn of Islam, strict observation of hand hygiene with freely running water has been advocated for all Muslims, whatever their occupation.

Unfortunately, the above-mentioned hypothesis that community behaviour influences HCWs' professional behaviour has been corroborated by scanty scientific evidence until now (see also Part I, Section 16). In particular, no data are available on the impact of religious norms on hand hygiene compliance in health-care settings where religion is very deep-seated. This is a very interesting area for research in a global perspective, because this kind of information could be very useful in identifying the best components of a programme for hand hygiene promotion. It could be established that in some contexts emphasizing the link between religious and health issues may be very advantageous. An assessment survey, moreover, may also show that in populations with a high religious observance of hand hygiene, compliance with hand hygiene in health care will be higher than in other settings and, therefore, does not need to be further strengthened or, at least, education strategies should be oriented towards different aspects of hand hygiene and patient care.

With the exceptions of ritual hand aspersion before the consecration of bread and wine, and of the cleansing of hands after touching the holy oil (the latter only in the Catholic Church), the Christian faith seems to belong to the third category of the above classification regarding hand hygiene behaviour. It must be highlighted that there are some episodes of Christ's life where the act of hand cleansing apparently had negative connotations. Jesus criticized the Pharisees and scribes for their strict compliance with the ritual of washing hands before meals (Matthew 15:2, 20). It is important to understand that this is a symbolic criticism, in order to refer to the priority given to interior purity as opposed to exterior appearance. Similarly, the negative meaning given to Pilate's act of washing hands to refer to his innocence has to be interpreted in a symbolic manner (Matthew 27:24). In general, the indications given by Christ's example refer more to behaviour in a Christian's spiritual life than in everyday life and are aimed to free believers from those formal and repetitive acts that do not always reflect interior purity. The emphasis on this specific point of view does not imply, though, that personal hygiene and body care are not important in the Christian way of life.

Similarly, specific indications regarding hand hygiene are nonexistent in the Buddhist faith. No mention is made of hand cleansing in everyday life, nor during ritual occasions. According to Buddhist habits, only two examples of pouring water over hands can be given, both with symbolic meaning. The first is the act of pouring water on the hands of the dead before cremation in order to demonstrate forgiveness to each other, between the dead and the living. The second, on the occasion of the New Year, is the young person's gesture of pouring some water over the hands of elders to wish them good health and a long life.

In some African countries (e.g. Ghana and some other West African countries) hand hygiene is commonly practised in specific situations of daily life according to some ancient traditions. For instance, hands must always be washed before raising anything to one's lips. In this regard, there is a local proverb: "when a young person washes well his hands, he eats with the elders". Furthermore, it is customary to provide facilities for hand aspersion (a bowl

of water with special leaves) outside the house door to welcome visitors and to allow them to wash their face and hands before even enquiring the purpose of their visit.

## 15.2 THE CONCEPT OF "VISIBLY DIRTY" HANDS

Both the CDC guidelines and the present WHO guidelines recommend that HCWs wash their hands with soap and water when visibly soiled and that they clean their hands with an alcohol-based rub at all other opportunities for hand hygiene during patient care.

Infection control practitioners have already experienced difficulties to define precisely the meaning of "visibly dirty" and to give practical examples while schooling HCWs in hand hygiene practices. In a transcultural perspective, it could be increasingly difficult to find a common understanding of this term. In fact, actually seeing dirt on hands can be impeded by the colour of the skin: it is, for example, more difficult to see a spot of blood or other proteinaceous material on very dark skin. Furthermore, in some very hot and humid climates, the need to wash hands with fresh water may also be driven by the feeling of having sticky or humid skin.

According to some religions, the concept of dirt is not strictly visual, but reflects a wider meaning which refers to interior and exterior purity. In some cultures, it may be difficult to train some HCWs to limit handwashing with soap and water to some rare situations only. For instance, external and internal cleanliness is a scripturally enjoined value in Hinduism, consistently listed among the cardinal virtues in authoritative Hindu texts *(Bhagavadgita, Yoga Shastra of Patanjali*).

Furthermore, in the Jewish religion, the norm of washing hands immediately after waking in the morning refers to the fact that during the night, which is considered one sixtieth of death, hands may have touched an impure site and therefore implies that dirt can be invisible to the naked eye.

Therefore, the concept of dirt does not refer only to situations in which it is visible. This understanding among HCWs may produce a further need to wash hands when they feel themselves to be impure and this may be an obstacle to the use of alcohol-based handrubs.

From a global perspective, the above considerations highlight the importance of making every possible effort to consider the concept of "visibly dirty" in accordance with racial, cultural and environmental factors, and to adapt it to local situations while promoting hand hygiene with the appropriate implementation strategy.

## 15.3 HAND GESTURES

Hand use and specific gestures take on considerable significance in certain cultures. The most common popular belief about hands, for instance in the African, Jewish and Hindu cultures, is to consider the left hand as being solely used for anything judged dirty. It is thought inappropriate to use the left hand for giving, receiving or eating, for pointing at something or when gesticulating in some way. It is indeed culturally imperative to use the right hand to perform these acts.

In the Sikh culture a specific cultural meaning is given to the habit of folding hands together as a way of greeting, as well as in prayer.

There are many hand gestures in Mahayana and Tibetan Buddhism. In Theravada Buddhist countries, putting two hands together shaped like a lotus flower is representative of the flower offered to pay respect to the Buddha, *Dhamma* (teaching) and *Sangha* (monk). Walking clockwise around the relic of the Buddha or stupa is also considered to be a proper

and positive form of respect towards the Buddha. When wiping alcohol across any part of the body before a vaccination, it is thus good to wipe the alcohol-imbibed cotton in a clockwise direction, as opposed to no specific direction. Washing hands in a clockwise movement is suggested and goes well with the positive manner of cheerful and auspicious occasions.

The reason for mentioning hand gestures in this section is primarily because of the potential advantage of considering specific gestures to be represented in pictorial images for educational purposes in different cultures. In fact, in multimodal campaigns to promote hand hygiene, posters placed in crucial points in health-care settings have been shown to be very effective tools for reminding HCWs to wash their hands. The effort of taking into account specific hand uses and gestures according to local habits in these posters and other promotional products may certainly help to convey the intended message more effectively.

## 15.4 PROHIBITION OF ALCOHOL USE

In order to optimize HCWs' compliance with hand hygiene and eventually reduce the burden of HCAI through the present guidelines, WHO promotes the use of hygienic handrubbing with an alcohol-based solution in health care, instead of handwashing with soap and water, in settings where this is feasible. According to scientific evidence arising from efficacy and cost–effectiveness, alcohol-based handrubs are currently considered the gold standard approach. For this purpose, WHO is recommending specific formulations to prepare alcohol-based solutions which will be tested for feasibility at country level, taking into consideration production, distribution and cost issues (see also Part I, Section 10).

According to some religions, alcohol use is prohibited or considered an offence requiring a penance (Sikhism), because it is considered to cause mental impairment (Hinduism, Islam). As a result, the adoption of alcohol-based formulations as the gold standard for hand hygiene may be unsuitable or inappropriate for some HCWs, either because of their reluctance to have contact with alcohol, or because of their concern about alcohol ingestion or absorption via the skin. Even the simple denomination of the product as an "alcohol-based formulation" could become a real obstacle in the implementation of WHO recommendations.

In some religions and even within the same religious affiliation, various degrees of interpretation exist concerning alcohol prohibition. According to some other faiths, on the contrary, the problem does not exist (Table I.15.1). In general, despite alcohol prohibition in everyday life, most religions give priority to health principles, and a pragmatic view of care is followed by the acceptance of the most valuable approach, in the perspective of the optimal delivery of care. Consequently, no objection is raised against the use of alcohol-based products for environmental cleaning, disinfection, or hand hygiene. This is the most common approach in the case of faiths such as Sikhism and Hinduism. For example, in a fundamental Hindu textbook, the *Shantiparvan*, it is explicitly stated that it is not sinful to drink alcohol for medicinal purposes.

In Buddhism, obstacles to the use of alcohol in health care are certainly present, from a completely different perspective. According to the Law of *kamma*, the act or the intention to kill living creatures is considered an unskilful act or even a sin. As microorganisms are living beings, killing them with an alcohol-based handrub may lead to demerit. According to Expositor (1:128), the five conditions for the act of killing are: a living being, knowledge that it is a being, intention of killing, effort and consequent death. Nevertheless, considering that HCWs for the most part have good intentions in doing what they do, namely to protect patients from pathogen transmission, the result of this unskilful action does not bear heavy consequences. Therefore, when comparing a human patient's life with a bacterium's life, most people adhering to the Buddhist *kamma* agree that a patient's life is more valuable.

Furthermore, according to Phra Depvethee, a Thai Buddhist monk and scholar, the consequences of killing depends on the size and good contribution of that being[550].

The tradition posing the toughest criticism to alcohol use is the Islamic one. Fortunately, this is also the only context where reflection on alcohol use in health care has begun.

Alcohol is clearly designated as ***haram*** (forbidden) in Islam because it is a substance leading to ***sukur***, or intoxication leading to an altered state of mind. For Muslims, any substance or process leading to a disconnection from a state of awareness or consciousness (a state in which she or he may forget her or his Creator) is called ***sukur***, and this is ***haram***. For this reason, an enormous taboo has become associated with alcohol for all Muslims. Some Muslim HCWs may undoubtedly feel that applying alcohol-containing solutions to their hands may specifically defile their own cleanliness, because they think they have touched a spiritually unclean, ***haram*** substance. Most Muslims understand that abstinence from alcohol can have significant benefits on health, but what many overlook is that alcohol as a medicinal agent is clearly permitted within Islam. Indeed, any substance that man can manufacture or develop in order to alleviate illness or contribute to better health is permitted by Islam. In this context, the substance is not being used as an agent of ***sukur***. Thus, cocaine is permitted as a local anaesthetic (***halal***, allowed) but is inadmissible as a recreational drug (***haram***, forbidden).

In an effort to understand Muslim HCWs' attitudes to alcohol-based hand cleansers in an Islamic country, the experience at the King Abdul Aziz Medical Center (KAAMC) in Riyadh, Kingdom of Saudi Arabia, is very instructive. At the KAAMC, the policy of using alcohol handrub is not only permitted, but has been actively encouraged in the interest of infection control since 2003. No difficulties or reluctance were encountered in the adoption of alcohol-containing hand hygiene substances. Though Saudi Arabia is the custodian of the holy sites of both Mecca and Medina and considered to be the historic epicentre of Islam, no state policy or permission was sought in implementing alcohol-based hand hygiene solutions.

It is worth noting that most of the HCWs at KAAMC and elsewhere in the entire Kingdom are in fact expatriate citizens; they are often not practising Muslims or, if Muslim, are highly westernized. Therefore the KAAMC experience with alcohol-containing handrub agents may not reflect the indigenous response of other, less westernized, Muslim HCWs encountered in facilities in other countries. Because of the diverse nationalities and the very westernized sensibilities among many of the Muslim staff at KAAMC, compliance difficulties relating to the alcohol-based handrubs were less of a problem than anticipated by colleagues working in the region. Indeed, no other hospital in the Kingdom, or indeed in the Gulf, has reported any inability to comply because of religious beliefs. This regional, albeit anecdotal, experience leading to acceptance is encouraging and demonstrates well that alcohol-containing handrub solutions are indeed acceptable to many Muslim HCWs. Western attitudes to the medicinal benefits of alcohol, coupled with a compassionate interpretation of Qu'ranic teachings, have resulted in a readiness to adopt new hand hygiene policies, even within an Islamic Kingdom which is legislated by ***Sharia*** (Islamic law). Interestingly, KAAMC did not seek a ***fatwa*** (Islamic religious edict) for approval of the use of alcohol-containing handrubs, given that alcohol has long been a component present in household cleaning agents and other materials for public use, including perfume, without legislated restriction within the Kingdom. In all these instances, the alcohol content is permitted because it is not for ingestion.

It is clear that further assessment is required regarding the absorption of alcohol from applying topical alcohol-based handrub. At present, data on this issue are limited. Quantitative studies may provide much needed reassurance to the Muslim HCWs who may be currently

reluctant to accept scientific recommendations in place of what they believe are superseding spiritual decrees.

Considering the issues discussed above, possible solutions and areas for further research may be identified.

At the beginning of a process promoting a new HCAI prevention tool, such as alcohol-based handrubs, on a large scale, WHO intends to denominate these products prudently as antiseptic or disinfectant handrubs, avoiding the use of the term alcohol, especially in settings where the observance of related religious norms is very strict.

While preparing guidelines, international and local religious authorities should be consulted and their advice clearly reported. For instance, it would be worthwhile referring to the recent statement of the Muslim Scholar Board of the World Muslim League, which declared: "It is allowed to use medicines that contain alcohol in any percentage that may be necessary for manufacturing, if it cannot be substituted. Alcohol may be used as an external wound cleanser, to kill germs and in external creams and ointments".

Within hand hygiene promotion campaigns in health-care settings where Muslims or other religious affiliations refusing the use of alcohol are strongly represented, education strategies should include focus groups on this topic to facilitate HCWs to raise their concerns openly regarding the use of alcohol-based handrubs, to understand the scientific evidence underlying this recommendation and to identify possible solutions to overcome the related religious and cultural obstacles. The results of this discussion may subsequently be summarized as "issues and solutions" in information leaflets to be produced and distributed locally.

Alcohol skin absorption and its smell are additional perceptive barriers to the use of alcohol-based handrubs. Serious concerns have been expressed about the potential systemic diffusion of alcohol or its metabolites following dermal absorption or airborne inhalation related to the use of alcohol-based handrub formulations. Currently available scientific data are unfortunately limited, even though some published[355] and unpublished but reliable (A. Kramer, personal communication, 2005) investigations clearly demonstrate that the quantity of alcohol absorbed in these situations is minimal and well below toxic levels for human beings. More consistent information is required on this topic and further research should be undertaken to eliminate the alcohol smell from handrub preparations. Both WHO solutions may provide much needed reassurance to HCWs who may be reluctant to 'trade' scientific recommendations for their beliefs in overriding spiritual decrees.

Finally, the opportunity to involve patients in a multimodal strategy to promote hand hygiene in health care should be carefully evaluated. Despite its potential value, this intervention may be premature in settings where religious norms are taken literally; rather, it could be a subsequent step, following the achievement of awareness and compliance among HCWs.

# 16. BEHAVIOURAL CONSIDERATIONS

## 16.1 SOCIAL SCIENCES AND HEALTH BEHAVIOUR

Hand hygiene behaviour varies significantly among HCWs within the same institution or unit[485], thus suggesting that individual features could play a role in determining behaviour. Social psychology attempts to understand these features, and individual factors such as social cognitive determinants may provide additional insight on hand hygiene behaviour[541,551,552].

### 16.1.1 SOCIAL COGNITIVE VARIABLES

Over the last quarter of the 20th century, it was stated that social behaviour could be best understood as a function of people's perceptions rather than as a function of real life (objective facts, etc.)[553]. This assumption gave birth to several models which were based on social cognitive variables and tried to better understand human behaviour. The determinants that shape behaviour are acquired through the socialization process and, more importantly, are susceptible to change – for which reason they are the focus of behavioural models. In other areas of health-care promotion, the application of social cognitive models in intervention strategies has regularly resulted in a change towards positive behaviour[553]. Some of the so-called "social cognitive models" applied to evaluate predictors of health behaviour include: Health Belief Model (HBM); Health Locus of Control (HLC); Protection Motivation Theory (PMT); Theory of Planned Behaviour (TPB); and Self-efficacy Model (SEM). The cognitive variables used in these models are:

- knowledge;
- motivation;
- intention: a person's readiness to behave in a given way, which is considered to be the immediate antecedent of behaviour;
- outcome expectancy: an individual's expectation that a given behaviour can counteract or increase a threat and how one perceives the threat;
- perception of threat is based on the perceived risk/susceptibility and the perceived severity of the consequences;
- perceived behavioural control (self-efficacy): the perception that performance of a given behaviour is within one's control;
- subjective norm: beliefs about the expectations of an important referent towards a given behaviour[553,554];
- behavioural norm: an individual's perception of the behaviour of others[555]. Subjective and behavioural norms represent the perceived social pressure towards a certain behaviour.

### 16.1.2 MODELLING HUMAN BEHAVIOUR

Current models and theories that help to explain human behaviour, particularly as they relate to health education, can be classified on the basis of being directed at the individual (intrapersonal), interpersonal, or community levels. The social cognitive models mentioned above deal with intrapersonal and interpersonal determinants of behaviour. Among the community-level models, the theory of Ecological Perspective (also referred to as the Ecological Model of Behavioural Change) can successfully result in behavioural change. This theory is based on two key ideas: (i) behaviour is viewed as being affected by and affecting mul-

tiple levels of influence; and (ii) behaviour both influences and is influenced by the social environment. Levels of influence for health-related behaviour and conditions include intrapersonal (individual), interpersonal, institutional and community factors[556].

Intrapersonal factors are individual characteristics that influence behaviour such as knowledge, attitudes, beliefs and personality traits.These factors are contained in social cognitive determinants[553].

Interpersonal factors include interpersonal processes and primary groups, i.e. family, friends and peers, who provide social identity, support and role definition. HCWs can be influenced by or are influential in their social environments. Behaviour is often influenced by peer group pressure, which indicates that responsibilities for each HCW's individual group should be clearly recognized and defined.

Community factors are social networks and norms that exist either formally or informally between individuals, groups and organizations. For example, in the hospital, the community level would be the ward[556]. Community-level models are frameworks for understanding how social systems function and change, and how communities and organizations can be activated. The conceptual framework of community organization models is based on social networks and support, focusing on the active participation and development of communities that can help evaluate and solve health problems. Public policy factors include local policies that regulate or support practices for disease prevention, control and management.

### 16.1.3 APPLICATION OF SOCIAL SCIENCES TO THE INFECTION CONTROL FIELD

Few studies have applied social sciences to assess HCWs' behaviour related to infection control practices. Seto identified three fields of study in the behavioural sciences with some degree of relevance to the field of infection control: social psychology, organizational behaviour and consumer behaviour[551]. By applying a basic concept from each field, Seto and colleagues demonstrated the potential value of these theories to achieve staff compliance with different infection control policies in the hospital[551,556,557].

Social cognitive models have been applied to evaluate HCWs' cognitive determinants towards hand hygiene behaviour[263,543,544,558,559] and are discussed in the next section (Part I, Section 16.2).

Curry & Cole[560] applied the theory of Ecological Perspective and reported their experience in the medical and surgical ICUs in a large teaching hospital experiencing an increased patient colonization rate with VRE. Their intervention consisted of a multifaceted approach to the problem, considering the five levels of influence (individual, interpersonal, institutional, community and administrative factors). They implemented in-service education and developed references, policies and programmes directed at each of the five levels of influence. The Health Belief Model was employed for assessment of beliefs and intervention design. The authors observed a significant decrease in the number of patients with active surveillance cultures or clinical isolates positive for VRE within six months in both ICUs, and the benefit seemed to persist even two years later.

## 16.2 BEHAVIOURAL ASPECTS OF HAND HYGIENE

The inability over two decades to motivate HCW compliance with hand cleansing[539,561] suggests that modifying hand hygiene behaviour is a complex task. Human health-related behaviour is the consequence of multiple influences from our biology, environment, education and culture. While these influences are usually interdependent, some have more effect than others; when the actions are unwise, they are usually the result of trade-offs with acknowledged or denied consequences. Thus, this complexity of individual, institutional

and community factors must be considered and investigated when designing behavioural interventions[537,541,552].

Research into hand hygiene using behavioural theory has primarily focused on the individual, though this may be insufficient to effect sustained change. O'Boyle and colleagues[543] investigated the possible association of cognitive factors with hand hygiene compliance, the first-ever attempt using a well-established behavioural model. However, none of the three major factors was strongly predictive of intention, and while intention related to self-reported estimates of compliance, the relationship was not strong (r=0.38) nor did intention to wash hands predict observed handwashing behaviour. In a neonatal ICU, a perceived positive opinion of a senior staff member towards hand hygiene and the perception of control over hand hygiene behaviour were independently associated with the intention to perform hand hygiene among HCWs[544]. Perceived behavioural control and intention were significant predictors of hand hygiene behaviour in another study[558].

Focus group data[542] suggested that hand hygiene patterns are likely to be firmly established before the age of 9 or 10 years, probably beginning at the time of toilet training. They are patterns of a ritualized behaviour carried out to be, in the main, self-protective from infection. However, the drivers to practise hand cleansing both in the community and in the health-care setting are not overtly microbiologically based and appear seriously influenced by the emotional concepts of "dirtiness" and "cleanliness"[542,562]. This same behaviour pattern has previously been recognized in developing countries[563], and Curtis & Biran have postulated that the emotion of disgust in humans is an evolutionary protective response to environmental factors that are perceived to pose a risk of infection[564]. Yet in most communities, this motivation results in levels of hand hygiene that are, in microbiological terms, suboptimal for ideal protection[565,566].

An individual's hand hygiene behaviour is not homogenous and can be classified into at least two types of practice[542]. Inherent hand hygiene practice, which drives the majority of community and HCW hand hygiene behaviour, occurs when hands are visibly soiled, sticky or gritty. Among nurses, this also includes occasions when they have touched a patient who is regarded as "unhygienic" either through appearance, age or demeanour, or after touching an "emotionally dirty" area such as the axillae, groin or genitals[542]. This inherent practice appears to require subsequent handwashing with water or with soap and water. The other element to hand hygiene behaviour, elective hand hygiene practice, represents those opportunities for hand cleansing not encompassed in the inherent category. In HCWs, this component of hand hygiene behaviour would include touching a patient such as taking a pulse or blood pressure, or having contact with an inanimate object around a patient's environment. This type of contact is similar to many common social interactions such as shaking hands, touching for empathy, etc. As such, it does not trigger an intrinsic need to cleanse hands, though in the health-care environment may lead to hand contamination with the risk of cross-transmission of organisms. It therefore follows that it is this component of hand hygiene which is likely to be omitted by busy HCWs.

Compliance with hand cleansing protocols is most frequently investigated in nurses as this group represents the majority of HCWs in hospitals. However, it is also well documented that doctors are usually less compliant with practices recommended for hand hygiene than are other HCWs[262,454,485]. Yet these clinicians are possibly the peer facilitators of hand hygiene compliance for nurses[542] with different groups acting as peer facilitators for other HCWs 263. Behavioural modelling[542] suggests that the major influence on nurses' handwashing practices in hospitals is the translation of their community attitudes into the health-care setting. Thus, activities which would lead to inherent community handwashing similarly induce inherent handwashing in the health-care setting. The perceived protective nature of this

component of hand hygiene behaviour means that it will be carried out whenever nurses believe that hands are physically or emotionally soiled, regardless of barriers, and will require washing with water. This model indicates that other factors including perceived behaviour of peers and other influential social groups, together with a nurse's own attitude towards hand hygiene, have much less effect on inherent hand hygiene behavioural intent[542].

Elective community behaviour has been shown to have a major impact on nurses with regard to their intention to undertake elective in-hospital hand cleansing. Also important are attitude and perceived peer behaviour. Reduction in effort required to undertake hand hygiene has no influence on inherent hand hygiene behaviour and only minimal impact on elective hand hygiene intent.

The nursing behaviour model predicts a positive influence by senior administrators and doctors on the hand hygiene compliance of nurses, but surprisingly there was no influence by senior nurses on junior nurses. Lankford and colleagues[567] found that poor hand hygiene practices in senior medical and nursing staff could provide a negative influence on others, while Pittet and colleagues[263] reported that doctors' perception of being role models to other colleagues had a positive influence on their compliance, independent of system constraints and hand hygiene knowledge.

All influences in the model for nursing hand hygiene behaviour[542] act independently of behavioural intent. This suggests that the effective component of the Geneva programme[262], which has demonstrated significantly improved and sustained hand hygiene compliance over a period of several years[364], was not only the introduction of an alcohol-based handrub per se, but were those components of the programme that directly promoted the desired behaviour: peer support from high-level hospital administrators and clinicians[552].

Results of a behaviour modification at an organizational level further support these conclusions. Larson and colleagues[535] described a significant increase in handwashing compliance in a teaching hospital sustained over a 14-month period. The focus of this behaviour-based programme was directed to induce an organizational cultural change toward optimal handwashing, with senior clinical and administrative staff overtly supporting and promoting the intervention.

The dynamic of behavioural change is complex and multifaceted[262,535,542,552]. It involves a combination of education, motivation and system change[552]. With our current knowledge, it can be suggested that programmes to improve hand hygiene compliance in HCWs must take into account the major barriers of altering an individual's pre-existing hand hygiene behaviour.

### FACTORS INFLUENCING BEHAVIOUR

1. Patterns of hand hygiene behaviour are developed and established in early life. As most HCWs do not begin their careers until their early twenties, improving compliance means modifying a behaviour pattern that has already been practised for decades and continues to be reinforced in community situations.
2. Self-protection: this is not invoked on a true microbiological basis, but on emotive sensations including feelings of unpleasantness, discomfort and disgust. These sensations are not normally associated with the majority of patient contacts within the health-care setting. Thus, intrinsic motivation to cleanse hands does not occur on these occasions.

i. Education. While HCWs must be schooled in how, when and why to clean hands, emphasis on the derivation of their community and occupational hand hygiene behaviour patterns may assist in altering attitudes.

ii. Motivation. Influenced by role modelling and perceived peer pressure by senior medical, nursing and administrative staff, motivation requires overt and continuing support by a hospital's administration of hand hygiene as an institutional priority[552]. This will, in due course, act positively at both the individual and organizational levels. Such support must be embedded in an overall safety climate directed by a top-level management committee, with visible safety programmes, an acceptable level of work stress, a tolerant and supportive attitude towards reported problems, and a belief in the efficacy of preventive strategies.

iii. Reinforcement of appropriate hand hygiene behaviour.

iv. Cues to action, such as cartoons and even alcohol-based rub itself, should continue to be employed.

v. While involvement of patients in hand hygiene programmes for HCWs has been demonstrated to be effective[568,569] and also incorporated in a national programme[570], further study of this approach is required before its widespread application. Possible obstacles to be addressed include cultural constraints, the barrier of patient dependency on caregivers, and the lack of applicability of this tactic to ventilated, unconscious and/or seriously ill patients who are often at most risk of cross-infection[485]. Furthermore, whether patients reminding HCWs that they have to clean their hands before care would interfere with the patient–caregiver relationship remains to be properly assessed in different sociocultural and care situations.

vi. System change.

a) Structural. As successful behavioural hand hygiene promotion programmes induce increased compliance, the convenience and time-saving effects of cosmetically acceptable alcohol-based handrubs will prove of further benefit. However, inherent hand hygiene behaviour will always persist and will continue to require hand-washing with water and soap; thus, the accessibility of sinks must still be carefully considered.

b) Philosophical. Heightened institutional priority for hand hygiene will require that a decision be made, at least at the organizational level as for many social behaviours, as to whether these other promotional facets of hand hygiene are then supported by law or marketing. Rewards and/or sanctions for acceptable or unacceptable behaviour may prove necessary and effective in both the short and long term, given both the duration of pre-existing hand hygiene behaviour inappropriate to the health-care setting and its continued reinforcement in the community. This approach has been successfully applied in many countries to other public health issues such as smoking and driving under the influence of alcohol, but further studies are necessary to assess its application to hand hygiene promotion. Alternatively, the philosophy of marketing may be considered; such an approach takes particular consideration of self-interest, which may be extremely pertinent given that self-protection continues to be the primary motivational force behind all hand hygiene practice. The value of active participation at the institutional level and its impact on HCWs' compliance with hand hygiene have been demonstrated in several studies[262,530,535].

Patterns of hand hygiene both in the community and in health care represent a complex, socially entrenched and ritualistic behaviour. It is thus not surprising that single interventions

have failed to induce a sustained improvement in HCW behaviour. Multilevel, multimodal and multidisciplinary strategies, responding to these behavioural determinants, would seem to hold most promise[262,526,552].

RESEARCH IMPLEMENTATION

i. Confirmation of behavioural determinants of hand hygiene in all other health-care occupational groups and in varying ethnic and professional groups is essential to ensure that these findings are constant and the implications that flow from them are universally relevant.

ii. The impact in practice of each behavioural factor impacting, in theory, on hand hygiene must be carefully measured and considered, so as to design cost-effective motivational programmes suitable for both high- and low-resource health-care settings.

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## 17. ORGANIZING AN EDUCATION PROGRAMME TO PROMOTE HAND HYGIENE

HCW education is an inherent component of the work of the infection control team. Through education, the infection control team can alter inappropriate patient-care practices and traditionally, a formal programme of education is relied on to successfully introduce new infection control policies in health care. However, it is now recognized that for hand hygiene, education alone may not be sufficient. HCWs' attitudes and compliance with hand hygiene are extremely complex and multifactorial[552,561,571-573], and studies indicate that a successful programme would have to be multidisciplinary and multifaceted[526,572].

Education is important and critical for success and represents one of the cornerstones for improvement of hand hygiene practices[574]. The reasons why education is important can be summarized as follows:

1. Successful hand hygiene programmes reported in the literature inevitably have an educational component[262,518,526,530]. They are not all consistently successful and their impact is not always sustainable. Some[573] appear to have only a short-term influence, particularly the one-time educational interventions[507,575]. This is the reason for stressing again that educational programmes alone are inadequate and other behaviour modifying strategies must be included in a multifaceted approach to achieve change[526,572].There is also clear evidence that adequate physical facilities for hand cleansing could affect the success of the programme and these must certainly be in place[263,571]. However, all this does not negate the critical role of the formal education programme for achieving compliance with hand hygiene.

2. Surveys and studies on HCWs have shown that valid information and knowledge on hand hygiene do influence good practices[263,576]. This is consistent with the finding that informational power is the most influential social power in infection control[577]. An educational programme providing accurate and pertinent facts is therefore indispensable for success.

3. Educational programmes have been reported as an essential ingredient for success in other infection control strategies, including the control of ventilator-associated pneumonia[578], reducing needlestick injuries[579], and the implementation of isola-

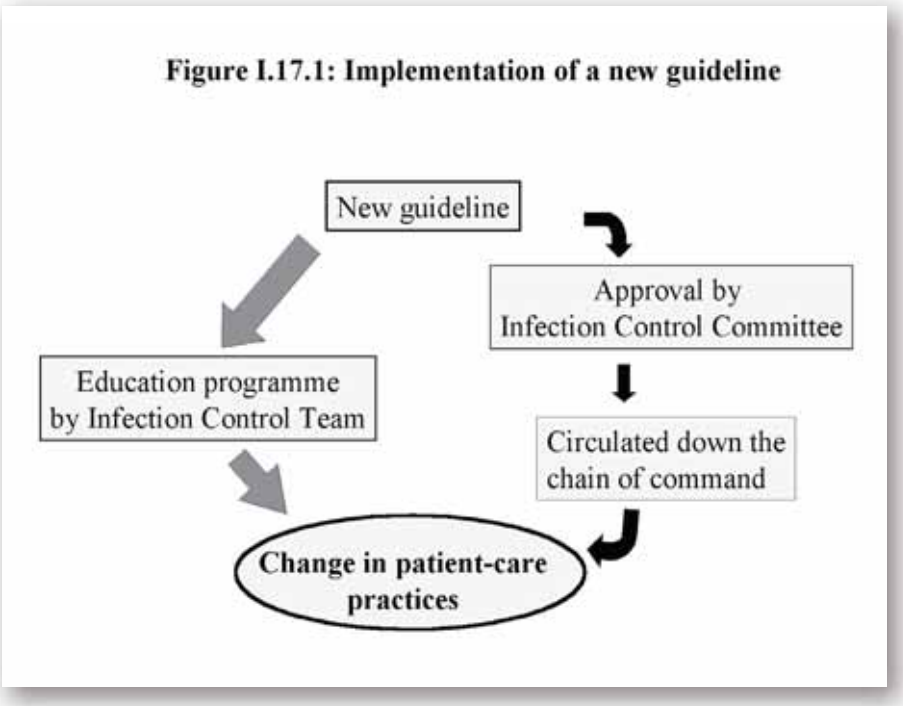
tion precautions[580]. There are also reports on the effective use of education for hand hygiene promotion strategies outside the acute hospital care setting[581,582]. It is important, therefore, to continue to use the formal education programme for the implementation of hand hygiene in the hospital.

It is noteworthy that good hand hygiene guidelines are now available for infection control teams around the world[7,583]. This is a distinct advantage because studies have shown that guidelines are in themselves an effective means of influencing behaviour regarding infection control[584]. If a formal education programme is organized to introduce the guidelines, the effects should be even further enhanced. In this section, guidance is given on the planning process of the education programme, together with a guideline review scheme that could help in developing an effective strategy for implementation.

## 17.1 IMPLEMENTATION PROCESS

The usual implementation process is depicted in Figure I.17.1. As shown, after a guideline is finalized, the infection control team will usually adopt a two-pronged implementation process. One of these prongs consists of submitting the guideline to the infection control committee for approval, and circulating it down the chain of command with instructions for implementation. The other prong would be the education programme, conducted by the infection control team and given directly to front-line staff. It is important to realize that HCWs' compliance can be extremely low when guidelines are simply circulated down the hospital hierarchy: research indicates that the compliance rate can be as low as 20%[557]. When monitored, compliance with MRSA precautions was only 28% in a teaching hospital[585]; compliance was as low as 8% during the evening shift, and 3% during the night shift. This underlines the importance of the education programme: the success of the implementation process depends on the effectiveness of this programme, and careful planning is essential.

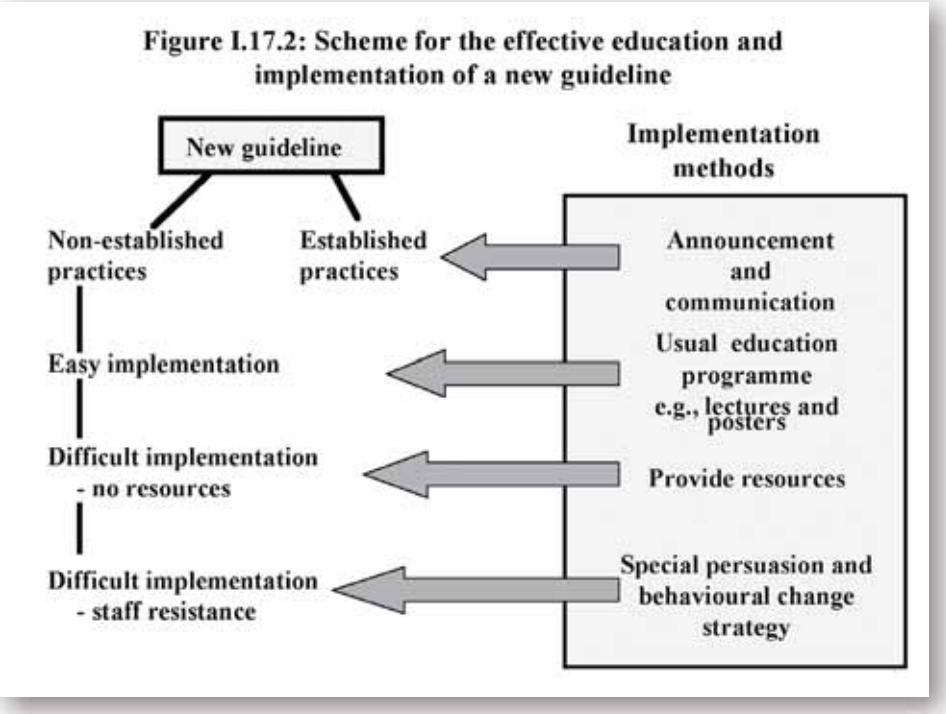
**Figure I.17.1: Implementation of a new guideline**




## 17.2 REVIEWING THE GUIDELINE FOR IMPLEMENTATION

The central part of this scheme is a method for reviewing guidelines before implementation[586,587]. After this review, the infection control team will obtain essential information for formulating the education programme (Figure I.17.2).

An infection control guideline generally consists of a list of recommendations on appropriate patient-care practices. In the education programme, instead of covering all the recommendations in a similar fashion for all categories of HCWs, a better strategy is to focus on the patient-care practices that require alterations, particularly those that would meet resistance from HCWs. The review scheme seeks to anticipate the educational needs so that the infection control team can plan accordingly. All recommendations in the guideline are categorized as follows:




### (I) ESTABLISHED PRACTICE

A policy for the practice is already present in the institution or is already standard practice. An example is the washing of hands that are visibly dirty or contaminated with proteinaceous material, or are visibly soiled with blood or other body fluids. Even without an official guideline for hand hygiene, many health-care facilities will usually already have such a practice in place.

### (II) NON-ESTABLISHED PRACTICE (EASY IMPLEMENTATION)

It is expected that HCWs would agree with the rationale of the recommendation and also that resources for implementation, if needed, are already in place. Therefore the practice should be easily implemented by the usual educational programme of in-service lectures or posters. An example is hand antisepsis before inserting peripheral vascular catheters or other invasive devices, as most HCWs will not object to such a reasonable practice.

### (III) NON-ESTABLISHED PRACTICE (LACK OF RESOURCES)

For this category, it is anticipated that implementation would be difficult mainly because of the lack of resources. An example is the need to provide a sufficient supply of alcohol-based handrub for use in areas of high workload and high intensity patient care, so that it is available at the entrance to the patient's room or at the bedside and other convenient locations.

### (IV) NON-ESTABLISHED PRACTICE (HCW RESISTANCE)

Implementation is difficult in this category because HCW resistance is expected to be high. An example is the recommendation for hand antisepsis after glove removal, as many HCWs may consider their hands to be clean, having been protected by the wearing of gloves.

It is recommended that a senior infection control professional in the hospital conducts the initial review[586]. Other senior nurses in the institution should also be coopted for this exercise. Using this scheme, studies have shown that front-line senior nurses in the hospital are accurate in predicting actual practices on the wards. A survey comparing their predictions with practices reported on the wards showed a significant correlation[586].

Figure I.17.2 shows the different educational methods that can be used for each category of recommendations. Implementation of established practices simply requires adequate communication and a formal announcement because HCWs are already putting these recommendations into practice. Non-established practices (easy implementation) are recommendations for which a high level of agreement is expected. When there is agreement, the intent for practice is already present and attitude change is usually not required. Azjen & Fishbein have shown that, under such circumstances, the desired behaviour will often

follow the intent[588]. Studies have shown that where there is agreement for a patient-care practice, a standard educational programme of lectures or posters will be effective[557].

In the next category, non-established practices (no resources), the lack of resources is the limiting factor. A list of such resources should be compiled for the new guideline, and the infection control team must ensure that these materials are in place before launching the implementation programme.

The successful implementation of the new guideline usually hinges on the last category, non-established practices (HCW resistance). Disagreement from HCWs is anticipated, and a programme of persuasion is needed to institute the required change. It will be worth while for the infection control team to understand the reasons for resistance, and both quantitative and qualitative studies may be required to elicit these factors. Special studies or surveys may be carried out on the various barriers to hand hygiene that have been identified in the literature. After understanding the reasons for resistance, a special behavioural change strategy might also be adopted to implement these practices[551,589] (see Part I, Sections 16 and 18).

## 17.3 STEPS IN GUIDELINE IMPLEMENTATION

Using the scheme just described, there are seven basic steps in implementation:

1. Elaborate a final draft of the guideline for the health-care institution/centre. After obtaining various international guidelines on hand hygiene from the literature, the infection control team needs to customize the recommendations according to the requirements of its health-care facility. It might highlight some of the recommendations that are deemed to be critically important for success or, on the other hand, choose to exclude recommendations that are not relevant for the institution. The document should provide specific information, such as the actual person to contact for queries and the precise location of the supply of hand antisepsis products. A final draft of the guideline will often require endorsement for implementation from the management of the institution or from the infection control committee. Importantly, institutional experts need to be knowledgeable about evidence-based information regarding hand hygiene.
2. Categorize all recommendations into the four types of practices as described above, with the help of a panel of experienced HCWs in the institution.
3. Work with the institution to provide the necessary resources for the non-established practice (no resources) recommendations. The infection control team must ensure that these resources are actually available on the wards when the guideline is introduced.
4. Conduct research on reasons for resistance for the non-established practices (HCW resistance). The easiest method will be to convene a focus group consisting of HCWs from the relevant wards. This can be followed, if necessary, by a simple survey of the key issues identified by the focus group.
5. Measure baseline rates before the introduction of the new guideline. The infection rate may be included, but by itself it may be difficult to document improvement because large numbers are usually needed. Other structural, process or outcome indicators may be measured and it is also pragmatic to obtain the compliance rate or evidence of behavioural change. This involves assessing the level of several key practices before introduction of the guideline, e.g. observations for hand hygiene compliance rates before and after patient contact, or the amount of antisepsis product usage in the institution.

6. Formulate and execute an education programme focusing on the resistance factors of the non-established practices (staff resistance). Many techniques[551,589] for persuasion, such as the use of opinion leaders[556] and participatory decision-making have been described, and successful application in the health-care facility context has been reported[551,589]. The use of these persuasion interventions could be time-consuming and should be reserved only for programmes requiring attitude change, i.e. the non-established practice (HCW resistance) recommendations. Specific elements that should be considered for inclusion in educational and motivational programmes are listed in Table I.17.1.

7. Evaluate and monitor progress. This is the last step but of no less importance. The same practices evaluated in step 5 should be re-evaluated. Even when improvement in these practices is documented, it is worth surveying HCWs for feedback on the effectiveness of the whole guideline. With this information, further improvement can be made.

## 17.4 THE INFECTION CONTROL LINK HEALTH-CARE WORKER

Research has indicated that the effect of a formal education programme for infection control would be significantly improved when front-line ward HCWs have been recruited to participate in the education programme for the guideline[556,590]. The infection control link HCW programme is an attempt to apply this principle in practice and has been widely used to assist in the implementation of guidelines in health-care facilities.

In the infection control link HCW programme, a senior member of staff would be appointed from each hospital ward from the pool of staff HCWs presently working in that clinical area. She or he would be the ward or department representative assisting the infection control team in implementing new policies in the institution. The position of the infection control link HCW is generally a voluntary assignment without monetary remuneration and the HCW is under no obligation to accept the appointment. Special training must be provided for the infection control link HCW so that she or he can be the person on the spot to enhance compliance with the guideline.

The infection control link HCW could be enlisted to participate in the educational programme of the hand hygiene guideline, and could help to identify the reasons for resistance to the non-established practice (HCW resistance) recommendations. An initial educational session should be organized for the infection control link HCWs before the launch of the formal programme for the entire institution. They could then begin preparing their wards for better acceptance of the guideline. Subsequently, in the institution-wide formal educational programme, they could also be present to assist in providing comments and answering questions especially for HCWs who are from their clinical areas.

Compliance with guidelines is critical for the success of the entire field of infection control, and not only for hand hygiene. Therefore, organizing an effective formal educational programme is vitally important.

# 18. FORMULATING STRATEGIES FOR HAND HYGIENE PROMOTION

## 18.1 ELEMENTS OF PROMOTION STRATEGIES

Targets for the promotion of hand hygiene are derived from studies assessing risk factors for non-adherence, reported reasons for the lack of adherence to recommendations, and additional factors perceived as important to facilitate appropriate HCW behaviour (see also Part I, Section 14.3). Although some factors cannot be modified (Table I.18.1), others are definitely amenable to change. Based on the studies and successful experiences in some institutions described below, it appears that strategies to improve adherence to hand hygiene practices should be multimodal and multidisciplinary.

The last 20 years have shown an increasing interest in the subject and many intervention studies aimed at identifying effective strategies to promote hand hygiene have been conducted[152,261,262,359,360,459,489,504,507,508,511,522,524,526,528-531,535,536,568,569,591,592]. These studies differed very much in their duration and intervention approach. In addition, the outcome measure of hand hygiene compliance varied in terms of the definition of a hand hygiene opportunity and assessment of hand hygiene by means of direct observation[152,261,262,359,360,426,459,504,507,508,511,522,524,528-530] or consumption of hand hygiene products[261,262,360,535,568,569,591,592], making comparison difficult, if not impossible. Despite different methodologies, most interventions have been associated with an increase in hand hygiene compliance, but a sustainable improvement has rarely been documented[262]. Most studies used multiple strategies, which included: HCWs' education[261,262,359,360,459,504,507,508,511,518,524,526,528-530,535,591,592], feedback performance[261,262,359,360,504,507,508,511,518,522,524,526,528-530,535], reminders[261,262,359,504,507,508,522,524,528-530,592], use of automated sinks, and/or introduction of an alcohol-based handrub[359,360,524,528-530,591-593].

Lack of knowledge of guidelines for hand hygiene and unawareness of hand hygiene indications during daily patient care and potential risks of transmission of microorganisms to patients constitute barriers to hand hygiene compliance. Lack of awareness of the very low average adherence rate to hand hygiene of most HCWs and lack of knowledge about the appropriateness, efficacy and understanding of the use of hand hygiene and skin care protection agents contribute to poor hand hygiene performance[561].To overcome these barriers, education has been one of the cornerstones of improvement in hand hygiene practices[7,261,262,359,360,459,504,507,508,511,518,524,526,528-531,535,536,572,591,592]. However, lack of knowledge of infection control measures after training has been repeatedly shown[552].

Audits of hand hygiene practices (see also Part III, Section 1.1) and feedback performance have comprised several multifaceted promotion campaigns and are valued as one of the most effective strategies[561].Two studies have reported a very positive impact on hand hygiene due to feedback performance[507,518]. Conversely, these results should be viewed with caution. In one study[507], no statistical evaluation is provided and the very low number of observed opportunities during the three surveys precludes further conclusions. Tibballs and colleagues[518] showed an extraordinary improvement after feedback of hand hygiene practices. One of the caveats in this study is that baseline compliance was obtained by covert observation and the subsequent survey was overtly performed, which might have favoured better results[263].

The change in system from the time-consuming handwashing practice to handrub with an alcohol-based preparation has revolutionized hand hygiene practices, and is now considered the standard of care[7]. Several studies show a significant increase in hand hygiene compliance after the introduction of handrub solutions[261,262,359,360,459,524,528,529,592]. Of note, handrub promotion with an alcohol-based preparation only started to be tested in intervention studies during the late 1990s. In most of these studies, baseline hand hygiene compliance was below 50%, and the introduction of handrubs was associated with a significant improvement in hand hygiene compliance. On the other hand, in the two studies with baseline compliance equal to or higher than 60%[459,524], no significant increase was observed. These findings may suggest that high profile settings may require more specific targeted strategies to achieve further improvement.

Most studies conducted to test the efficacy of hand hygiene promotion strategies were multimodal and used a quasi-experimental design, and all but one[535] used internal comparison. Consequently, the relative efficacy of each of these components remains to be evaluated.

HCWs necessarily evolve within a group, which functions within an institution. It appears that possible targets for improvement in hand hygiene behaviour not only include factors linked to the individual, but also those related to the group and the institution as a whole[541,552,561]. Examples of possible targets for hand hygiene promotion at the group level include education and performance feedback on hand hygiene adherence, efforts to prevent high workloads (i.e. downsizing and understaffing), and encouragement and role modelling from key HCWs in the unit. At the institutional level, targets for improvement are the lack of written guidelines, available or suitable hand hygiene agents, skin care promotion/agents or hand hygiene facilities, lack of culture or tradition of adherence, and the lack of administrative leadership, sanctions, rewards or support. Enhancing individual and institutional attitudes regarding the feasibility of making changes (self-efficacy), obtaining active participation at both levels, and promoting an institutional safety climate all represent major challenges that go well beyond the current perception of the infection control professional's usual role.

Table I.18.1 reviews published strategies for the promotion of hand hygiene in hospitals and indicates whether these require education, motivation or system change. Some of the strategies may be unnecessary in certain circumstances, but may be helpful in others. In particular, changing the hand hygiene agent could be beneficial in institutions or hospital wards with a high workload and a high demand for hand hygiene when alcohol-based handrub is not available[120,123,485,594]. A change in the recommended hand hygiene agent could be deleterious, however, if introduced during winter in the northern hemisphere at a time of higher hand skin irritability and, in particular, if not accompanied by skin care promotion and availability of protective cream or lotion.

Whether increased education, individual reinforcement technique, appropriate rewarding, administrative sanction, enhanced self-participation, active involvement of a larger number of organizational leaders, enhanced perception of health threat, self-efficacy, and perceived social pressure[537,541,552,595,596], or combinations of these factors would improve HCWs' adherence to hand hygiene needs more research. Ultimately, adherence to recommended hand hygiene practices should become part of a culture of patient safety where a set of interdependent elements of quality interact to achieve the shared objective[597].

It is important to note, however, that the strategies proposed in Table I.18.1 reflect studies conducted mainly in developed countries. Whether their results can be generalized to different backgrounds for implementation purposes still needs further research.

## 18.2 DEVELOPING A STRATEGY FOR GUIDELINE IMPLEMENTATION

Most guidelines, including these, contain a relatively large number of recommendations which vary in their degree of supporting evidence and importance in preventing infection. Moreover, some recommendations focus on interrupting the transmission of pathogens from patient to patient, while others focus on preventing contamination of intravenous catheters and other devices with the patient's own microbial flora. Because of the complexity and scope of these recommendations, prioritization is critical to achieve rapid improvement. These strategic priorities should guide education and guideline implementation.

The first step is to choose the specific recommendations that are most likely to result in fundamental change if practised reliably (in other words, performed correctly almost all the time). Consideration should be given to the specific site and complexity of local health-care delivery, as well as the cultural norms that are in play. These guidelines provide recommendations on a package (so-called 'bundle') of interventions that are most likely to have the largest impact on preventing infection in a wide variety of health-care delivery settings. These recommendations balance formal evidence with consensus regarding each specific intervention.

The second step is to perform an assessment (see also Part III, Section 1) to determine whether these practices are indeed being performed. This assessment need not be exhaustive. Sampling strategies should be employed. For example, was hand hygiene practised after the next 10 patient contacts in the dispensary or ward when monitored one day a week over a one-month period? What percentage of bedsides had a filled, operative alcohol dispenser present at 07:00 on one day, 12:00 on another day, and 18:00 on a third? For each recommended high-priority intervention, determine whether:

- the practice is being performed rarely, or not at all;
- the practice is being performed, but not reliably (for example, hand hygiene is performed on leaving a patient's bedside less than 90% of the time);
- the practice is well established and is performed reliably (for example, at least 90% of the time).

Clearly, if a practice is being performed reliably, it is not necessary to have a major education campaign or quality improvement intervention. Simple continuing education and reinforcement, along with monitoring to ensure that performance has not deteriorated, should suffice. For practices that are not being performed at all, or should be performed more reliably, consider the following factors in deciding how to prioritize and focus education and improvement work:

- Do we agree and can we convince others that the practice really is important and is supported by sufficient evidence or consensus?
- Is implementation likely to be easy and timely (for example, will HCWs resist, are there key opinion leaders who will object, will a long period of culture change be required, etc.)?
- Do we have the resources to implement the practice now, and if not, are we likely to obtain the resources (for example, a reliable supply of alcohol at a price we can afford)?
- Is change within our own power, and if not, what would be required to be successful (for example, will success require a change in policy by the government, or the development of a reliable, high-quality source for required materials)?

If possible, try to implement the high priority practices as a bundle, emphasizing that the greatest impact can be expected if ALL of the practices are performed reliably. Experience

has demonstrated that this bundled approach catalyses breakthrough levels of improvement and fundamental change in attitude and practice in infection control (see, for example, the "100 000 Lives" campaign at www.ihi.org)[598]. Educational programmes are easier to design and digest if they have a coherent theme and emphasize a limited number of critical points. In addition, competency checks and compliance monitoring are simplified.

## 19. IMPACT OF IMPROVED HAND HYGIENE

The lack of scientific information on the definitive impact of improved hand hygiene compliance on HCAI rates has been reported as a possible barrier to appropriate adherence with hand hygiene recommendations. However, there is convincing evidence that improved hand hygiene can reduce infection rates. Failure to perform appropriate hand hygiene is considered to be the leading cause of HCAI and spread of multiresistant organisms, and has been recognized as a significant contributor to outbreaks.

Several hospital-based studies of the impact of hand hygiene on the risk of HCAI have been published between 1977 and 2004 (Table I.19.1)[67,119,120,132,133,262,363,489,500,504,508,535,536]. Despite study limitations, most reports showed a temporal relation between improved hand hygiene practices and reduced infection rates.

Maki[132] found that HCAI rates were lower when antiseptic handwash was used by HCWs. Doebbeling et al.[500] compared hand antisepsis using a chlorhexidine-containing detergent to a combination regimen that permitted either handwashing with plain soap or use of an alcohol-based hand rinse. HCAI rates were lower when the chlorhexidine-containing product was in use. However, because relatively little of the alcohol rub was used during periods when the combination regimen was in operation and because adherence to policies was higher when chlorhexidine was available, it was difficult to determine whether the lower infection rates were attributable to the hand hygiene regimen used or to the differences in HCW compliance with policies.

A study by Larson and colleagues[535] found that the frequency of VRE infections, but not MRSA, decreased as adherence of HCWs to recommended handwashing measures improved. In a district hospital in the United Kingdom, the incidence of hospital-acquired MRSA cases significantly decreased after a successful hand hygiene promotion programme[363].

In 2000, a landmark study by Pittet and colleagues[262] demonstrated that implementing a multidisciplinary programme to promote increased use of an alcohol-based handrub led to increased compliance of HCWs with recommended hand hygiene practices, and to reduced prevalence of HCAI. Individual bottles of handrub solution were distributed in large numbers to all wards, and custom-made holders were mounted on all beds to facilitate access to hand antisepsis. HCWs were also encouraged to carry a bottle in their pocket. The promotional strategy was multimodal and involved a multidisciplinary team of HCWs, the use of wall posters, the promotion of bedside handrubs throughout the institution and regular performance feedback to all HCWs (see www.hopisafe.ch for further details on methodology). HCAI rates, attack rates of MRSA cross-transmission, and consumption of handrub were measured in parallel. Adherence to recommended hand hygiene practices improved progressively from 48% in 1994 to 66% in 1997 ($P < 0.001$). While recourse to handwashing with soap and water remained stable, the frequency of handrubbing markedly increased over the study period ($P < 0.001$), and the consumption of alcohol-based handrub solution increased from 3.5 litres to 15.4 litres per 1000 patient-days between 1993 and

1998 ($P$ <0.001). Importantly, increased recourse to handrubbing was associated with a significant improvement in compliance in critical care[261], suggesting that time constraint bypassing was critical. The increased frequency of hand antisepsis was unchanged after adjustment for known risk factors of poor adherence. During the same period, both overall HCAI and MRSA transmission rates decreased (both $P$ <0.05). The observed reduction in MRSA transmission may well have been affected by both improved hand hygiene adherence and the simultaneous implementation of active surveillance cultures for detecting and isolating patients colonized with MRSA [599]. The experience from the University of Geneva Hospitals constitutes the first report of a hand hygiene campaign demonstrating a sustained improvement over several years, since most experiences in the literature are limited to 6–9 months. The multimodal programme implemented by Larson and colleagues[535] also yielded sustained improvements in hand hygiene practices over an extended period. The intervention lasted eight months, and a follow-up survey six months after the end of the intervention showed a sustained improvement in hand hygiene practices.

Subsequently, several smaller studies conducted over shorter time periods have also shown that hand hygiene promotion programmes that included the introduction of an alcohol-based handrub led to increased hand hygiene compliance among HCWs and a decrease in HCAI[529,536]. In several other studies in which hand hygiene compliance was not monitored, multidisciplinary programmes that involved the introduction of an alcohol-based handrub were associated with a decrease in HCAI rates[363,496,592,600]. The beneficial effects of hand hygiene promotion on the risk of cross-transmission have also been reported in surveys conducted in schools or day care centres[601-607], as well as in a community setting[4,5,177,608,609].

While none of the studies conducted in the health-care setting represented randomized controlled trials, they provide substantial evidence that increased hand hygiene compliance is associated with reduced HCAI rates. Methodological and ethical concerns make it difficult to set up randomized controlled trials with appropriate sample sizes that could establish the relative importance of hand hygiene in the prevention of HCAI. The studies so far conducted could not determine a definitive causal relationship owing to the lack of statistical significance, the presence of confounding factors, or the absence of randomization. On the other hand, the unique large, randomized, controlled trial to test the impact of hand hygiene promotion clearly demonstrated reduction of upper respiratory pulmonary infection, diarrhoea, and impetigo among children in a Pakistani community with positive effect on child health[4,5]. Although it remains important to generate additional scientific and causal evidence for the impact of enhanced adherence with hand hygiene on infection rates in health-care settings, these results strongly suggest that improved hand hygiene practices reduce the risk of transmission of pathogenic microorganisms.

# 20. OTHER POLICIES RELATED TO HAND HYGIENE

## 20.1 GLOVING POLICIES

Glove wearing by HCWs is recommended for two main reasons: (i) to prevent microorganisms which may be infecting, commensally carried, or transiently present on HCWs' hands from being transmitted to patients and from one patient to another; and (ii) to reduce the risk of HCWs acquiring infections from patients[7,610].

Prior to the emergence of the Human Immunodeficiency Virus (HIV) and the Acquired Immunodeficiency Syndrome (AIDS) epidemic, gloves were worn primarily by HCWs either caring for patients colonized or infected with certain pathogens or exposed to patients with a high risk of hepatitis B. Since 1987, a dramatic increase in glove use has occurred in an effort to prevent the transmission of HIV and other bloodborne pathogens from patients to HCWs[611]. The National Institute for Occupational Safety and Health Administration in the USA (NIOSHA) mandates that gloves be worn during all patient-care activities that may involve exposure to blood or body fluids that may be contaminated with blood[612]. In addition, gloves should be worn in activities that include contact with potentially infectious material other than blood, such as mucous membranes, and non-intact skin, or during outbreak situations, as recommended by specific requirements for Personal Protective Equipment (PPE)[7,612].

Gloves used by HCWs are usually made of natural, rubber latex or synthetic non-latex materials such as vinyl, nitrile and neoprene (polymers and copolymers of chloroprene). Because of the increasing prevalence of latex sensitivity among HCWs and patients, the FDA has approved a variety of powdered and powder-free latex gloves with reduced protein contents, as well as synthetic gloves that can be made available by health-care institutions for use by latex-sensitive individuals. This leads to calls for access to latex-free gloves for HCWs who are sensitive to latex or who are caring for patients with latex hypersensitivity[613].

In published studies, the barrier integrity of gloves has varied considerably based on the type and quality of glove material, intensity of use, length of time used, manufacturer, whether gloves were tested before or after use, and the method used to detect glove leaks[614-621]. In some published studies, vinyl gloves more frequently had defects than did latex gloves, the difference being greatest after use[614,615,618,622]. However, vinyl gloves that are intact provide protection comparable to that given by latex gloves[614]. Limited studies suggest that nitrile gloves have leakage rates that are close to those of latex gloves[623-626]. It is appropriate to have more than one type of glove available, allowing HCWs to select the type that best suits their patient-care activities. Although recent studies suggest that improvements have been made in the quality of gloves[620], the laboratory and clinical studies cited above provide strong evidence that hands should still be decontaminated or washed after glove removal[13,29,69,85,377,615].

Use of petroleum-based hand lotions or creams may adversely affect the integrity of latex gloves[627]. Following the use of powdered gloves, some alcohol-based handrubs may interact with residual powder on HCWs' hands, resulting in a gritty feeling on hands. In facilities where powdered gloves are commonly used, a variety of alcohol-based handrubs should be tested following removal of powdered gloves in order to avoid selecting a product that causes this undesirable reaction[377,615].

The effectiveness of gloves in preventing contamination of HCWs' hands has been confirmed in several clinical studies[28,63,85]. One study found that HCWs who wore gloves during patient contact contaminated their hands with an average of only 3 CFUs per minute of patient care, compared with 16 CFUs per minute for those not wearing gloves[28]. Two other studies of HCWs caring for patients with *C. difficile* or VRE found that wearing gloves prevented hand contamination among a majority of those having direct contact with patients[63,85]. Wearing gloves also prevented HCWs from acquiring VRE on their hands when touching contaminated environmental surfaces[85]. Preventing gross contamination of the hands is considered important because handwashing or hand antisepsis may not remove all potential pathogens when hands are heavily contaminated[44,204].

Furthermore, several studies provide evidence that wearing gloves can help reduce transmission of pathogens in health-care settings. In a prospective controlled trial that required

HCWs routinely to wear vinyl gloves when handling any body substances, the incidence of *C. difficile* diarrhoea among patients decreased from 7.7 cases/1000 patient discharges before the intervention to 1.5 cases/1000 discharges during the intervention[326]. The prevalence of asymptomatic *C. difficile* carriage also decreased significantly on "glove" wards, but not on control wards. In ICUs where VRE or MRSA have been epidemic, requiring all HCWs to wear gloves to care for all patients in the unit (universal glove use) appeared to contribute to the control of outbreaks[628,629].

A few caveats regarding the use of gloves by HCWs are needed. HCWs should be informed that gloves do not provide complete protection against hand contamination. Bacterial flora colonizing patients may be recovered from the hands of up to 30% of HCWs who wear gloves during patient contact[69,85]. Doebbeling and colleagues[377] conducted an experimental study where the artificial contamination of gloves was undertaken with conditions close to clinical practice. The authors cultured the organisms used for artificial contamination from 4–100% of the gloves and observed counts between 0 and 4.7 log on hands after glove removal. In a recent study identifying neonatal-care activities at higher risk for hand contamination, the use of gloves during routine neonatal care did not fully protect HCWs' hands from bacterial contamination with organisms such as *Enterobacteriacae*, *S. aureus* and fungi[29]. In such instances, pathogens presumably gain access to the caregivers' hands via small defects in gloves or by contamination of hands during glove removal[69,377,614,615]. Furthermore, wearing gloves does not provide complete protection against the acquisition of infections caused by the hepatitis B virus and herpes simplex virus[614,630]. These studies provide definitive evidence that gloves must be removed after care of a single patient and during the care of a patient, when moving from a contaminated to a clean body site or procedure within the same patient, and that hand cleansing must be performed after glove removal.

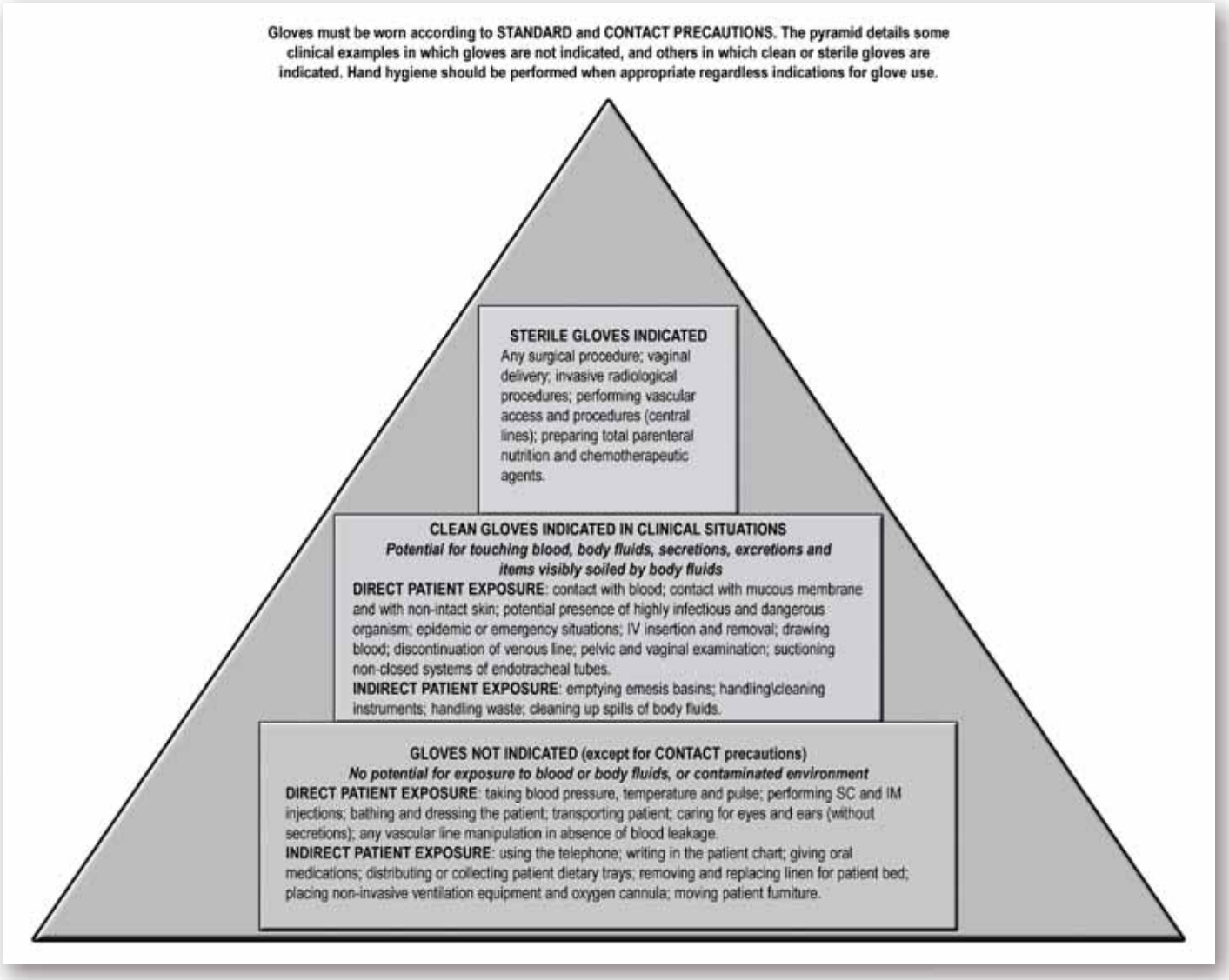
The impact of wearing gloves on adherence to hand hygiene policies has not been definitively established since published studies have yielded contradictory results[151,502,513,631]. Several studies found that HCWs who wore gloves were less likely to cleanse their hands upon leaving a patient's room[502,532,631,632]. In contrast, two other studies found that HCWs who wore gloves were significantly more likely to cleanse their hands following patient care[151,513,567]. One study found that the introduction of gloves increased the overall compliance with hand hygiene, but the introduction of isolation precautions did not result in a better compliance with hand hygiene[633].

Different groups of HCWs have shown different rates of compliance with infection control procedures. In one study, glove use compliance rates were 75% or higher in all HCW groups except doctors, whose compliance was only 27%[73]. HCWs should be reminded that the failure to remove gloves between patients or between different body sites of the same patient may contribute to the transmission of organisms[29,629,632,634]. In two reports, failure to remove gloves and gowns and failure to wash hands between patients were associated with an increase in transmission of MRSA during the SARS outbreak[635,636]. In addition to this type of misuse of gloves which could contribute to the transmission of pathogens, the unnecessary use of gloves in situations when their use is not indicated represents a waste of resources without necessarily leading to a reduction of cross-transmission[632].

Several new technologies are emerging, e.g. impregnated glove materials which release chlorine dioxide when activated by light or moisture to produce a disinfecting microatmosphere[637]. None of these has so far led to changes in glove-use recommendations. The correct and consistent use of existing technologies with documented effectiveness is encouraged before new technologies are introduced. Studies are needed to identify specific indications for new, potentially more expensive products.

Key recommendations on glove use are included in Part II, Section 6. It is important that HCWs are able to select correctly the most appropriate type of gloves to be worn and to differentiate between specific clinical situations when gloves should be worn and changed and those where their use is not indicated (see Figure I.20.1).

***Figure I.20.1: Key recommendations on glove use***




## 20.2 GLOVE USE IN SETTINGS WITH LIMITED RESOURCES

Infection control programmes in developing countries, when they exist, face one common limitation: scarce resources. Although the use of gloves as part of personal protective equipment for standard and transmission-based precautions is regularly recommended in many infection control guidelines in developing countries, it is more often the exception that a secure supply of necessary personal protective equipment, including gloves, is available. Consequently, and often coupled with inadequate training, even in institutions where gloves are available, HCWs often fail to remove their gloves between patients, thus facilitating the spread of microorganisms[96,638-641]. In addition, barrier material such as examination gloves is often of poor quality. Factors which contribute to glove failure are the purchase of inferior

quality gloves, reuse, shortage of appropriate glove size, and imprecision of tests for perforations prior to reprocessing, if necessary[642].

Although no recommendation exists concerning the washing and reuse of gloves nor the washing or decontamination of gloved hands followed by reuse on another patient, these are common practices in many health-care settings in developing countries where glove supply is limited[642]. In one study, washing gloved hands between patient treatments using 4% chlorhexidine and 7.5% povidone-iodine liquid soaps for 30 seconds eradicated all organisms inoculated from both glove surfaces[643]. Another study describes a significant reduction of bacterial count on perforated gloves to permit their reuse for non-sterile procedures after cleansing of the gloved hand using an alcohol-based preparation with chlorhexidine[644].

The practice of autoclaving used plastic gloves in case of shortage and of autoclaving new plastic gloves meant for examination for use as surgical gloves has been described[645]. The reprocessing at 125°C leads to gloves sticking together and separation causes tears and holes. The authors found 41% of recycled gloves with impaired integrity[645].

Another potential hazard is often witnessed in developing countries: many reprocessing units use powder inside reprocessed latex gloves to prevent material sticking together and to facilitate reuse. The consequences of use of powdered latex gloves in terms of the development of latex allergies and impaired working conditions leading to sickness in HCWs are well documented[646].

Cleansing gloved hands to allow for prolonged use on the same patient can result in considerable savings of disposable examination gloves in resource-poor settings. This practice depends on the type of gloves and the agent used. Some evidence exists that cleansing latex-gloved hands using an alcohol-based handrub solution is effective in removing microorganisms, and shows increasing contamination rates of hands only after 9–10 cycles of cleansing (M. Rotter, personal communication). However, cleansing plastic-gloved hands with an alcohol-based formulation leads to early dissolving of the plastic material.

In general, one of the major risks of reprocessing gloves is that they could show a higher rate of non-apparent holes and tears after the reprocessing cycle than new ones. Interestingly, a study by Tokars et al. showed that surgeons wearing a single layer of new surgical gloves had blood contact in 14% of the procedures, and blood contact was 72% lower among surgeons who double-gloved[647]. Therefore, double-gloving in countries with a high prevalence of HBV, HCV and HIV for long surgical procedures (>30 minutes), for procedures with contact with large amounts of blood or body fluids, for some high-risk orthopaedic procedures, or when using reprocessed gloves is considered an appropriate practice.

The opinion of international experts consulted by WHO is that glove reprocessing must be strongly discouraged and should be avoided, mainly because at present no standardized, validated and affordable procedure for safe glove reprocessing exists. Every possible effort should be made to prevent glove reuse in health-care settings and financial constraints in developing countries leading to such practices should be assessed and addressed.

Before planning or continuing the reprocessing of used gloves, every health-care facility should first undertake an assessment of factors leading to the shortage of single-use gloves, such as budget constraints or interrupted supply chains. Efforts should focus on reducing the need for gloves by avoiding wastage due to unnecessary use and by providing a secure stock of good quality single-use surgical and examination gloves, together with a budget for regular restocking. Health administrators are encouraged to purchase good quality disposable gloves and replenish stocks in time. In addition, clinic managers and supervisors should check that gloves are not wasted and HCWs should be educated to avoid inappropriate use of gloves (see Figure I.20.1).

In institutions with limited resources, some authors suggest that if the necessity for the reprocessing of single-use gloves persists after a thorough evaluation, the reprocessing of previously decontaminated and thoroughly cleaned surgical gloves using sterilization (autoclaving) or high-level disinfection (steaming) can produce an acceptable product; when combined with double-gloving, this may constitute a temporary tolerable practice[641,649]. If reprocessing does take place, the institution should develop clear policies to define clinical situations where gloves are not needed at all, when only new sterile gloves should be used, when the use of reprocessed gloves can be tolerated, and when gloves should be discarded and not reprocessed (e.g. when holes are detected). Only surgical latex gloves may be reused either as surgical gloves using double-gloving or as gloves for examination purposes. Examination gloves are made of thin, often inelastic material, which can tear easily, and should never be reprocessed.

Systematic research is urgently needed to evaluate reprocessing methods and to develop and validate a process which leads to a product of acceptable quality. Research is also needed to assess the integrity of different examination glove material (e.g. latex rubber, vinyl or nitril) when exposed to different formulations used for hand antisepsis or handwashing (e.g. alcohol, chlorhexidine, or iodine solutions).To this end, we call upon the manufacturers of gloves for medical application to address this issue and to conduct research to develop recyclable gloves for both examination and surgical use, and to provide also information about safe reprocessing methods for the reuse of gloves in resource-limited settings.

Well-conducted cost–benefit studies are required to evaluate the potential benefits of reprocessing gloves and the general need for investing in preventive measures. By analysis of the financing structures of health-care delivery systems in developing countries, incentives for investment in the prevention of HCAIs from the individual, institutional as well as societal perspectives can be identified.

The following reprocessing process has been suggested by the Johns Hopkins Program for International Education in Reproductive Gynecology and Obstetrics (JHPIEGO)[641]. This process is not standardized nor validated and no recommendation of this or any other reprocessing process can be expressed by the group of experts in the absence of good quality research. Furthermore, if used, a careful evaluation should be made of the existence of sufficient knowledge and locally-available resources and structures to correctly perform the procedure.

### DECONTAMINATION AND CLEANING OF GOOD QUALITY SURGICAL GLOVES BEFORE STERILIZATION OR HIGH-LEVEL DISINFECTION

- Before removing soiled surgical gloves, hands should be briefly immersed in a container filled with 0.5% chlorine solution.
- Gloves should then be removed by turning inside out and should be soaked in the chlorine solution for 10 minutes.
- These two steps ensure that both surfaces of the gloves are decontaminated.
- Gloves should be washed in soapy water, cleaning inside and out.
- Gloves should then be cleaned until no soap or detergent remains, which could interfere with the sterilization or high-level disinfection procedure.

- To test for holes, gloves should be inflated and held under water. Air bubbles indicate holes.
- The inside and outside should be gently dried. Gloves that remain wet for long periods of time will absorb water and become tacky.

### STERILIZATION OF GOOD QUALITY SURGICAL GLOVES FOR REUSE AS EXAMINATION GLOVES OR AS SURGICAL GLOVES, WHEN DOUBLE GLOVING IS PERFORMED

After decontamination, cleaning and drying, gloves must be packaged before sterilization by autoclaving. The cuffs of the gloves must be folded out towards the palm. This allows putting them on after sterilization without and placed in a wire basket on their side to allow optimal steam penetration. If gloves are stacked in piles, penetration of steam under the cuffs may be poor. Gloves need to be autoclaved at 121°C for 30 minutes at a pressure of 106 kPa. Higher temperature and pressure can destroy the gloves.

Immediately after autoclaving, gloves are very friable and tear easily. Gloves should not be used for 24–48 hours to allow them to regain their elasticity and to prevent stickiness.

### HIGH-LEVEL DISINFECTION OF GOOD QUALITY SURGICAL GLOVES FOR REUSE AS EXAMINATION GLOVES OR AS SURGICAL GLOVES, WHEN DOUBLE GLOVING IS PERFORMED

After decontamination and washing, gloves are ready for high-level disinfection by steaming.

- Cuffs of gloves need to be folded to avoid recontamination after high-level disinfection.
- This process can be repeated until up to three steamer pans have been filled with gloves. The three pans are stacked on top of a bottom pan containing water for boiling. A second empty, dry pan (without holes) should be placed on the counter next to the heat source.
- The top pan needs to be closed and the water brought to the boil.
- When steam starts to come out between the pans and the lid, start the timer and record the time in the high-level disinfection log book.
- Gloves should be steamed for 20 minutes. Sufficient water is needed in the bottom pan for the entire 20 minutes of steaming.
- The first steamer pan should be taken off and excess water removed by gently shaking the pan.
- After this, the removed steamer pan should be placed on the empty, dry bottom pan nearby. This process should be repeated until all pans containing gloves are restacked on the empty pan and the top pan is covered with a lid. This step allows gloves to cool down and dry without becoming contaminated.
- Gloves should be allowed to air dry in the steamer pans for 4–6 hours before using.
- Using high-level disinfected forceps, gloves can be transferred to a high-level disinfected container with a tight fitting top. Gloves can also be stored in the stacked and covered steamer pans as long as a bottom pan without holes is used. Pans containing gloves should not be placed on a tabletop, counter or other surface, as the gloves will be contaminated.

Alternatively, gloves can be used “wet”. For this, they should cool down for 5–10 minutes before wearing. Gloves should be used within 30 minutes. After this time, the fingers of the

gloves stick together and the gloves are difficult to put on despite being damp. Gloves that have been removed from the steamer pans to be worn wet but were not used during the clinic session should be reprocessed again before actually using.

Gloves that are cracked, peeling or have detectable holes or tears should never be reprocessed.

Some authors recommend that latex rubber surgical gloves should be discarded after three reprocessing cycles because gloves tear more easily with additional reprocessing[650,651].

Table I.20.1 summarizes the main problems related to the reprocessing of gloves and recommends some solutions.

In summary, institutions and health-care settings should firmly avoid the reuse of gloves. In circumstances where the reprocessing of gloves has been carefully evaluated but cannot be avoided, a clear policy should be in place to limit reprocessing and reuse of gloves until a budget is allocated to ensure a secure supply of single-use gloves. Policies for exceptional reprocessing should ensure a process that follows strict procedures for collection, selection and reprocessing, including instructions for quality/integrity control and discarding of unusable gloves.

The illegal recovery and recycling of discarded gloves from hospital waste dumping sites, often using dubious and uncontrolled reprocessing methods, can constitute an additional health hazard and is of growing concern in countries with limited resources. Hospitals are therefore encouraged to destroy each glove integrally before discarding.

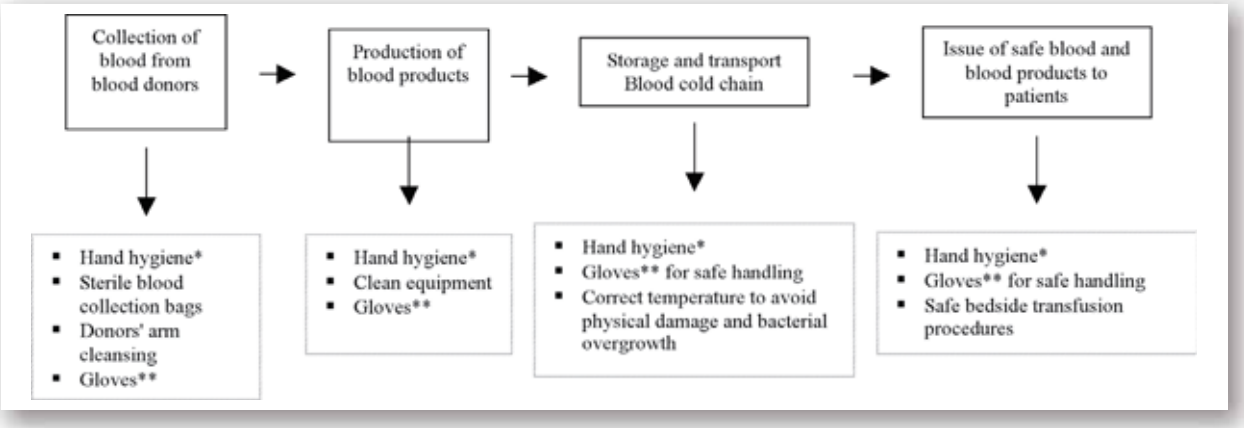
## 20.3 IMPORTANCE OF HAND HYGIENE FOR SAFE BLOOD AND BLOOD PRODUCTS

Providing a safe unit of blood to a patient who requires blood transfusion is a multistep process, from identifying safe blood donors for blood donation, safe blood collection without harming the blood donor and the donated blood unit, testing the blood for HIV and hepatitis, processing the blood into blood products, and issue of blood or blood product to the patient, when prescribed, also making sure that it contributes to improved health and the survival of the patient.

Appropriate hand hygiene practice is crucial to the safety of blood and blood products as there are many steps in the transfusion chain during which the donated blood units are handled. The microbial contamination of blood or blood products may occur at the time of blood collection or during the processing into blood products, labelling or distribution. This can have fatal consequences for the recipients of the transfusion.

Hand hygiene is crucial at all stages but particularly at the time of blood collection, as is thorough cleansing of the venepuncture site. Blood collection staff also frequently needs to collect blood in environments that are especially challenging. Special care must be exercised in hand hygiene while collecting blood in outdoor situations, where the area may be challenging, such as where there is no running water, or in the middle of a busy shopping mall. It is essential that all those who work in areas where blood is handled pay strict attention to hand hygiene. Standard operating procedures should be available to staff, detailing exactly how hands should be decontaminated in order to protect blood donors, patients and the staff themselves, as well as the blood and blood products. Figure I.20.2 depicts the crucial steps during blood collection, processing and transfusion with an associated risk for the contamination of blood or blood products due to poor hand hygiene of the staff involved in these processes. At each step, there are several critical procedures, including meticulous hand hygiene, which ultimately lead to the safety of blood and blood products.

***Figure I.20.2: Blood safety: crucial steps for hand hygiene action***




* Hand hygiene before and after the procedure.

** Clean non-sterile gloves.

## 20.4 JEWELLERY

Several studies have shown that skin underneath rings is more heavily colonized than comparable areas of skin on fingers without rings[652-654]. A study by Hoffman and colleagues[653] found that 40% of nurses harboured Gram-negative bacilli such as *E. cloacae*, *Klebsiella* spp., and *Acinetobacter* spp. on skin under rings and that some nurses carried the same organism under their rings for months. In one study involving more than 60 ICU nurses, multivariable analysis revealed that rings were the only significant risk factor for carriage of Gram-negative bacilli and *S. aureus* and that the organism bioburden recovered correlated with the number of rings worn[655]. Another study showed a stepwise increased risk of contamination with *S. aureus*, Gram negative bacilli, or *Candida* spp. as the number of rings worn increased[656].

A survey of knowledge and beliefs regarding nosocomial infections and jewellery showed that neonatal ICU HCWs were not aware of the relationship between bacterial hand counts and rings, and did not believe rings increased the risk of nosocomial infections; 61% regularly wore at least one ring to work[639].

Whether the wearing of rings results in greater cross-transmission of pathogens is not known. Two studies found that mean bacterial colony counts on hands after handwashing were similar among individuals wearing rings and those not wearing rings[654,657]. Further studies are needed to establish if wearing rings results in a greater transmission of pathogens in health-care settings. Nevertheless, it is likely that poorly maintained (dirty) rings and jewellery might harbour microorganisms that could contaminate a body site with potential pathogens. Rings with sharp surfaces may puncture gloves. Hand hygiene practices are likely to be performed in a suboptimal way if voluminous rings or rings with sharp edges or surfaces are worn. Jewellery may also be a physical danger to either patients or the HCW during direct patient care, e.g. a necklace may be caught in equipment or bracelets may cause injury during patient handling.

The consensus recommendation is to discourage the wearing of rings or other jewellery during health care; the use of a wedding ring for routine care may be acceptable, but in high-risk settings, such as the operating theatre, all rings or other jewellery should be

removed[658]. A simple and practical solution allowing effective hand hygiene is for HCWs to wear their ring(s) around their neck on a chain as a pendant.

## 20.5 FINGERNAILS AND ARTIFICIAL NAILS

Numerous studies have documented that subungual areas of the hand harbour high concentrations of bacteria, most frequently coagulase-negative staphylococci, Gram-negative rods (including *Pseudomonas* spp.), *Corynebacteria*, and yeasts[20,390,659]. Freshly applied nail polish does not increase the number of bacteria recovered from periungual skin, but chipped nail polish may support the growth of larger numbers of organisms on fingernails[660,661]. Even after careful handwashing or surgical scrubs, HCWs often harbour substantial numbers of potential pathogens in the subungual spaces[96,662,663]. In particular, the presence of fingernail disease may reduce the efficacy of hand hygiene and result in the transmission of pathogens. A cluster of *P. aeruginosa* surgical-site infections resulted from colonization of a cardiac surgeon's onychomycotic nail[664].

Whether artificial nails contribute to the transmission of HCAIs has been a matter of debate for several years. A growing body of evidence suggests that wearing artificial nails may contribute to the transmission of certain health care-associated pathogens. HCWs who wear artificial nails are more likely to harbour Gram-negative pathogens on their fingertips than those who have natural nails, both before and after handwashing[96,390,663,665] or handrub with an alcohol-based gel[96]. It is not clear if the length of natural or artificial nails is an important risk factor, since most bacterial growth occurs along the proximal 1 mm of the nail, adjacent to subungal skin[96,661,663]. An outbreak of *P. aeruginosa* in a neonatal ICU was attributed to two nurses (one with long natural nails and one with long artificial nails) who carried the implicated strains of *Pseudomonas* spp. on their hands[666]. Case patients were significantly more likely than controls to have been cared for by the two nurses during the exposure period, suggesting that colonization of long or artificial nails with *Pseudomonas* spp. may have played a role in causing the outbreak. HCWs wearing artificial nails have also been epidemiologically implicated in several other outbreaks of infection caused by Gram-negative bacilli or yeast[100,107,667]. In a recent study, multiple logistic regression analysis showed the association of an outbreak of extended-spectrum beta-lactamase-producing K. pneumonia in a neonatal ICU resulting from exposure to an HCW wearing artificial fingernails[668]. Although the above reports provide the best evidence to date that wearing artificial nails poses an infection hazard, additional studies of this issue are warranted. Long, sharp fingernails, either natural or artificial, can puncture gloves easily[69]. They may also limit HCWs' performance in hand hygiene practices. In a recent survey among neonatal ICU HCWs, 8% wore artificial fingernails at work, and knowledge among them about the relationship between Gram-negative bacterial hand contamination and long or artificial fingernails was limited[639].

Jeanes & Green[669] reviewed other forms of nail art and technology in the context of hand hygiene in health care including: applying artificial material to the nails for extensions; nail sculpturing; protecting nails by covering them with a protective layer of artificial material; and nail jewellery, where decorations such as stones may be applied to the nails or the nails are pierced. In addition to possible limitations of care practice, there may be many potential health problems, including local infection for individuals who have undergone some form of nail technology[669].

Each health-care facility should develop policies on the wearing of jewellery, artificial fingernails or nail polish by HCWs. The policies should take into account the risks of transmission of infection to patients and HCWs, rather than cultural preferences.

Consensus recommendations are that HCWs should not wear artificial fingernails or extenders when having direct contact with patients and that natural nails should be kept short (≤ 0.5 cm long).

## 21. HAND HYGIENE RESEARCH AGENDA

Although the number of published studies dealing with hand hygiene has increased considerably in recent years, many questions regarding hand hygiene products and strategies for improving HCW compliance with recommended policies remain unanswered. Table I.21.1 lists a number of areas that should be addressed by researchers, scientists and clinical investigators. Table I.21.2 includes a series of open questions on specific unsolved issues, which require research activities and field testing. Some of the research questions will be covered by studies conducted within the framework of the World Alliance for Patient Safety. In particular, also taking advantage of integration with the other components of the Global Patient Safety Challenge, the implementation strategies of the Challenge are expected to evaluate the impact of some of these issues and find practical solutions in the field experience.

# PART II. CONSENSUS RECOMMENDATIONS

### RANKING SYSTEM FOR EVIDENCE

It was agreed that the CDC/HICPAC system for categorizing recommendations be adapted as follows:

**Category IA**. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiological studies.

**Category IB**. Strongly recommended for implementation and supported by some experimental, clinical, or epidemiological studies and a strong theoretical rationale.

**Category IC**. Required for implementation, as mandated by federal and/or state regulation or standard.

**Category II**. Suggested for implementation and supported by suggestive clinical or epidemiological studies or a theoretical rationale or a consensus by a panel of experts.

## 1. INDICATIONS FOR HANDWASHING AND HAND ANTISEPSIS

A. Wash hands with soap and water when visibly dirty or contaminated with proteinaceous material, or visibly soiled with blood or other body fluids, or if exposure to potential spore-forming organisms is strongly suspected or proven (IB) or after using the restroom (II)[117,213,266,323,324,327,670-675].

B. Preferably use an alcohol-based handrub for routine hand antisepsis in all other clinical situations described in items C(a) to C(f) listed below, if hands are not visibly soiled (IA)[156,256,262,350,359-361,506]. Alternatively, wash hands with soap and water (IB)[132,133,262,500].

C. Perform hand hygiene:
   a) before and after having direct contact with patients (IB)[6,29,44,63,67,103,676];
   b) after removing gloves (IB)[29,69,85,377,677,678];
   c) before handling an invasive device for patient care, regardless of whether or not gloves are used (IB)[44,679];
   d) after contact with body fluids or excretions, mucous membranes, non-intact skin, or wound dressings (IA)[676];
   e) if moving from a contaminated body site to a clean body site during patient care (IB)[29,44,71,72,103];
   f) after contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient (IB)[29,64,71,72,74,76,103].

D. Wash hands with either plain or antimicrobial soap and water or rub hands with an alcohol-based formulation before handling medication or preparing food (IB)[670-675].

E. When alcohol-based handrub is already used, do not use antimicrobial soap concomitantly (II)[463].

## 2. HAND HYGIENE TECHNIQUE

A. Apply a palmful of the product and cover all surfaces of the hands. Rub hands until hands are dry (IB)[145]. (The technique for handrubbing is illustrated on page 100.)

B. When washing hands with soap and water, wet hands with water and apply the amount of product necessary to cover all surfaces. Vigorously perform rotational handrubbing on both hand palms and backs, interlace and interlock fingers to cover all surfaces. Rinse hands with water and dry thoroughly with a single-use towel. Use running and clean water whenever possible. Use towel to turn off tap/faucet (IB)[93,155,157,498,680]. (The technique for handwashing is illustrated on page 101.)

C. Make sure hands are dry. Use a method that does not recontaminate hands. Make sure towels are not used multiple times or by multiple people (IB)[31,65,142,183,434,512]. Avoid using hot water, as repeated exposure to hot water may increase the risk of dermatitis (IB)[433,434].

D. Liquid, bar, leaf or powdered forms of plain soap are acceptable when washing hands with a non-antimicrobial soap and water. When bar soap is used, small bars of soap in racks that facilitate drainage should be used (II)[191,192,491,492].

## 3. RECOMMENDATIONS FOR SURGICAL HAND PREPARATION

A. If hands are visibly soiled, wash hands with plain soap before surgical hand preparation (II). Remove debris from underneath fingernails using a nail cleaner, preferably under running water (II)[20,681].

B. Sinks should be designed to reduce the risk of splashes (II)[169,407].

C. Remove rings, wrist-watch, and bracelets before beginning the surgical hand preparation (II)[653,657,682]. Artificial nails are prohibited (IB)[96,390,663,665].

D. Surgical hand antisepsis should be performed using either an antimicrobial soap or an alcohol-based handrub, preferably with a product ensuring sustained activity, before donning sterile gloves (IB)[104,208,348,379,683,684].

E. If quality of water is not assured (as described in Table I.9.2) in the operating theatre, surgical hand antisepsis using an alcohol-based handrub is recommended before donning sterile gloves when performing surgical procedures (II)[104,178,208,348,379,683,684].

F. When performing surgical hand antisepsis using an antimicrobial soap, scrub hands and forearms for the length of time recommended by the manufacturer, 2 to 5 minutes. Long scrub times (e.g. 10 minutes) are not necessary (IB)[210,302,304,345,396-398,402].

G. When using an alcohol-based surgical handrub product with sustained activity, follow the manufacturer's instructions. Apply the product on dry hands only (IB)[418-420]. Do not combine surgical hand scrub and surgical handrub with alcohol-based products sequentially (II)[463].

H. When using an alcohol-based product, use sufficient product to keep hands and forearms wet with the handrub throughout the procedure (IB)[411,423].

I. After application of the alcohol-based product as recommended, allow hands and forearms to dry thoroughly before donning sterile gloves (IB)[134,348,411,423,683].

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## 4. SELECTION AND HANDLING OF HAND HYGIENE AGENTS

A. Provide HCWs with efficacious hand hygiene products that have low irritancy potential (IB)[154,155,190,256,426].

B. To maximize acceptance of hand hygiene products by HCWs, solicit their input regarding the feel, fragrance, and skin tolerance of any products under consideration. In some settings, cost may be a primary factor (IB)[155,156,256,445,454,456,475].

C. When selecting hand hygiene products:
   - determine any known interaction between products used to clean hands, skin care products, and the types of gloves used in the institution (II)[268,627];
   - solicit information from manufacturers about the risk of contamination (IB)[101,494,495];
   - ensure that dispensers are accessible at the point of care (IB)[263];
   - ensure that dispensers function adequately and reliably and deliver an appropriate volume of the product (II)[262,490];
   - ensure that the dispenser system for alcohol-based formulations is approved for flammable materials (IC);
   - solicit information from manufacturers regarding any effect that hand lotions, creams, or alcohol-based handrubs may have on the effects of antimicrobial soaps being used in the institution (IB)[268,685,686].

D. Do not add soap to a partially empty soap dispenser. If soap dispensers are reused, follow recommended procedures for cleansing (IA)[102,282].

## 5. SKIN CARE

A. Include information regarding hand-care practices designed to reduce the risk of irritant contact dermatitis and other skin damage in education programmes for HCWs (IB)[464,469].

B. Provide alternative hand hygiene products for HCWs with allergies or adverse reactions to standard products used in the health-care setting (II).

C. When needed to minimize the occurence of irritant contact dermatitis associated with hand antisepsis or handwashing, provide HCWs with hand lotions or creams (IA)[468-470].

## 6. USE OF GLOVES

A. The use of gloves does not replace the need for hand cleansing by either handrubbing or handwashing (IB)[29,69,85,377,614,615,630].

B. Wear gloves when it can be reasonably anticipated that contact with blood or other potentially infectious materials, mucous membranes, or non-intact skin will occur (IC)[612].

C. Remove gloves after caring for a patient. Do not wear the same pair of gloves for the care of more than one patient (IB)[29,69,85,377,634].

D. When wearing gloves, change or remove gloves during patient care if moving from a contaminated body site to a clean body site within the same patient (II). Change or remove gloves after touching a contaminated site and before touching a clean site or the environment (II)[28,69,85].

E. Avoid the reuse of gloves (IB)[645]. If gloves are reused, implement an adequate reprocessing method to ensure glove integrity and microbiological decontamination (II).

## 7. OTHER ASPECTS OF HAND HYGIENE

A. Do not wear artificial fingernails or extenders when having direct contact with patients (IA)[96,100,107,666,667].

B. Keep natural nails short (tips less than 0.5 cm long) (II)[666].

## 8. EDUCATIONAL AND MOTIVATIONAL PROGRAMMES FOR HEALTH-CARE WORKERS

A. In hand hygiene promotion programmes for HCWs, focus specifically on factors currently found to significantly influence behaviour, and not solely on the type of hand hygiene products. The strategy must be multifaceted and multimodal and include education and senior executive support for implementation (IB)[262,535,567].

B. Educate HCWs about the type of patient-care activities that can result in hand contamination and about the advantages and disadvantages of various methods used to clean their hands (II)[262,504,507,511].

C. Monitor HCWs' adherence to recommended hand hygiene practices and provide them with performance feedback (IA)[262,475,504,507,511,518,522].

D. Encourage partnerships between patients, their families and HCWs to promote hand hygiene in health care settings (II)[568,569].

## 9. GOVERNMENTAL AND INSTITUTIONAL RESPONSIBILITIES

### 9.1 FOR HOSPITAL ADMINISTRATORS

A. Provide HCWs with access to a safe, continuous water supply at all outlets and access to the necessary facilities to perform handwashing (IB)[504,535].

B. Provide HCWs with a readily accessible alcohol-based handrub at the point of patient care (IA)[256,262,359,360,461,486,506,687,688].

C. Make improved hand hygiene adherence an institutional priority and provide appropriate leadership, administrative support and financial resources (IB)[262,535].

D. Assign health-care professionals with dedicated time and training for institutional infection control activities, including the implementation of a hand hygiene promotional programme (II)[689,690].

E. Implement a multidisciplinary, multifaceted and multimodal programme designed to improve adherence of HCWs to recommended hand hygiene practices (IB)[262,535].

F. With regard to hand hygiene, ensure that the water supply is physically separated from drainage and sewerage within the health-care setting, and provide routine system monitoring and management (IB)[162].

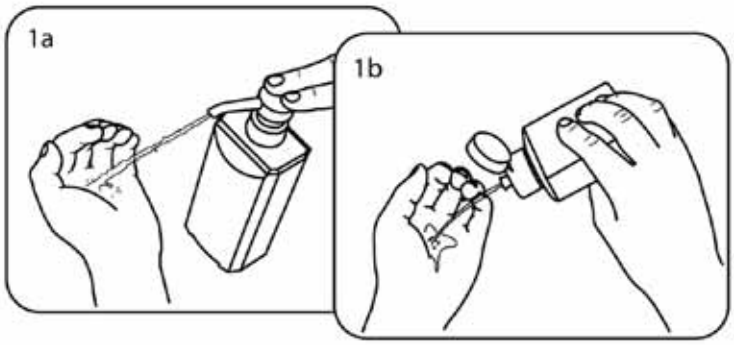
### 9.2 FOR NATIONAL GOVERNMENTS

A. Make improved hand hygiene adherence a national priority and consider provision of a funded, coordinated and implemented programme for improvement (II)[691].

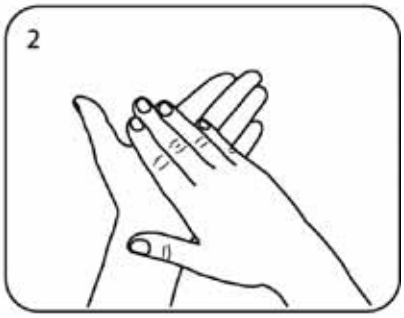
B. Support strengthening of infection control capacities within health-care settings (II)[689,690].

C. Promote hand hygiene at the community level to strengthen both self-protection and the protection of others (II)[562].

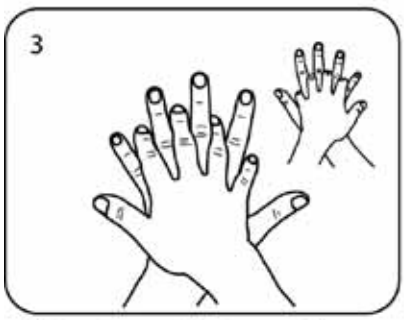
# Hand Hygiene Technique with Alcohol-Based Formulation



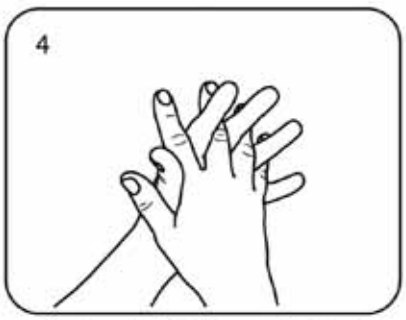

Apply a palmfull of the product in a cupped hand and cover all surfaces.



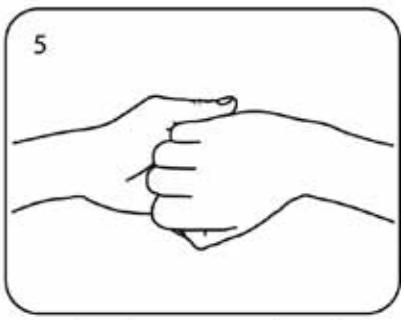

Rub hands palm to palm




right palm over left dorsum with interlaced fingers and vice versa

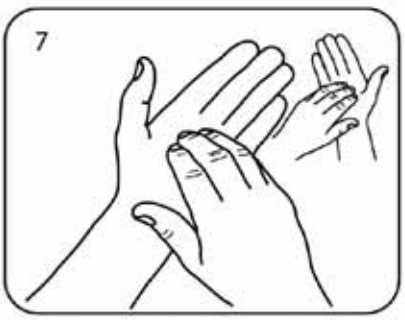



palm to palm with fingers interlaced

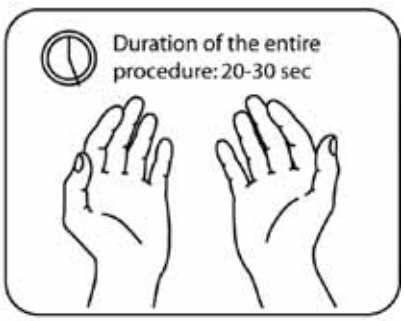



backs of fingers to opposing palms with fingers interlocked


rotational rubbing of left thumb clasped in right palm and vice versa




rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa




...once dry, your hands are safe.

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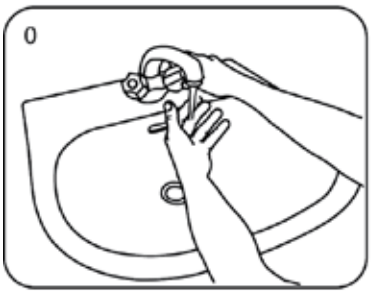
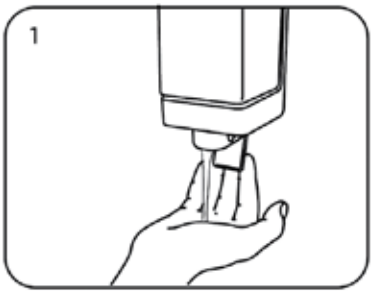
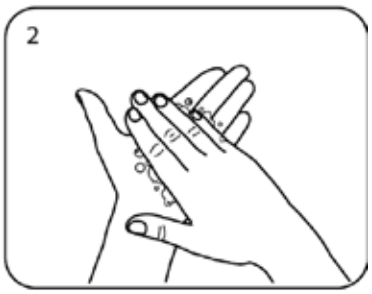
## Handwashing Technique with Soap and Water



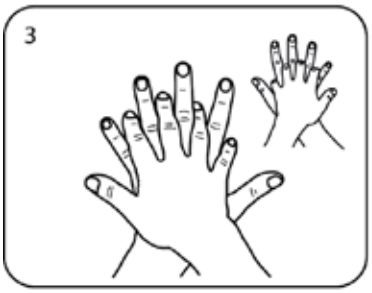

Wet hands with water



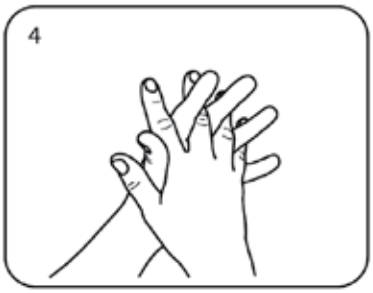

apply enough soap to cover all surfaces



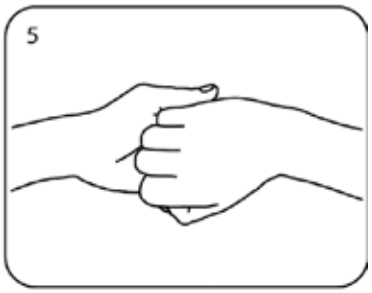

rub hands palm to palm



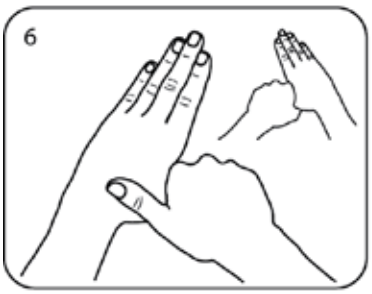

right palm over left dorsum with interlaced fingers and vice versa



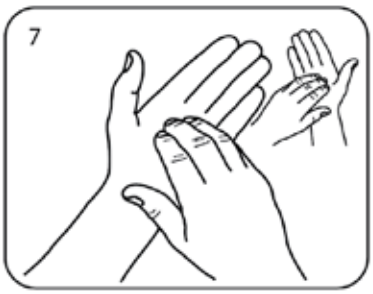

palm to palm with fingers interlaced



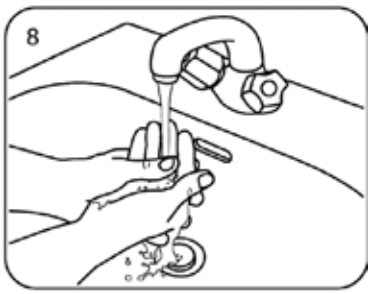

backs of fingers to opposing palms with fingers interlocked



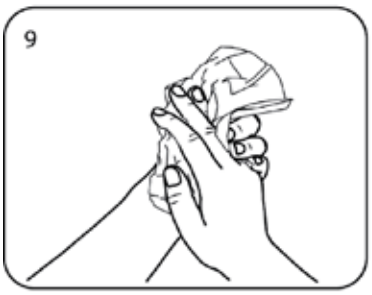

rotational rubbing of left thumb clasped in right palm and vice versa



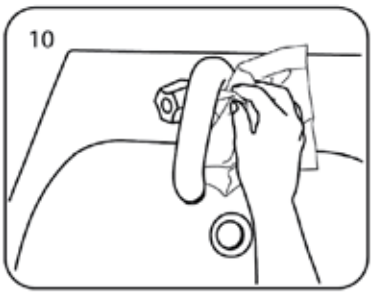

rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa



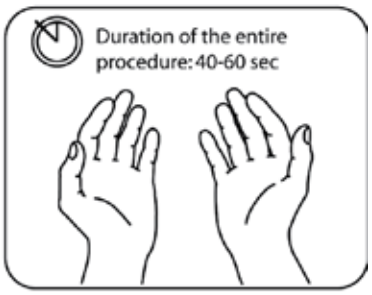

rinse hands with water




dry thoroughly with a single use towel




use towel to turn off faucet/tap




...and your hands are safe.

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# PART III. OUTCOME MEASUREMENTS

## 1. MONITORING HAND HYGIENE COMPLIANCE

Monitoring hand hygiene practices is an activity of crucial importance to assess baseline compliance by HCWs, to evaluate the impact of promotion interventions and to provide feedback to HCWs. Monitoring can also be helpful in investigating infection outbreaks, in assessing the potential role of ongoing hand hygiene practices, and also in determining the extent to which infection can be decreased depending on the different rates of compliance (see Part I, Section 20.1).

Compliance with hand hygiene can be evaluated directly or indirectly. Direct methods include observation, patient assessment or self-reports. Indirect methods include monitoring consumption of products, such as soap or handrub, and electronic monitoring of the use of handwash basins. Direct methods are necessary to determine precisely hand hygiene compliance rates. A direct method, according to the definitions for hand hygiene indications, consists of a count of the number of hand hygiene episodes performed by HCWs divided by the number of hand hygiene opportunities. Performance feedback on hand hygiene behaviour is critical to improve compliance with hand hygiene among HCWs[262,504,507,511,518,526,528,530,531,535,536].

### 1.1 DIRECT OBSERVATION

Direct observational survey is currently the "gold standard" and the most reliable method for assessing adherence rates[7]. Data can be collected on the types of patient procedures, moment (time, day), and practices before and after the use of gloves. HCWs are not usually identified personally on the data collection forms. Awareness of being observed may improve HCW compliance because of a "Hawthorne effect"[261,571,692]. If observational surveys are conducted periodically, this bias would be equally distributed among all observations[583]. A major drawback of direct observation is the cost as it requires a trained person (either HCW or non-HCW). This can be time-consuming and expensive. Furthermore, defining the ideal methodology for direct observation may be very difficult, especially because the interpretation of the recommended indications for hand hygiene in practical daily care may be very complicated. An accurate evaluation of hand hygiene compliance is valuable for performance feedback purposes. Such audits are best performed by staff who routinely come to the unit for other reasons, such as quality improvement professionals, as this tends to reduce the Hawthorne effect. However, HCWs will generally pay less and less attention to auditors over time if they are seen as a routine part of system monitoring. Direct observation for routine surveillance needs to be kept simple. It is best to focus on a few major types of hand hygiene opportunities rather than trying to be comprehensive. For example, hand hygiene before and after contact with the patient, before performing an aseptic procedure such as intravenous catheter site care, and after glove removal would be suitable targets. Observation for research purposes may be more complicated, depending on the research objectives. Compliance with proper precaution procedures could also be monitored. Whichever parameters of care are monitored, the definition of non-compliance should be clear so that trained observers will have high inter-rater reli-

ability, data will be credible, and compliance trends can be monitored over time. Examples of hand hygiene compliance monitoring tools can be obtained from reference[693] or at: www.handhygiene.org/downloads/HHMonitoring%20Tool.doc.

There have been some attempts to improve hand hygiene by empowering patients[694]. The value of patient involvement has been assessed by McGuckin[569,695]. In two studies, patients were encouraged to find out if HCWs had washed their hands before patient contact. These studies recommended that patients should be empowered to take responsibility for their health care, including infection control. Patient monitoring of hand hygiene compliance is not well documented, however, and has never been objectively evaluated[696]. Patients may not feel comfortable monitoring an HCW's compliance with hand hygiene[697,698]. Furthermore, patient empowerment is not possible for the critically ill.

Self-assessment by HCWs can be carried out. It has been demonstrated, however, that self-reports of compliance do not correlate well with compliance actually measured by direct observation, and self-assessment tends to overestimate compliance with hand hygiene[153,155,507,508,518,545].

## 1.2 INDIRECT MONITORING

Indirect monitoring includes counting used paper hand towels[699], monitoring the amount of alcohol-based handrub or liquid soap used[261,262,360,363,489,535,568,592], or estimating the required amount using a computerized database of nursing activities[591]. These methods are not as consuming of time and resources as direct observation, but can be affected by a number of biases, such as lack of adjustment for patient case-mix and workload[583]. Some studies[261,262,360] have shown that the consumption of products used for hand hygiene correlated with observed hand hygiene compliance; thus, the use of this measure as a surrogate for monitoring hand hygiene practices deserves further validation. Other studies found that feedback by measuring soap and paper towel levels did not have an impact on hand hygiene[567,699].

## 1.3 ELECTRONIC MONITORING

The use of sinks in patient rooms and in hospital lavatories can be monitored electronically. A recent study[489] tested an electronic monitoring system that monitored entry and exit into patient rooms and tracked the use of sinks and hand hygiene materials. A computer system linked each entry and exit with the presence or absence of a hand hygiene activity. Although useful for assessing general personal hygiene, these systems are not appropriate for measuring hand hygiene compliance with patient care, as such devices do not take into account the number of hand hygiene opportunities. Table III.1.1 lists the advantages and disadvantages of direct and indirect monitoring of hand hygiene compliance.

These guidelines include recommendations relating to the wearing of rings, wrist watches, bracelets, nail polish and artificial nails (see Part I, Section 20). Monitoring adherence to these policies can also involve direct and indirect observation, self-assessment and patient assessment, though little work has been carried out to assess the validity or correlation of these monitoring methods in terms of infection prevention.

## 2. HAND HYGIENE AS A QUALITY INDICATOR FOR PATIENT SAFETY

Patient safety has become the touchstone of contemporary medical care. Medical errors and adverse events occur with distressing frequency, as outlined persuasively in the United States Institute of Medicine's *To err is human*[700]. HCAIs are second only to medication errors as a cause of adverse events in hospitalized patients. Hospital infection control provides a mature template for patient safety with a long track record of research, evidence-based practice standards, and practice improvement efforts. Moreover, infection control professionals and hospital epidemiologists have pioneered real-time methods to detect the occurrence of HCAI and monitor compliance with infection control standards. Nonetheless, as documented in this report, compliance with hand hygiene – the pillar of infection control – remains woeful in the vast majority of health-care institutions. The current emphasis on hand hygiene by the WHO World Alliance for Patient Safety and many regulatory and accrediting agencies reflects the slow progress of the health professions in meeting even modest performance standards.

Donabedian's quality paradigm of structure, process and outcome[701,702] provides a useful framework for considering efforts to improve hand hygiene compliance. Clearly, if sinks and alcohol dispensers are not readily accessible (faulty structure) and hand hygiene is not performed (inadequate process), the risk of infection and its attendant morbidity, mortality and cost (outcomes) will increase. Quality indicators can be developed according to Donabedian's framework.

Hazard analysis critical control point is another valuable method to examine the system of patient care as it relates to hand hygiene. Originally developed to provide astronauts with pathogen-free food, hazard analysis critical control point is now widely employed in good manufacturing practice, food and drug safety, and blood banking. In brief, the method identifies error-prone aspects of systems (critical control points), evaluates the risk they pose, and designs them out. Critical control points are scored according to their probability of occurrence, probability of avoiding detection, and severity of downstream impact. Failure mode and effects analysis is closely related to hazard analysis critical control point and is being exploited increasingly in patient safety. A desirable feature of both hazard analysis critical control point and failure mode and effects analysis is their emphasis on systems' errors and their consequences. An empty alcohol dispenser, failure to educate staff in proper hand hygiene technique, and failure to practise hand hygiene after glove removal are serious failures at key points in the patient-care system. When multidisciplinary care teams map their institution's system for hand hygiene, they not only identify error-prone critical control points and barriers to compliance, but also identify which aspects of the system are most critical to improve and monitor. This collaborative approach to identifying key quality indicators vastly improves these indicators' local credibility and relevance and provides a guide to ongoing improvement and auditing efforts.

Failures at critical control points in the hand hygiene system can be seen as problems in the reliability of the system. The concept of reliability is the bedrock of modern manufacturing (for example, it transformed the quality of automobile production) but has been applied to health care only recently. Reliability looks at the defect or failure rate in key aspects of production (i.e. patient care). Industry often seeks to achieve defect rates of one per million or less (a component of so-called six-sigma reliability). While such a high degree of reliability seems impossible in many aspects of health care, it is worth noting that most institutions have hand hygiene defect rates of six per ten opportunities or greater. Moreover, these rates

do not even reflect current thinking about rigorous reliability, in which the entire system either performs correctly or does not. For example, defect-free care of a central venous catheter would require perfect hand hygiene, maximal barrier precautions, optimal skin preparation, and aseptic care of connections in the administration system. Failure at any one of these steps means "no credit". Clearly, current defect rates in the hand hygiene system are no longer tolerable. Even in a setting with severely constrained resources, basic hand hygiene can and should be performed very reliably.

Although health-care providers – particularly managers in relatively complex organizations – will find it valuable to understand and apply Donabedian's quality paradigm, hazard analysis critical control point, failure mode and effects analysis, and reliability theory, it should be relatively easy for health-care providers in virtually every setting to start evaluating, improving and monitoring the reliability of the hand hygiene infrastructure and practice immediately. Table III.2.1 provides a variety of structure and process quality indicators that are derived directly from these WHO guidelines. Health-care providers and multidisciplinary teams (in collaboration with quality improvement and infection control experts where available) may want to begin by considering some of these indicators. The emphasis is on structure and process because the ultimate outcomes – reduced infection and antibiotic resistance rates – are likely to be linked closely with improvements in structure and process, are more time-consuming to measure, and may not be immediately discernible. Many indicators in Table III.2.1 are relatively easy to measure and provide real-time feedback to caregivers and managers.

For example, at the most basic level: are user-friendly, clear policies in place, and are these accessible to HCWs in the workplace? Are the design of the work space and the placement of sinks and other hand hygiene equipment and supplies conducive to compliance? Are appropriate education programmes available to all HCWs, including trainees and rotating personnel, and is continuing education provided on a regular basis? What is the actual attendance at these programmes, and is it mandated? During what percentage of shifts are nurse staffing ratios adequate?

It is particularly important to verify the competency of all HCWs in performing hand hygiene procedures – a critical certification step that is applied all too rarely, especially to doctors. In addition, do surveys demonstrate that providers understand the indications for hand hygiene and important facts about hand hygiene products and performance? Are they motivated, and do they have a strong sense of self-efficacy? How do they view the unit or department's social norms regarding hand hygiene? Can they identify an opinion leader in their unit or department who takes the lead in education and the promotion of hand hygiene?

Quick, real-time checks of the health-care environment can be extremely useful for monitoring barriers to compliance. Are the alcohol dispensers conveniently placed near every bed space (or are they hiding behind the ventilator)? What percentage of the antiseptic or alcohol dispensers are full? Operational? It should be recalled that the most rigorous reliability standards will require that 100% of bed spaces have conveniently located, operational alcohol dispensers that are never empty. Are hand lotions always available to HCWs and conveniently placed?

Random audits of actual practice are indispensable (see Part III, Section 1.1). While hand hygiene practice can be considered a process of care, when it is not performed appropriately it can also be viewed as an important intermediate step in the chain leading to the colonization and infection of patients. Moreover, audit and feedback of compliance data is a major component of any multifaceted behaviour change programme. Simple graphics of compliance rates (or, alternatively, defect rates) should be prominently displayed where they

can be seen during routine work. Data should be incorporated into HCW's education and fed back in real time.

The ultimate customer, or course, is the patient. Patients and their families can be given a "tip sheet" to help them understand their role as partners in patient safety. They should be encouraged to point out lapses in hand hygiene technique without fear of retribution. Surveys can help HCWs determine if patient perceptions match their own view of their performance.

## 3. COST–EFFECTIVENESS OF HAND HYGIENE

To date, no formal prospective studies have been conducted to establish the cost–effectiveness of hand hygiene in health-care settings. In general, cost–effectiveness has been estimated by comparing the costs of hand hygiene promotion programmes versus the potential cost savings from preventing HCAIs. However, a recent report has reviewed all economic studies relating to the overall impact of alcohol-based hand hygiene products in health care[703] and concluded that, while further research is required to measure the direct impact of improved hand hygiene on infection rates, the potential benefit of providing alcohol-based handrubs is likely to outweigh costs and their wide-scale promotion should continue. The report also recommended that those planning local improvements should note that multimodal interventions are more likely to be effective and sustainable than single-component interventions, and although these are more resource-intensive, they have a greater potential to be cost effective.

The costs of hand hygiene promotion programmes include the costs of hand hygiene products plus the costs associated with HCW time and the educational and promotional materials required by the programme. The costs of products needed for handwashing include soap, water and materials used for drying hands (e.g. towels), while the costs of hand antisepsis using an alcohol-based handrub include the cost of the handrub product plus dispensers and pocket-sized bottles, if made available. In general, non-antimicrobial soaps are often less expensive than antimicrobial soaps. In health-care settings, mainly in resource-poor countries, basic handwashing equipment such as sinks and running water is often not available or of limited quality. In calculating costs for hand hygiene, these substantial construction costs need also to be taken into account. In addition, overhead costs for used water and maintenance need to be added to the calculation.

The cost per litre of commercially prepared alcohol-based handrubs varies considerably, depending on the formulation, the vendor and the dispensing system. Products purchased in 1.0–1.2 litre bags for use in wall-mounted dispensers are the least expensive; pump bottles and small pocket-sized bottles are more expensive; and foam products that come in pressurized cans are the most expensive. Presumably, a locally produced solution composed of only ethanol or isopropanol plus 1% or 2% glycerol would be less expensive than commercially produced formulations but may not meet quality control standards achieved by most manufacturers. Boyce estimated that a 450-bed community teaching hospital spent US$ 22 000 (US$ 0.72 per patient-day) on 2% chlorhexidine-containing preparations, plain soap, and an alcohol hand rinse[362]. When hand hygiene supplies for clinics and non-patient care areas were included, the total annual budget for soaps and hand antiseptic agents was US$ 30 000 (about US$ 1 per patient-day).

Annual hand hygiene product budgets at other institutions vary considerably because of differences in usage patterns and varying product prices. Countries/states/regions/localities with centralized purchasing can achieve economies on a scale that can result in considerable cost reduction of products. A recent cost comparison of surgical scrubbing with an antimicrobial soap versus brushless scrubbing with an alcohol-based handrub revealed that costs and time required for preoperative scrubbing were less with the alcohol-based product 255. In a trial conducted in two ICUs, Larson and colleagues[256] found that the cost of using an alcohol-based handrub was half that of using an antimicrobial soap for handwashing (US$ 0.025 versus US$ 0.05 per application, respectively). In another study conducted in two neonatal ICUs, investigators looked at the costs of a traditional handwashing regimen using soap, use of an alcohol-based handrub supplemented by a non-antimicrobial soap, use of hand lotion, and nursing time required for hand hygiene[497]. Although product costs were higher when the alcohol-based handrub was used, the overall cost of hand hygiene was lower with the handrub because it required less nursing time.

To assess the cost–effectiveness of hand hygiene programmes, it is necessary to consider the potential cost savings that can be achieved by reducing the incidence of HCAIs. The excess hospital costs associated with only four or five HCAIs of average severity may equal the entire annual budget for hand hygiene products used in inpatient care areas. Just one severe surgical site infection, lower respiratory infection, or bloodstream infection may cost the hospital more than the entire annual budget for antiseptic agents used for hand hygiene[362]. For example, in a study conducted in a Russian neonatal ICU, the authors estimated that the excess cost of one health care-associated bloodstream infection (US$ 1100) would cover 3265 patient-days of hand antiseptic use (US$ 0.34 per patient-day)[529]. The authors estimated that the alcohol-based handrub would be cost effective if its use prevented approximately 3.5 bloodstream infections per year or 8.5 pneumonias per year. In another study, it was estimated that cost savings achieved by reducing the incidence of *C. difficile*-associated disease and MRSA infections far exceeded the additional cost of using an alcohol-based handrub[592].

Several studies provided some quantitative estimates of the cost–effectiveness of hand hygiene promotion programmes[119,262]. Webster and colleagues[119] reported a cost saving of approximately US$ 17 000 resulting from reduced use of vancomycin following the observed decrease in MRSA incidence in a seven-month period. Similarly, MacDonald and colleagues reported that the use of an alcohol-based hand gel combined with education sessions and performance feedback to HCWs reduced the incidence of MRSA infections and expenditures for teicoplanin (used to treat such infections)[363]. For every £1 spent on alcohol-based gel, £9–20 were saved on teicoplanin expenditure.

Including both direct costs associated with the intervention (increased use of handrub solution, poster reproduction and implementation) and indirect costs associated with HCW time, Pittet and colleagues[262] estimated the costs of the programme to be less than US$ 57 000 per year for a 2600-bed hospital, an average of US$ 1.42 per patient admitted. Supplementary costs associated with the increased use of alcohol-based handrub solution averaged US$ 6.07 per 100 patient-days. Based on conservative estimates of US$ 100 saved per infection averted, and assuming that only 25% of the observed reduction in the infection rate has been associated with improved hand hygiene practice, the programme was largely cost effective. A subsequent follow-up study performed in the same instititution determined the direct costs of the alcohol-based handrub used, other direct costs, indirect costs for hand hygiene promotion, and the annual prevalence of HCAI for 1994 to 2001[364]. Total costs for the hand hygiene programme averaged Swiss francs (CHF) 131 988 between 1995 and 2001, or about CHF 3.29 per admission. The prevalence of HCAI decreased from 16.9 per 100

***Case study: United Kingdom national programme, a programme with potential benefits***

*National programmes can achieve economies of scale in terms of the production and distribution of materials. In the United Kingdom, the National Patient Safety Agency (NPSA) "clean**your**hands" campaign is a collaboration between national government bodies and the commercial sector in the development, piloting, evaluation and implementation of the programme. The national procurement body for the National Health Service (NHS) and the national NHS Logistics Authority, which has expertise in distributing products across the NHS, have worked in partnership with the NPSA to ensure the campaign achieves its objectives. The national NHS Logistics Authority is responsible for the distribution of both the alcohol-based handrubs and the campaign materials to each hospital implementing the campaign.*

*The NPSA campaign is funded centrally for its first year; thereafter, all campaign materials will be produced and funded by commercial companies on the national alcohol-based handrub contract. The companies will fund this by paying a licence fee in proportion to their turnover on the contract.*

*At the outset, the six main sources of possible financial benefits to the wider health-care economy resulting from a successful campaign were identified as those relating to:*

- *reduced hospital costs;*
- *reduced primary care costs;*
- *reduced costs incurred by patients;*
- *reduced costs of informal carers;*
- *productivity gains in the wider economy;*
- *reduced costs associated with litigation and compensation.*

*Though there are some up-front costs for hospitals associated with implementing the campaign, for a 500-bed hospital it would cost around UK£ 3000 initially to put alcohol-based handrub at each bedside. The analysis suggested that the campaign would deliver net savings from the outset. An Excel spreadsheet for self-completion by an individual health-care institution has been produced, which allows for the input of local data and will indicate likely cost savings over time (Appendix 3). Even if financial savings were not to be realized, the likely patient benefits in terms of lives saved and relatively modest costs mean that the intervention would still be highly cost effective compared with many other NHS activities (NPSA 2004). The economic evaluation went on to suggest that the campaign would be cost saving even if the reduction in hospital-acquired infection rates were as low as 0.1%.*

admissions in 1994 to 9.5 per 100 admissions in 2001. Total costs of HCAIs were estimated to be CHF 132.6 million for the entire study period. The authors concluded that the hand hygiene programme was cost-saving if less than 1% of the reduction in HCAIs observed was due to improved hand hygiene practices. An economic analysis of the United Kingdom's "clean***your***hands" hand hygiene promotional campaign concluded that the programme would be cost beneficial if HCAI rates were decreased by as little as 0.1%[691]. The impact of the "clean***your***hands" campaign is the subject of a four-year research programme which will look at the effectiveness of the various components of the multimodal approach.

Despite the fact that the above-mentioned studies strongly suggest a clear benefit of hand hygiene promotion, budget constraints are a fact, particularly in developing countries, and cost–effectiveness analysis might be used to identify the most efficient strategies. To achieve this goal, data on the incidence of HCAI and the resulting opportunity costs, as well as on the cost and effectiveness of competing infection control strategies, are required[704]. Since these variables may vary by and large according to the region and institution, local studies may be necessary to help choose best strategies[704]. Well-conducted local studies may suggest other infection control interventions of even greater cost–benefit, depending on the socioeconomic and cultural environments of the health-care system.

Taking into account the many financial constraints in resource-poor countries and the considerably high cost investment required (e.g. secure water supply and sinks), the investment in programmes using alcohol-based handrubs as the primary or sole means of hand hygiene seems to be an obvious solution. It should nevertheless be taken into account that investment in the infrastructure of health-care facilities, such as secure water supply and sinks, is necessary in the long run to improve the quality of health-care delivery as a whole. This investment can show benefits other than an improvement in hand hygiene practices.

## 3.1 FINANCIAL STRATEGIES TO SUPPORT NATIONAL PROGRAMMES

Interventions designed to improve hand hygiene across a country may require significant financial and human resources, particularly multifaceted campaigns. Costs must be balanced in terms of anticipated reduction in HCAI. The economies of scale achieved by centralized design and production of supporting materials will logically result in less cost to the overall health economy. This approach was used in the United Kingdom's "clean***your-***hands" campaign (see the box below). Countries without centralized distribution networks might not achieve sufficient economies of scale to make such an approach feasible without additional massive investment from the commercial sector.

# PART IV. PROMOTING HAND HYGIENE ON A LARGE SCALE

## 1. COUNTRYWIDE ISSUES

Countrywide or national hand hygiene improvement programmes in health-care settings have not been widely reported in the literature. However, infection control itself has emerged in recent years across the developed world as a national priority in health care[705].

The United Kingdom's National Audit Office[705] commissioned a comparative review of international practices in the management of HCAI in developed countries, to determine whether there were international lessons that could be learnt. All of the countries reviewed (Australia, Belgium, Denmark, France, Germany, New Zealand, Spain, the Netherlands and the USA) had a national strategy in place for preventing HCAI. More recent strategies in Australia, France, New Zealand and the USA had been influenced by patient safety and risk management agendas and were linked to the accreditation of services. All of these national strategies universally promote the necessity for local systems and processes to improve hand hygiene guidelines and policies. There was, however, no reference to nationally driven programmes of improvement.

There are a number of examples of national improvement programmes relating to specific aspects of HCAI prevention and/or patient safety enhancement. The recent "100 000 Lives" campaign[598] in the USA is being coordinated by the Institute for Healthcare Improvement (www.ihi.org), and health-care organizations are invited to join the campaign and commit to implementing changes associated with six interventions. The campaign is free to participating hospitals who must commit to making changes in the way in which the interventions are managed. Participants are provided with a range of tools and materials.

The "Speak Up" campaign in the USA (2002), where patient pressure is engaged to encourage patients to observe whether HCWs have cleaned their hands and to remind them to do so when necessary, is sponsored by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). In the USA, research has been conducted in elementary schools across a number of states to determine the effectiveness of the introduction of hand hygiene products, including alcohol-based handrubs[706]. Large-scale programmes of this nature are described as beneficial in terms of the reduction of common community infections such as colds, but even in industrialized countries resources to implement such programmes remain an issue.

JCAHO has included the risk of HCAI in its 2005 National Patient Safety Goals. Organizations are required to fulfil these goals to improve safety and quality. One of the requirements of the safety goals is that health-care organizations must comply with the current CDC hand hygiene guidelines[7].

## 2. THE NATIONAL PATIENT SAFETY AGENCY "CLEAN*YOUR*HANDS" CAMPAIGN

In September 2004, the United Kingdom's National Patient Safety Agency (NPSA) issued Patient Safety Alert 04 advising all acute in-patient National Health Service (NHS) organizations to install alcohol-based handrubs at points of patient care. The call to action is time bound and will be monitored nationally. At the same time a national "clean***your***hands" campaign was launched which aimed to increase hand hygiene compliance amongst HCWs and reduce the human and financial burden of HCAIs. The campaign is multimodal and evidence-based and consists of a toolkit of tangible products and recommended methods to facilitate improvement in hand hygiene compliance. The toolkit reinforces the need for the standard provision of alcohol-based handrub (either at each bedside or to each caregiver). The products include posters and promotional messages designed to act as psychological prompts to HCWs and information for the empowerment of patients in the hand hygiene process. The campaign materials are centrally funded and distributed directly to implementer hospitals via an established national distribution network.

A national programme as described here can act as a driver for action but does require monitoring and careful evaluation. The impact of the "clean***your***hands" campaign is being evaluated in England and Wales over a four-year period through the Patient Safety Research Programme of the Department of Health. The National Observational Study of the effectiveness of the "clean***your***hands" campaign will be carried out in all acute NHS Trusts.

The chief objective of the national research study is to develop and standardize robust measures of hand hygiene compliance, its clinical governance, organizational support and cost of implementation of the campaign. The research will also measure HCAI. The work will importantly test the hypothesis that the campaign and toolkit produce a significant rise in hand hygiene compliance and a significant reduction in HCAI and will add to the body of knowledge relating to national hand hygiene improvement by examining the results of adding a feedback intervention. The researchers will also examine whether the campaign, toolkit and feedback intervention are cost effective.

## 3. BENEFITS OF NATIONAL PROGRAMMES

The main benefits associated with national programmes of improvement in patient safety can be quantified in terms of avoiding a fragmented and cost-inefficient duplication of effort[707]. These authors call for national risk management and prevention strategies to deal cost-effectively with iatrogenic events and injuries, with a focus on producing practical tools that can be implemented across entire health-care systems. Pragmatic adaptations to standard national campaigns will be necessary in order to give such campaigns the best likelihood of local ownership which is critical to ensuring successful implementation.

When deciding on the suitability of national improvement in relation to hand hygiene, politicians or leaders need to consider a number of factors that can influence success. Characteristics of national strategies will be influenced by the key drivers for improvement[708] which, in the developed world, relate to the growing need to reassure patients and the public that care provided is clean and safe. Clinical governance has acted as a powerful driver for improvement in the United Kingdom, where structures have been cre-

ated to reinforce its principles (the National Institute for Clinical Excellence and National Service Frameworks). NHS organizations are monitored via the Health Care Commission which will be examining whether and to what extent organizations have implemented both the campaign and the near-patient handrubs. The United Kingdom's "Organization With a Memory" report (OWAM 2000)[709] recommended a centrally driven approach to achieve major improvements in the way the NHS approaches patient safety problems. The creation of the NPSA and its ability to disseminate solutions to safety problems rapidly across the NHS is an example of "active learning". The NPSA Alert 04 is itself an example of active learning. Any national improvement will be influenced by the capacity or ability of the health-care system to implement learning from existing information sources[709] and, importantly, whether there is a central body to do this. Barriers to active learning can be overcome by creating an informed culture at a local level which results in local active management of safety improvement[709].

Improvement is, however, a dynamic process and success will be affected by internal as well as external factors[710]. Improvement must be preceded by an analysis and understanding of existing patient safety and infection control structures, policies and programmes – and this is emphasized by the WHO World Alliance for Patient Safety. Political commitment and national ownership of programmes are essential, but inevitably those strategies that are dependent on social and political dynamics are subject to risk. The integration of all levels of the programme is crucial; national and hospital programmes should be harmonized. At the hospital level, chief executive officers (CEOs) should be made aware of any recommendations/requirements for hand hygiene promotion campaigns that are issued by organizations that accredit or license health-care facilities. For example, in the USA, JCAHO has issued a statement that hospitals are expected to comply with the CDC/HICPAC hand hygiene guideline. Since CEOs place considerable importance on complying with JCAHO guidelines, it is imperative to notify them of such recommendations. In other countries, there could be comparable situations.

The benefit of national improvement will be influenced by how health care is regulated and operated nationally, regionally and locally[710]. Furthermore, there is no clear picture of how health-care systems internationally are dealing with pressures to improve. Olsson and colleagues[710] offer to identify which methods, concepts or technologies are valuable in improvement activities and, in particular, which provide local teams with "actionable knowledge".

## 4. RISK MANAGEMENT

National campaigns are accompanied by a degree of risk and uncertainty which requires careful management. The NPSA campaign employed a formal risk assessment using the "structured what-if technique" (SWIFT) for hazard identification. The major areas of concern related to the distribution strategy to ensure that alcohol-based handrub is available, reliably, wherever and whenever required. The second significant risk related to the ability of the national campaign to gain "buy-in" from the upper levels of hospital management. Both of these risks were targeted in the implementation planning process.

## 5. BARRIERS TO NATIONAL PROGRAMMES

Jumaa[2] emphasizes that using hand hygiene as the sole measure to reduce infection is unlikely to be successful if other factors such as environmental hygiene, crowding, staffing levels and education are inadequate. Indeed, hand hygiene is just one of a range of interventions designed to reduce the transmission of infection in health care. Hand hygiene must therefore be part of an integrated approach. The existence of guidelines does not in itself improve hand hygiene and therefore the impetus given by a national drive to assist in the local implementation can be a useful tool. Most of the literature relating to hand hygiene in health-care settings is concerned with developed countries, yet the threat from infectious disease in less developed countries is high. The extra hurdles faced by less developed countries in terms of technical and human resource capacities have been cited as potential barriers to national health improvement programmes[711]. In addition, the limited or non-existent public health infrastructures, including access to basic sanitation, and the wider geographical and cultural influences cannot be overlooked. Increasing hand hygiene in less developed countries therefore requires a different approach to that in developed countries. The need for a culture promoting hand hygiene at all levels of society can provide a foundation on which to establish a structure promoting compliance[2].

For less developed countries, the public–private partnership under the title of the Global Hand Hygiene Campaign[712] is attempting to tackle the problems across nations exacerbated by low compliance with hand hygiene in the community setting. Problems faced by countries in less developed countries differ to those of the developed world, where hand hygiene is not just an issue for health-care settings. The global campaign involves close working with the private sector with the aim of developing and executing far reaching improvement strategies. Given the emphasis on motivational factors as influencers of the ultimate effectiveness of strategies in less developed countries, Curtis and colleagues[563] describe the importance of promoting hand soap as a desirable consumer product rather than employing a broader health campaign. The potential for extending such an approach as part of a wider hand hygiene strategy in the less developed countries requires further exploration. Ethical issues relating to partnership working with corporate business should not be a barrier, but do need to be explored in a straightforward manner.

A national campaign within less developed countries to promote the use of near-patient alcohol-based handrubs would overcome some of the issues relating to the lack of availability of water for handwashing – but success would be influenced by the cost of products and the internal distribution networks to ensure that the products were available when needed. Integration with other collaborations, e.g. the Global WASH Forum (a public health campaign working with industry in developing countries to address sanitation and hygiene in communities)[713], would be necessary for success. The Forum combines the expertise and resources of the soap industry with the facilities and resources of governments to promote handwashing with soap and calls for country-level acceptance of the need for sanitation and water programmes, principally through political commitment.

The objectives of the initiative are to reduce the incidence of diarrhoeal diseases in poor communities through public–private partnerships promoting handwashing with soap. A list has been drawn up of critical factors that are necessary to drive forward this improvement: political will; policies and strategies which enable improvement; finance; coalition and partnerships; local governments and local action; and external support agencies. Fewtrell and colleagues[714] emphasize the importance of selecting interventions for less developed countries based on local desirability, feasibility and cost–effectiveness.

# 6. PRINCIPLES OF COUNTRYWIDE HAND HYGIENE IMPROVEMENT

Attempts to implement a national campaign along the lines of the United Kingdom NPSA's "clean***your***hands" requires careful consideration of context and community[708]; for this reason alone there can be no universal model or framework for spreading good practice such as hand hygiene improvement. However, an overall programme can be developed capable of dramatically enhancing success within nations. The chief benefits in favour of national programmes relate to the avoidance of fragmentation, cost inefficiency and duplication of effort.

The critical factors for success are hinged around:

- the presence of drivers for improvement;
- the adaptability of the programme;
- political commitment;
- policies and strategies that enable spread and sustainability;
- availability of finance;
- coalitions and partnerships;
- local ownership;
- presence of external support agencies;
- capacity for rapid dissemination and active learning;
- links to health-care regulation;
- economies of scale to be achieved through central production;
- capacity for public–private partnership working.

These factors will differ in a number of ways across developed and less developed countries, not least in the absence of robust public health infrastructures in less developed nations. Fewtrell and colleagues[714] emphasize the importance of making intelligent choices of interventions for specific settings and that these should be underpinned by considerations of feasibility, social issues, cost–effectiveness and sustainability. The learning from the "clean***your***hands" campaign outlines the importance of risk assessment prior to the introduction of a nationally driven improvement. To achieve such improvement inevitably requires the combined expertise of many professional groups[714].

The WHO World Alliance for Patient Safety, and in particular the Global Patient Safety Challenge 2005–2006, have committed to developing a self-assessment toolkit to enable countries to evaluate their state of progress in relation to patient safety, and the appropriateness of a national or countrywide hand hygiene improvement programme could be incorporated into this toolkit. Furthermore, *The World Health Report 2004*[711] emphasizes the motivating effect of a time-bound target.

It is clear that while further research is required into the feasibility and long-term impact of national interventions for hand hygiene improvement, such programmes do have the potential to raise the stakes, focus minds and act as a catalyst for action. They can add value to the daily efforts designed to ensure local implementation of currently existing policies and guidelines. While the barriers and facilitators differ across developed and less developed countries, the broad principles behind the need for carefully designed interventions to ensure effectiveness, cost–effectiveness and sustainable improvement remain similar.

# PART V. PROVIDING INFORMATION TO THE PUBLIC

## 1. THE IMPORTANCE OF INFORMING THE PUBLIC

Information to the public outlines processes and strategies for disseminating specific information. This is important for various reasons. Firstly, many public health advocates argue that large numbers of target populations (mothers, children, adolescents, etc.) cannot make informed decisions or exhibit informed behaviours about their own or their families' health. Secondly, patients' families and community volunteers, particularly in developing countries, often provide patient care or offer support during the delivery of care in hospitals and community health centres and at home. Accordingly, efforts are needed on the part of the government or health authorities to ensure that, for example, appropriate hand hygiene information and messages are brought to the attention of the public. Thirdly, the knowledge, training, practices and motivation of HCWs, who are also members of the public, can be further reinforced with secondary information and messages.

It has been proposed by many authors active in the area of hand hygiene that multimodal and multidisciplinary strategies are necessary for improving hand hygiene practices in health-care settings[572]. Delivering information to the public can be seen as one of the many strategies and a key factor within the overall framework of hand hygiene promotion.

## 2. DOCUMENTING PUBLIC INFORMATION CAMPAIGNS

The mass media are probably the most influential promotional vehicle at our disposal. They frequently cover health-related issues and are the leading source of information to the public. Other methods for disseminating information to the public and raising awareness include the use of nongovernmental organizations or national agencies to reach communities through grass-roots activities and products such as leaflets, radio and television broadcasts, web sites and portals, health visitors, community plays and meetings. School-based hand hygiene education and dissemination of information at the workplace are also effective means for disseminating health information to target groups.

In *The World Health Report 2002*[715], WHO reported on a series of comprehensive approaches that have been implemented at the national level to reduce specific risks in health care, taking into account a variety of interventions that include disseminating information to the public, mainly through media outreach. The report presents several examples of mass media campaigns that have had a positive impact on target audiences. These include a mass media campaign to diminish the risks of high blood pressure and cholesterol[716], a population-wide mass media campaign to prevent HIV/AIDS[717], and information to the public to reduce tobacco consumption[718,719].

As many international and national health campaigns have demonstrated, the media play a key role in mobilizing public support, influencing behavioural change and setting the local political agenda. A 2001 Cochrane review[720] showed that the use of the mass media was a way of presenting information about important health issues, targeted by those who aim to influence the behaviour of health professionals and patients. The review concluded that the mass media should be considered one of the tools that may influence the use of health-care interventions.

## 3. EXAMPLES OF WHO PUBLIC INFORMATION CAMPAIGNS

Communication and public information strategies have been evolved by WHO and its partners to promote the activities of two technical programmes: the global control of tuberculosis (TB) through the Stop-TB programme, and the Tobacco-Free Initiative. Elements of these two public information campaigns are shown in Table V.3.1.

## 4. EXAMPLES OF NATIONAL PUBLIC INFORMATION CAMPAIGNS

To contribute to the reduction of diseases associated with a lack of hygienic practices, public health promotion and education strategies have been implemented in several developing countries to inform the public about the dangers of poor hygiene and to attempt to change behaviour. Overall, large-scale handwashing promotional programmes have been effective in initiating behavioural change among their target groups and have used a variety of innovative methods[721]. Programmes to improve handwashing behaviour appear to be feasible and sustainable, especially when they incorporate traditional hygiene practices and beliefs[722] and take into consideration locally appropriate channels of communication[723]. New and better approaches to behavioural change have been developed, including recent programmes in several developing countries that include a strong public information component. For example, the Central American Handwashing Initiative[724,725] is a large-scale programme that has shown excellent results through persuading the private sector (soap manufacturers and the media) to disseminate health information by advertising and marketing soap and its appropriate use for hand hygiene. In this initiative, the soap producers in Central America promoted beneficial health behaviour while promoting their products[726]. Consumer and market studies were carried out to understand the nature of the market, consumer attitudes, behaviours and most appropriate promotional strategies and communication channels. Public information, advertising and marketing campaigns (including promotional materials) were country-specific and developed by each soap manufacturer. Many local radio and TV stations donated air time and newspapers offered free space to run the sponsored advertisements. Public schools distributed posters and handwashing kits. The partners of this initiative and their products also made many appearances at community activities and fairs[716] (Table V.4.1).

A similar large-scale public information campaign is being implemented in Ghana and another is planned in Kerala State, India[724]. The objectives of both campaigns are to get

private industry and the public sector to work together to promote handwashing with non-branded soap. The private sector agreed to provide technical and managerial skills; at the same time, global advocacy ensured that the two campaigns received international visibility, including the dissemination of materials, through the global press as well as a dedicated web site. Consumer and market studies helped to understand consumer handwashing behaviour, target audiences, motivations, available communication channels, and the state of the soap market. In Kerala, a detailed communication package and strategies were developed and tested by the soap industry. An interesting outcome of the work was that at least six effective contacts a month were required to generate new behaviour. These contacts involved household visits by trained field workers to provide information and encourage handwashing with soap. "Drip-drip" approaches were not considered effective because a critical mass that can affect a change in habits is never reached[724]. Creative agencies were commissioned to sketch out and test advertisements for the radio and television, concepts for posters, kits for schools and health centres, and support materials for mobilizing country partners. Data on mass media helped target messages through appropriate communication routes (television, radio, newspapers and direct contact). In addition to using mass media, direct communications were necessary, involving visits to households[724]. The Kerala campaign is awaiting cabinet approval to begin implementation. The Ghana public information work is on going as a two-year campaign (2003–2005). Its communication material and events include car stickers, posters, poster stickers, advocacy leaflets, folders, bounty packs for mothers, billboards, badges, T-shirts, caps, polo shirts, handwashing basins/buckets, bars of soap, training materials for teachers and school health coordinators, newsletters/quizzes/prizes, advocacy materials, handwashing "information cards", mass media launch events and community events (e.g. drama)[727] (Table V.4.1).

China, Nepal, Peru and Senegal are following or planning public–private partnership campaigns to promote good hand hygiene practices in vulnerable target groups.

## 5. THE PUBLIC INFORMATION COMPONENT OF NATIONAL CAMPAIGNS TO PREVENT HEALTH CARE-ASSOCIATED INFECTION

In the past year, health authorities in several industrialized countries have mobilized to use their knowledge, skills and resources to reverse the devastating impact of HCAI through practising hand hygiene mainly in hospitals.

The recent United Kingdom "clean***your***hands" campaign aims to enlist the acute hospitals of the NHS to implement a hand hygiene campaign (see also Part IV). Research by the country's NPSA in 2002 identified low compliance with hand hygiene as a patient safety concern contributing to current levels of HCAI. To overcome this, the campaign aimed to place alcohol-based handrubs near every patient in all acute hospitals by April 2005 and to provide the hospital with a toolkit and addresses for a multimodal promotion strategy to improve compliance.

The three-month preparatory stage of the campaign focused on developing information starter packs for empowering health-care providers and patients alike in hand hygiene practices. Table V.5.1 lists the information materials developed for this campaign. In addition, many health trusts embarked on media launches, conferences, activities and a television

debate that resulted in increasing public awareness of the importance of hand hygiene in health-care settings.

A recent national campaign in the USA, the "100 000 Lives" campaign[598], relates to specific aspects of preventing HCAI by focusing on preventing central line and surgical site infections among a total of six quality improvement changes. Maintaining hand hygiene is one of the critical actions outlined in this campaign. The campaign has presently enrolled about 3000 hospitals and has mounted awareness-raising efforts (listed in Table V.5.1) to engage hospital participation.

## 6. DOCUMENTING LESSONS LEARNT

WHO, in *The World Health Report 2002*, outlines the importance of communicating information to the public[715], as well as some important lessons that have been learnt on the role of dialogue between the public and government in communicating health risks. These lessons cover the most effective ways to handle and communicate with the public about important risks. In view of the serious implications of HCAI on the patient, his or her family, the health authority and the government, communicating information to the public is of essential importance. The main points can be summarized as follows[715].

- Governments and public agencies should make public a full account of known facts. Political credibility and public trust are rapidly lost if the public believes it has not been given full information on the risks that affect it.
- Information to the public should be released by an independent and trusted professional agency. This should be done by recognized experts who are well qualified in the subject and who are seen to be fully trustworthy, politically independent and without conflicts of interest. For public health in many countries, this important function is often best performed by the chief medical officer.
- An atmosphere of trust is needed between government officials, health experts, the general public and the media. This trust has to be developed and fostered. Condescending attitudes and the withholding of information can rapidly lead to public cynicism and accusations of a cover-up or a hidden scandal. Trust is easily lost but very difficult to regain.

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## WHO GUIDELINES ON HAND HYGIENE IN HEALTH CARE (ADVANCED DRAFT)

# TABLES

## GLOBAL PATIENT SAFETY CHALLENGE 2005–2006: "CLEAN CARE IS SAFER CARE"

***Table I.8.1:***
***Basic experimental design of current methods to test the efficacy of hand hygiene and surgical hand preparation formulations***

| Method no. | Test organism(s) | Basic procedure |
|---|---|---|
| **EN 1499** (hygienic handwash) | *Escherichia coli* (K12) | Hands washed with a soft soap, dried, immersed in broth culture for 5 s, excess fluid drained off, and air-dried for 3 min. Bacteria recovered for the initial values by kneading the fingertips of each hand separately for 60 s in 10 ml of broth without neutralizers. Hands removed from the broth and treated with the product following the manufacturer's instructions (but for no longer than 1 min) or the reference solution (a 20% solution of soft soap). Recovery of bacteria for final values (see EN 1500). |
| **EN 1500** (hygienic handrub) | *Escherichia coli* (K12) | Basic procedure for hand contamination and initial recovery of test bacteria same as in EN 1499. Hands rubbed for 30 s with 3 ml of isopropanol 60% *V/V*; same operation repeated with a total application time not exceeding 60 s. The fingertips of both hands rinsed in water for 5 s and excess water drained off. Fingertips of each hand kneaded separately in 10 ml of broth with added neutralizers. These broths are used to obtain the final (post-treatment) values. Log10 dilutions of recovery medium containing neutralizer are prepared and plated out. Within 3 h, the same volunteers tested with the reference formulation or the test product. Colony counts obtained and log reductions calculated. |
| **ASTM E-1174** (effectiveness of health-care worker or consumer handwash formulation) | *Serratia marcescens; Escherichia coli* | To test the efficacy of handwash or handrub agents on the reduction of transient microbial flora. Before baseline bacterial sampling and prior to each wash with the test material, 5 ml of a suspension of test organism are applied to and rubbed over hands. Test material put onto hands and spread over hands and lower 1/3 of forearms with lathering. Hands and forearms rinsed with water. Elutions are performed after required number of washes using 75 ml of eluent for each hand in glove. The eluates are tested for viable bacteria. |
| **ASTM E-1838** (fingerpad method for viruses) | Adenovirus, rotavirus, rhinovirus and hepatitis A virus | 10 µl of the test virus suspension in soil load placed at the centre of each thumb- and fingerpad, the inoculum dried and exposed for 10–30 sec to 1 ml of test formulation or control. The fingerpads then eluted and eluates assayed for viable virus. Controls included to assess input titre, loss on drying of inoculum and mechanical removal of virus. The method applicable to testing both handwash and handrub agents. |

***Table I.8.1:***
***Basic experimental design of current methods to test the efficacy of hand hygiene and surgical hand preparation formulations (Cont.)***

| Method no. | Test organism(s) | Basic procedure |
|---|---|---|
| **ASTM E-2276** (fingerpad method for bacteria) | *Escherichia coli, Serratia marcescens, Staphylococcus aureus and Staphylococcus epidermidis* | Similar to **ASTM E-1838**. |
| **ASTM E-2011** (whole hand method for viruses) | Rotavirus and rhinovirus | This method is designed to confirm the findings of the fingerpad method (E-1838), if necessary. Both hands are contaminated with the test virus and test formulation is used to wash or rub on them. The entire surface of both hands eluted and the eluates assayed for infectious virus. |
| **prEN 12791** (surgical hand preparation): | Resident skin flora (no artificial contamination) | Same as for EN 1500 with the following exceptions: no artificial contamination, reference hand antisepsis 3 min rub with n-propanol 60% *V/V,* longest allowed treatment with product 5 min, 1 week between tests with reference and product. Test for persistence (3 h) with split hands model is optional (product shall be significantly superior to reference). |
| **ASTM E-1115** (test method for evaluation of surgical hand scrub formulations) | Resident skin flora (no artificial contamination) | The method is designed to assess immediate or persistent activity against the resident flora. Volunteers perform simulated surgical scrub and hands sampled by kneading them in loose-fitting gloves with an eluent. The eluates are assayed for viable bacteria. |

***Table I.9.1:***
***Waterborne pathogens and their significance in water supplies***

| Pathogen | Health significance | Persistence in water supplies | Relative infectivity |
|---|---|---|---|
| **Bacteria** | | | |
| *Campylobacter jejuni, C. coli* | High | Moderate | Moderate |
| Pathogenic *Escherichia coli* | High | Moderate | Low |
| Enterohaemorrhagic *E. coli* | High | Moderate | High |
| *Legionella* spp. | High | Multiply | Moderate |
| Non-tuberculosis mycobacteria | Low | Multiply | Low |
| *Pseudomonas aeruginosa* | Moderate | May multiply | Low |
| *Salmonella typhi* | High | Moderate | Low |
| Other salmonellae | High | Short | Low |
| *Shigella* spp. | High | Short | Moderate |
| *Vibrio cholerae* | High | Short | Low |
| *Burkholderia pseudomallei* | Low | May multiply | Low |
| *Yersinia enterocolitica* | High | Long | Low |
| **Viruses** | | | |
| Adenoviruses | High | Long | High |
| Enteroviruses | High | Long | High |
| Hepatitis A | High | Long | High |
| Hepatitis E | High | Long | High |
| Noroviruses and sapoviruses | High | Long | High |
| Rotaviruses | High | Long | High |
| **Protozoa** | | | |
| *Acanthamoeba* spp. | High | Long | High |
| *Cryptosporidium parvum* | High | Long | High |
| *Cyclospora cayetanensis* | High | Long | High |
| *Entamoeba histolytica* | High | Moderate | High |
| *Giardia lamblia* | High | Moderate | High |
| *Naegleria fowleri* | High | May multiply | High |
| *Toxoplasma gondii* | High | Long | High |
| **Helminths** | | | |
| *Dracunculus medinensis* | High | Moderate | High |
| *Schistosoma* spp. | High | Short | High |

Source: *WHO Guidelines for drinking-water quality,* 2004.

***Table I.9.2:***
***Microbiological indicators for water quality in health-care settings in France***

| Indicators | Level | Frequency |
|---|---|---|
| Aerobic flora at 22° and 36° C | No variation above a 10-fold compared to the usual value at the entry point | 1 control/100 beds/year with a minimum of 4 controls per year |
| *Pseudomonas aeruginosa* | < 1 FCU/100 ml | Quarterly |
| Total coliforms | < 1 FCU/100 ml | Quarterly |

Adapted from:

*L'eau dans les établissements de santé – guide technique [Water in health-care facilities – technical guide]*. Ministère des Solidarités, de la Santé et de la Famille en France, 2004.

***Table I.9.3:***
***Virucidal activity of antiseptic agents***

| | Reference | Test method | Viruses | Agent | Results |
|---|---|---|---|---|---|
| Enveloped viruses | 728 | Suspension | HIV | 19% EA | LR=2.0 in 5 min |
| | 729 | Suspension | HIV | 50%EA<br>35%IPA | LR>3.5<br>LR>3.7 |
| | 730 | Suspension | HIV | 70%EA | LR=7.0 in 1 min |
| | 731 | Suspension | HIV | 70%EA | LR= 3.2–5.5 in 30 s |
| | 732 | Suspension | HIV | 70% IPA + 0.5% CHG<br>4% CHG | LR= 6.0 in 15 s<br>LR= 6.0 in 15 s |
| | 733 | Suspension | HIV | Chloroxylenol<br>Benzalkonium chloride | Inactivated in 1 min<br>Inactivated in 1 min |
| | 734 | Suspension | HIV | Povidone-iodine<br>Chlorhexidine | Inactivated<br>Inactivated |
| | 735 | Suspension | HIV | Detergent + 0.5% PCMX | Inactivated in 30 s |
| | 736 | Suspension/ dried plasma Chimpanzee challenge | HBV | 70% IPA | LR= 6.0 in 10 min |
| | 737 | Suspension/ plasma Chimpanzee challenge | HBV | 80% EA | LR= 7.0 in 2 min |
| | 738 | Suspension | HSV | 95% EA<br>75% EA<br>95% IPA<br>70% EA + 0.5% CHG | LR>5.0 in 1 min<br>LR>5.0<br>LR>5.0<br>LR>5.0 |
| | 223 | Suspension | RSV | 35% IPA<br>4% CHG | LR>4.3 in 1 min<br>LR>3.3 |
| | 235 | Suspension | Influenza<br>Vaccinia | 95% EA<br>95% EA | Undetectable in 30 s<br>Undetectable in 30 s |
| | 235 | Hand test | Influenza<br>Vaccinia | 95% EA<br>95% EA | LR> 2.5<br>LR> 2.5 |

***Table I.9.3:***
***Virucidal activity of antiseptic agents (Cont.)***

| | Reference | Test method | Viruses | Agent | Results |
|---|---|---|---|---|---|
| **Non-enveloped viruses** | 739 | Suspension | Rotavirus | 4% CHG<br>10% Povidone-iodine<br>70% IPA/0.1% HCP | LR<3.0 in 1 min<br>LR>3.0<br>LR>3.0 |
| | 235 | Hand test | Adenovirus<br>Poliovirus<br>Coxsackie | 95% EA<br>95% EA<br>95% EA | LR> 1.4<br>LR=0.2–1.0<br>LR=1.1–1.3 |
| | | Finger test | Adenovirus<br>Poliovirus<br>Coxsackie | 95% EA<br>95% EA<br>95% EA | LR> 2.3<br>LR=0.7–2.5<br>LR=2.9 |
| | 738 | Suspension | ECHO virus | 95% EA<br>75% EA<br>95% IPA<br>70% IPA+0.5%CHG | LR> 3.0 in 1 min<br>LR<1.0<br>LR=0<br>LR=0 |
| | 234 | Finger pad | HAV | 70% EA<br>62% EA foam<br>Plain soap<br>4% CHG<br>0.3% Triclosan | 87.4% reduction<br>89.3% reduction<br>78.0% reduction<br>89.6% reduction<br>92.0% reduction |
| | 198 | Finger tips | Bovine rotavirus | n-propanol+IPA<br>70% IPA<br>70% EA<br>2% Triclosan<br>Water (control)<br>7.5% povidone-iodine<br>Plain soap<br>4% CHG | LR=3.8 in 30 s<br>LR=3.1<br>LR=2.9<br>LR=2.1<br>LR=1.3<br>LR=1.3<br>LR=1.2<br>LR=0.5 |
| | 183 | Finger pad | Human rotavirus | 70% IPA<br>Plain soap | 98.9% reduction in 10 s<br>77.1% |
| | 230 | Finger pad | Human rotavirus | 70% IPA<br>Plain soap | 80.3%<br>72.5% |
| | 231 | Finger pad | Rotavirus<br>Rhinovirus<br>Adenovirus | 60% EA gel<br>60% EA gel<br>60% EA gel | LR>3.0 in 10 s<br>LR>3.0<br>LR>3.0 |
| | 233 | Finger pad | Poliovirus | 70% EA<br>70% IPA | LR=1.6 in 10 s<br>LR=0.8 |
| | 296 | Finger tips | Poliovirus | Plain soap<br>80% EA | LR=2.1<br>LR=0.4 |

HIV = human immunodeficiency virus; EA = ethanol; LR = $Log_{10}$ Reduction; IPA = isopropanol; CHG = chlorhexidine gluconate; HBV = hepatitis B virus; RSV = respiratory syncytial virus; HSV = herpes simplex virus; HAV = hepatitis A virus.

***Table I.9.4:***

***Studies comparing the relative efficacy (based on $log_{10}$ reductions achieved) of plain soap or antimicrobial soaps versus alcohol-based antiseptics in reducing counts of viable bacteria on hands***

| Reference | Year | Skin contamination | Assay method | Time (s) | Relative efficacy |
|---|---|---|---|---|---|
| 239 | 1965 | Existing hand flora | Finger tip agar culture | 60 | Plain soap < HCP < 50% EA foam |
| 212 | 1975 | Existing hand flora | Handrub broth culture | -- | Plain soap < 95% EA |
| 199 | 1978 | Artificial contamination | Finger tip broth culture | 30 | Plain soap < 4% CHG < P-I < 70% EA = alc. CHG |
| 247 | 1978 | Artificial contamination | Finger tip broth culture | 30 | Plain soap < 4% CHG < 70% EA |
| 200 | 1979 | Existing hand flora | Handrub broth culture | 120 | Plain soap < 0.5% aq. CHG < 70% EA < 4% CHG < alc.CHG |
| 240 | 1980 | Artificial contamination | Finger tip broth culture | 60-120 | 4% CHG < P-I < 60% IPA |
| 71 | 1980 | Artificial contamination | Finger tip broth culture | 15 | Plain soap < 3% HCP < P-I < 4% CHG < 70% EA |
| 201 | 1982 | Artificial contamination | Glove juice test | 15 | P-I < alc. CHG |
| 202 | 1983 | Artificial contamination | Finger tip broth culture | 120 | 0.3-2% triclosan = 60% IPA = alc. CHG < alc. Triclosan |
| 241 | 1984 | Artificial contamination | Finger tip agar culture | 60 | Phenolic < 4% CHG < P-I < EA < IPA < n-P |
| 242 | 1985 | Existing hand flora | Finger tip agar culture | 60 | Plain soap < 70% EA < 95% EA |
| 203 | 1986 | Artificial contamination | Finger tip broth culture | 60 | Phenolic = P-I < alc. CHG < n-P |
| 156 | 1986 | Existing hand flora | Sterile broth bag technique | 15 | Plain soap < IPA < 4% CHG = IPA-H = alc. CHG |
| 82 | 1988 | Artificial contamination | Finger tip broth culture | 30 | Plain soap < triclosan < P-I < IPA < alc. CHG < n-P |
| 44 | 1991 | Patient contact | Glove juice test | 15 | Plain soap < IPA-H |
| 243 | 1991 | Existing hand flora | Agar plate/image analysis | 30 | Plain soap < 1% triclosan < P-I < 4% CHG < IPA |
| 204 | 1992 | Artificial contamination | Finger tip agar culture | 60 | Plain soap < IPA < EA < alc. CHG |
| 158 | 1992 | Artificial contamination | Finger tip broth culture | 60 | Plain soap < 60% n-P |
| 205 | 1994 | Existing hand flora | Agar plate/image analysis | 30 | Plain soap < alc. CHG |
| 244 | 1999 | Existing hand flora | Agar plate culture | N.S. | Plain soap < commercial alcohol mixture |
| 245 | 1999 | Artificial contamination | Glove juice test | 20 | Plain soap < 0.6% PCMX < 65% EA |
| 246 | 1999 | Artificial contamination | Finger tip broth culture | 30 | 4% CHG < plain soap < P-I < 70% EA |

Existing hand flora = without artificially contaminating hands with bacteria. alc. CHG = alcohol-based chlorhexidine gluconate; aq. CHG = aqueous chlorhexidine gluconate; 4% CHG = chlorhexidine gluconate detergent; EA = ethanol;
HCP = hexachlorophene soap/detergent; IPA = isopropanol; IPA-H = isopropanol + humectants; n-P = n-propanol;
PCMX = para-chloro-meta-xylenol detergent; P-I = povidone-iodine detergent; N.S. = not stated.
Hexachlorophene has been banned worldwide because of its high rate of dermal absorption and subsequent toxic effects[26,290].

***Table I.9.5:***
***Hygienic handrub efficacy of various agents in reducing the release of test bacteria from artificially contaminated hands***

| Agent | Concentration[a] (%) | Test bacterium | Mean log reduction exposure time (min) | | |
|---|---|---|---|---|---|
| | | | 0.5 | 1.0 | 2.0 |
| n-Propanol | 100<br>60 | *E. coli* | | 5.8<br>5.5 | |
| | 50 | | | 5.0 | |
| | | | 3.7 | 4.7 | 4.9 |
| | 40 | | | 4.3 | |
| Isopropanol | 70 | *E. coli* | | 4.9<br>4.8 | |
| | | | 3.5 | | |
| | 60 | | | 4.4 | |
| | | | | 4.3 | |
| | | | | 4.2 | |
| | | | | 4.0 | |
| | | *S. marcescens* | | 4.1 | |
| | 50 | *E. coli* | 3.4 | 3.9 | 4.4 |
| Ethanol | 80 | *E. coli* | | 4.5 | |
| | 70 | | | 4.3 | 5.1 |
| | | | | 4.3 | 4.9 |
| | | | | 4.0 | |
| | | | 3.6 | 3.8 | 4.5 |
| | | | 3.4 | 4.1 | |
| | | *S. aureus* | 3.7 | | |
| | | | 2.6 | | |
| Tosylchloramide (aq. sol.) | 60 | *S. saprophyticus* | 3.5 | 3.8 | |
| Povidone-iodine (aq. sol.) | 2.0[b] | *E. coli* | | 4.2 | |
| Chlorhexidine diacetate (aq. sol.) | 1.0[b]<br>0.5[b] | *E. coli*<br>*E. coli* | | 4.0–4.3<br>3.1 | |
| Chloro-cresol (aq. sol.) | 1.0[b] | *E. coli* | | 3.6 | |
| Hydrogen peroxide | 7.5 | *E. coli* | | 3.6 | |

[a] If not stated otherwise, *V/V*.
[b] m/*V*.
Sources:[740,741].

***Table I.9.6:***

***Studies comparing the relative efficacy of plain soap or antimicrobial soap versus alcohol-containing products in reducing counts of bacteria recovered from hands immediately after use of products for pre-operative surgical hand preparation***

| Reference | Year | Assay method | Relative efficacy |
|---|---|---|---|
| [239] | 1965 | Finger tip agar culture | HCP < 50% EA foam + QAC |
| [346] | 1969 | Finger tip agar culture | HCP < P-I < 50% EA foam + QAC |
| [194] | 1973 | Finger tip agar culture | HCP soap < EA foam + 0.23% HCP |
| [227] | 1974 | Broth culture | Plain soap < 0.5% CHG det. < 4% CHG det. < alc. CHG |
| [212] | 1975 | Hand broth test | Plain soap < 0.5% CHG det. < 4% CHG det. < alc. CHG |
| [211] | 1976 | Glove juice test | 0.5% CHG det. < 4% CHG det. < alc. CHG |
| [207] | 1977 | Glove juice test | P-I < CHG det. < alc. CHG |
| [210] | 1978 | Finger tip agar culture | P-I = 46% EA + 0.23% HCP |
| [206] | 1979 | Broth culture of hands | Plain soap < P-I < alc. CHG < alc. P-I |
| [209] | 1979 | Glove juice test | 70% IPA = alc. CHG |
| [242] | 1985 | Finger tip agar culture | Plain soap < 70% - 90% EA |
| [208] | 1990 | Glove juice test, modified | Plain soap < triclosan < CHG det. < P-I < alc. CHG |
| [197] | 1991 | Glove juice test | Plain soap < 2% triclosan < P-I < 70% IPA |
| [347] | 1998 | Finger tip broth culture | 70% IPA < 90% IPA = 60% n-P |
| [348] | 1998 | Glove juice test | P-I < CHG det. < 70% EA |
| [683] | 2001 | Glove juice test | 4% CHG det. < CHG det./61% EA |
| [742] | 2004 | Glove juice test | P-I < CHG det. < 70% EA |

QAC = quaternary ammonium compound; alc. CHG = alcoholic chlorhexidine gluconate;
CHG det. = chlorhexidine gluconate detergent; EA = ethanol; HCP = hexachlorophene detergent; IPA = isopropanol;
P-I = povidone-iodine detergent.

***Table I.9.7:***
***Efficacy of surgical handrub solutions in reducing the release of resident skin flora from clean hands***

| Rub | Concentration[a] (%) | Time (min) | Mean log reduction | |
|---|---|---|---|---|
| | | | Immediate | Persistent (3h) |
| n-Propanol | 60 | 5 | 2.9[b] | 1.6[b] |
| | | 5 | 2.7[b] | NA |
| | | 5 | 2.5[b] | 1.8[b] |
| | | 5 | 2.3[b] | 1.6[b] |
| | | 3 | 2.9[c] | NA |
| | | 3 | 2.0[b] | 1.0[b] |
| | | 1 | 1.1[b] | 0.5[b] |
| Isopropanol | 90 | 3 | 2.4[c] | 1.4[c] |
| | 80 | 3 | 2.3[c] | 1.2[c] |
| | 70 | 5 | 2.4[b] | 2.1[b] |
| | | 5 | 2.1[b] | 1.0[b] |
| | | 3 | 2.0[c] | 0.7[c] |
| | | 3 | 1.7[c] | NA |
| | | 3 | 1.5[b] | 0.8[b] |
| | | 2 | 1.2 | 0.8 |
| | | 1 | 0.7[b] | 0.2 |
| | | 1 | 0.8 | NA |
| | 60 | 5 | 1.7 | 1.0 |
| Isopropanol + chlorhexidine gluc. (*m/V*) | 70 + 0.5 | 5 | 2.5[b] | 2.7[b] |
| | | 2 | 1.0 | 1.5 |
| Ethanol | 95 | 2 | 2.1 | NA |
| | 85 | 3 | 2.4[c] | NA |
| | 80 | 2 | 1.5 | NA |
| | 70 | 2 | 1.0 | 0.6 |
| Ethanol + chlorhexidine gluc. (*m/V*) | 95 + 0.5 | 2 | 1.7 | NA |
| | 77 + 0.5 | 5 | 2.0 | 1.5[d] |
| | 70 + 0.5 | 2 | 0.7 | 1.4 |
| Chlorhexidine gluc. (aq. Sol., *m/V*) | 0.5 | 2 | 0.4 | 1.2 |
| Povidone-iodine (aq. Sol., *m/V*) | 1.0 | 5 | 1.9[b] | 0.8[b] |
| Peracetic acid (*m/V*) | 0.5 | 5 | 1.9 | NA |

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NA = not available.
[a] volume/volume (*V/V*) unless otherwise stated.
[b] Tested according to Deutsche Gesellschaft fur Hygiene and Mikrobiologic (DGHM), German Society of Hygiene and Microbiology.
[c] Tested according to European Standard prEN.
[d] After 4 h.

***Table I.14.1:***
***Hand hygiene frequency among health-care workers***

| Reference | Year | Frequency of handwashing episodes | | |
|---|---|---|---|---|
| | | Average no./ time period | Range | Average no./h |
| [82] | 1988 | 5/8 h | N.S. | |
| [153] | 1984 | 5–10/shift | N.S. | |
| [188] | 2000 | 10/shift | N.S. | |
| [469] | 2000 | 12–18/day | 2–60 | |
| [190] | 2000 | 13–15/8 h | 5–27 | 1.6–1.8/h |
| [154] | 1977 | 20–42/8 h | 10–100 | |
| [743] | 2000 | 21/12 h | N.S. | |
| [468] | 2000 | 22/day | 0–70 | |
| [527] | 2002 | | | 0.7/h |
| [152] | 1991 | | | 1.7–2.1/h |
| [35] | 1998 | | | 2.1/h |
| [531] | 2004 | | | 2.2/h |
| [457] | 1978 | | | 3/h |
| [515] | 1994 | | | 3.3/h |
| [459] | 2001 | | | 3.5/h |
| [530] | 2003 | | | 10/h |
| [499] | 2003 | | | 11.6/h |
| [744] | 2001 | | | 12/h |

N.S. = not stated.

***Table I.14.2:***
***Hand hygiene adherence by health-care workers (1981–2004)***

| Reference | Year | Setting | Before/ after contact | Adherence baseline (%) | Adherence after intervention (%) | Intervention |
|---|---|---|---|---|---|---|
| 476 | 1981 | ICU | A | 16 | 30 | More convenient sink locations |
| 501 | 1981 | ICU | A | 41 | -- | |
| | | ICU | A | 28 | -- | |
| 502 | 1983 | All wards | A | 45 | -- | |
| 480 | 1986 | SICU | A | 51 | -- | |
| | | MICU | A | 76 | -- | |
| 475 | 1986 | ICU | A | 63 | 92 | Performance feedback |
| 503 | 1987 | PICU | A | 31 | 30 | Wearing overgown |
| 504 | 1989 | MICU | B/A | 14/28 * | 73/81 | Feedback, policy reviews, memo, posters |
| | | MICU | B/A | 26/23 | 38/60 | |
| 745 | 1989 | NICU | A/B | 75/50 | -- | |
| 506 | 1990 | ICU | A | 32 | 45 | Alcohol rub introduced |
| 507 | 1990 | ICU | A** | 81 | 92 | In-service first, then group feedback |
| 508 | 1990 | ICU | B/A** | 22 | 30 | |
| 509 | 1991 | SICU | A | 51 | -- | |
| 510 | 1991 | Pedi OPDs | B | 49 | 49 | Signs, feedback, verbal reminders to doctors |
| 511 | 1991 | Nursery & NICU | B/A *** | 28 | 63 | Feedback, dissemination of literature, results of environmental cultures |
| 512 | 1992 | NICU/others | A | 29 | -- | |
| 500 | 1992 | ICU | N.S. | 40 | -- | |
| 513 | 1993 | ICUs | A | 40 | -- | |
| 151 | 1994 | Emerg Room | A | 32 | -- | |
| 150 | 1994 | All wards | A | 32 | -- | |
| 482 | 1994 | SICU | A | 22 | 38 | Automated handwashing machines available |
| 514 | 1994 | NICU | A | 62 | 60 | No gowning required |
| 515 | 1994 | ICUs<br>Wards | A<br>A | 30<br>29 | -- | |
| 516 | 1995 | ICU<br>Oncol Ward | A | 56 | -- | |
| 517 | 1995 | ICU | N.S. | 5 | 63 | Lectures, feedback, demonstrations |
| 518 | 1996 | PICU | B/A | 12/11 | 68/65 | Overt observation, followed by feedback |
| 519 | 1996 | MICU | A | 41 | 58 | Routine wearing of gowns and gloves |
| 520 | 1996 | Emerg Dept | A | 54 | 64 | Signs/distributed review paper |

***Table I.14.2:***
***Hand hygiene adherence by health-care workers (1981–2004) (Cont.)***

| Reference | Year | Setting | Before/ after contact | Adherence baseline (%) | Adherence after intervention (%) | Intervention |
|---|---|---|---|---|---|---|
| 526 | 1997 | ICU | B/A** | 56 | 83 | Lectures based on previous questionnaire on HCWs' beliefs, feedback, administrative support, Automated handwashing machines available |
| 521 | 1998 | All wards | A | 30 | -- | |
| 522 | 1998 | Paediatric wards | B/A | 52/49 | 74/69 | Feedback, films, posters, brochures |
| 523 | 1999 | MICU | B/A | 12/55 | -- | |
| 262 | 2000 | All wards | B/A** and *** | 48 | 67% | Posters, feedback, administrative support, alcohol rub |
| 359 | 2000 | MICU | A | 42 | 61% | Alcohol handrub made available |
| 360 | 2000 | MICU<br>CTICU | B/A<br>B/A | 10/22<br>4/13 | 23%/48%<br>7%/14% | Education, feedback, alcohol gel made available |
| 524 | 2000 | Medical wards | A*** | 60 | 52% | Education, reminders, alcohol gel made available |
| 459 | 2001 | All wards | B/A | 62 | 67% | Education, alcohol gel made available |
| 527 | 2002 | ICU | B/A** | 15 | -- | |
| 261 | 2002 | MICU/ SICU NICU | B/A** and *** | 38 | 55% | Posters, feedback, administrative support, alcohol rub |
| 528 | 2002 | PICU / NICU | B/A** and *** | 33 | 37% | Posters, feedback, alcohol rub |
| 530 | 2003 | All wards 3 hospitals | B/A | 17 | 58% | Education, reminders, more sinks made available |
| 529 | 2003 | NICU | B/A** and *** | 44 | 48% | Education, feedback, alcohol gel made available |
| 499 | 2003 | PACU | B/A** and *** | 19.6 | -- | |
| 531 | 2004 | NICU | B/A*** | 40 | 53 | Education, reminders |
| 263 | 2004 | Doctors in all wards | B/A** and *** | 57 | -- | |
| 525 | 2005 | All wards | B/A** and *** | 39 | -- | -- |
| 533 | 2005 | Haemodialysis units | B/A and *** | B 13.8<br>Ar 35.6 | -- | -- |
| 534 | 2005 | Haemodialysis units* | B/A | 26 | -- | |

ICU = intensive care unit; SICU = surgical ICU; MICU = medical ICU; PICU = paediatric ICU; NICU = neonatal ICU; Emerg = emergency; Oncol = oncology; CTICU = cardiothoracic ICU; PACU = post-anaesthesia care unit: OPD = outpatient department; N.S = not stated.

* Percentage compliance before/after patient contact; ** Hand hygiene opportunities within the same patient also counted; *** After contact with inanimate objects; **** Use of gloves almost universal (93%) in all activities.

***Table I.14.3:***
***Factors influencing adherence to hand hygiene practices***

| |
|---|
| **A. Observed risk factors for poor adherence to recommended hand hygiene practices** |
| – Physician status (rather than a nurse) |
| – Nursing assistant status (rather than a nurse) |
| – Male sex |
| – Working in intensive care |
| – Working during the week (vs. week-end) |
| – Wearing gowns/gloves |
| – Automated sink |
| – Activities with high risk of cross-transmission |
| – Understaffing or overcrowding |
| – High number of opportunities for hand hygiene per hour of patient care |
| **B. Self-reported factors for poor adherence with hand hygiene** |
| – Handwashing agents cause irritations and dryness |
| – Sinks are inconveniently located or shortage of sinks |
| – Lack of soap, paper, towel |
| – Often too busy or insufficient time |
| – Patient needs take priority |
| – Hand hygiene interferes with health-care worker–patient relationship |
| – Low risk of acquiring infection from patients |
| – Wearing of gloves or belief that glove use obviates the need for hand hygiene |
| – Lack of knowledge of guidelines and protocols |
| – Not thinking about it; forgetfulness |
| – No role model from colleagues or superiors |
| – Scepticism about the value of hand hygiene |
| – Disagreement with the recommendations |
| – Lack of scientific information of definitive impact of improved hand hygiene on HCAI rates |
| **C. Additional perceived barriers to appropriate hand hygiene** |
| – Lack of active participation in hand hygiene promotion at individual or institutional level |
| – Lack of role model for hand hygiene |
| – Lack of institutional priority for hand hygiene |
| – Lack of administrative sanction of non-compliers or rewarding of compliers |
| – Lack of institutional safety climate |

Adapted from: [561].

***Table I.15.1:***
***Hand hygiene indications and alcohol prohibition in different religions***

| Religion | Specific indications for hand hygiene | Type of cleansing[a] | Alcohol prohibition | Reason for alcohol prohibition | Alcohol prohibition potentially affecting use of alcohol-based handrub |
|---|---|---|---|---|---|
| Buddhism | After each meal | H | Yes | It kills living organisms (bacteria) | Yes, but surmountable |
| | To wash the hands of the deceased | S | | | |
| | At New Year, young people pour water over elders' hands | S | | | |
| Christianity | Before the consecration of bread and wine | R | No | - | No |
| | After handling Holy Oil (Catholics) | H | | | |
| Hinduism | During worship ceremony (puja) (water) | R | Yes | It causes mental impairment | No |
| | End of prayer (water) | R | | | |
| | After any unclean act (toilet) | H | | | |
| Islam | Repeating ablutions at least three times with running water before prayers (5 times a day) | R | Yes | Disconnection from a state of awareness or consciousness | Yes, but surmountable. Very advanced and close scrutiny of the problem |
| | Before and after any meal | H | | | |
| | After going to the toilet | H | | | |
| | After touching a dog, shoes or a cadaver | H | | | |
| | After handling anything soiled | H | | | |
| Judaism | Immediately after waking in the morning | H | No | - | No |
| | Before and after each meal | H | | | |
| | Before praying | R | | | |
| | Before the beginning of the Shabbat | R | | | |
| | After going to the toilet | H | | | |
| Orthodox Christianity | After putting on liturgical vestments before beginning the ceremony | R | No | - | No |
| | Before the consecration of bread and wine | R | | | |
| Sikhism | Early in the morning | H | Yes | Unacceptable behaviour as disrespectful of the faith<br>Because it is considered an intoxicant | +/- |
| | Before every religious activity | R | | | |
| | Before cooking and entering the community food hall | H | | | |
| | After each meal | H | | | |
| | After taking off or putting on shoes | H | | | |

[a] H = hygienic; R = ritual; S = symbolic.

***Table I.17.1:***
***Elements of educational and motivational programmes for health-care workers***

**1. Rationale for hand hygiene, including:**

a) potential risks of transmission of microorganisms to patients

b) potential risks of health-care worker colonization or infection caused by organisms acquired from the patient

c) morbidity, mortality, and costs associated with health care-associated infections

**2. Indications for hand hygiene, including those patient contacts for which potential contamination is not readily apparent to the health-care worker, such as:**

a) contact with a patient's intact skin (e.g. taking a pulse or blood pressure, performing physical examinations, lifting the patient in bed) [28,44,45,63,67,71]

b) contact with environmental surfaces in the immediate vicinity of patients [28,64,71,74]

c) following glove removal [69,85,500]

**3. Techniques for hand hygiene, including:**

a) amount of hand hygiene solution

b) duration of hand hygiene procedure

c) selection of hand hygiene agents

1) alcohol-based handrubs are the most efficacious agents for reducing the number of bacteria on the hands of personnel. Antiseptic soaps and detergents are the next most effective, and non-antimicrobial soaps are the least effective [1,361]

2) soap and water are recommended for visibly soiled hands

3) alcohol-based handrubs are recommended for routine decontamination of hands for all clinical indications (except when hands are visibly soiled) and as one of the options for surgical hand hygiene

**4. Methods to maintain hand skin health:**

a) lotions and creams are acceptable and can prevent or minimize skin dryness and irritation due to irritant contact dermatitis

b) lotions or creams must be applied according to a recommended schedule

c) lotions or creams should be provided free of charge to the health-care worker

**5. Expectations of patient-care managers/administrators as evidenced by:**

a) written statements regarding the value of, and support for, adherence to recommended hand hygiene practices

b) role models demonstrating adherence to recommended hand hygiene practices [559]

**6. Indications for, and limitations of, glove use:**

a) hand contamination may occur as a result of small, undetected holes in examination gloves [377,615]

b) contamination may occur during glove removal [69]

c) wearing gloves does not replace the need for hand hygiene [85]

d) failure to remove gloves after caring for a patient may lead to transmission of microorganisms from one patient to another [634]

***Table I.18.1:***
***Strategies for successful promotion of hand hygiene in hospitals***

| Strategy | | Selected references* |
|---|---|---|
| 1. Education | | *261,262,507,518,526,528-531,536,591,592,746* |
| 2. Routine observation and feedback | | *261,262,506,518,526,528-530,746* |
| 3. Engineering control | Make hand hygiene possible, easy, convenient | *261,262,506,518,526,528-530,746* |
| | Make alcohol-based handrub available | *261,262,506,518,526,528-530,746* |
| 4. Patient education | | *261,262,506,518,526,528-530,746* |
| 5. Reminders in the workplace | | *261,262,506,518,526,528-530,746* |
| 6. Administrative sanction/rewarding | | *261,262,506,518,526,528-530,746* |
| 7. Change in hand hygiene agent | | *261,262,506,518,526,528-530,746* |
| 8. Promote/facilitate skin care for HCW hands | | *261,262,506,518,526,528-530,746* |
| 9. Active participation at individual and institutional level | | *261,262,506,518,526,528-530,746* |
| 10. Improve institutional safety climate | | *261,262,506,518,526,528-530,746* |
| 11. Enhance individual and institutional self-efficacy | | *262,535,541,530,592* |
| 12. Avoid overcrowding, understaffing, excessive workload | | *262,535,541 530,592* |
| 13. Combine several of above strategies | | *262,535,541 530,592* |

*Only selected references have been listed; readers should refer to more extensive reviews for exhaustive reference lists[1,13,541,561,749].

***Table I.19.1:***
***Association between improved adherence with hand hygiene practice and health care-associated infection rates***

| Year | Authors | Hospital setting | Significant results | Duration of follow-up | Ref |
|---|---|---|---|---|---|
| 1977 | Casewell & Phillips | Adult ICU | Reduction in Klebsiella spp. health care-associated infections | 2 years | *67* |
| 1982 | Maki & Hecht | Adult ICU | Reduction in health care-associated infection rates | N.S. | *750* |
| 1984 | Massanari & Hierholzer | Adult ICU | Reduction in health care-associated infection rates | N.S. | *133* |
| 1989 | Conly et al. | Adult ICU | Reduction in health care-associated infection rates | N.S. | *504* |
| 1990 | Simmons et al. | Adult ICU | No effect (hand hygiene improvement did not reach statistical significance) | 11 months | *508* |
| 1992 | Doebbeling et al. | Adult ICU | Significant difference in health care-associated infection rates between two different hand hygiene agents | 8 months | *500* |
| 1994 | Webster et al. | NICU | Elimination of MRSA, when combined with multiple other infection control measures. Reduction of vancomycin use | 9 months | *119* |
| 1995 | Zafar et al. | Newborn nursery | Elimination of MRSA, when combined with multiple other infection control measures | 3.5 years | *120* |
| 2000 | Larson et al. | MICU/NICU | Significant (85%) relative reduction of VRE rate in the intervention hospital; no significant change in MRSA | 8 months | *535* |
| 2000 | Pittet et al. | Hospital-wide | Significant reduction in the overall prevalence of health care-associated infections and MRSA rates. Active surveillance cultures and contact precautions were implemented during the same time period | 5 years | *262* |
| 2003 | MacDonald et al. | Hospital-wide | Significant reduction in hospital-acquired MRSA cases | N.S. | *363* |
| 2004 | Swoboda et al. | Adult intermediate care unit | Reduction in health care-associated infection rates did not reach statistical significance | 2.5 months | *489* |
| 2004 | Lam et al. | NICU | No significant reduction in health care-associated infection rates | 6 months | *531* |
| 2004 | Won et al. | NICU | Significant reduction of health care-associated infection rates | 3 years | *536* |

ICU = intensive care unit; NICU = neonatal ICU; MRSA = methicillin-resistant S. aureus; MICU = medical ICU; N.S. = not stated.

***Table I.20.1:***
***Possible problems and recommended solutions during the reprocessing of gloves***

| | Probable cause | Recommended solution |
|---|---|---|
| Problem: sticky gloves | Residual liquid soap or detergent | Reduce amount of liquid soap or detergent used when washing gloves<br>Rinse gloves at least three times in clean (running) water |
| | Heated to high temperature for too long | Use 30 minutes sterilizing time at 121°C and remove gloves from sterilizer as soon as cycle is completed |
| | Gloves sterilized with other items | Sterilize gloves separately |
| | Gloves not allowed to dry completely after steaming | Wear "wet" within 30 minutes or allow to dry for 4 to 6 hours before using |
| | Surfaces of gloves touching each other | Gauze or paper wicks should be inserted between palm and back of each glove and between the hand of the glove and the turned-back cuff (allows steam to contact all surfaces and prevents surfaces from adhering to each other) |
| | Deterioration of rubber (latex) gloves (used, unused) while stored | Store in a dry, cool place away from direct sunlight |
| Problem: excess tearing and rupturing | Gloves used too soon following sterilization | Do not use gloves for 24–48 hours after sterilization (allows gloves to regain their elasticity before use) |

Source: [641].

***Table I.21.1:***
***Hand hygiene research agenda***

| Area | In both developed and developing countries | More focus on developing countries |
|---|---|---|
| Education and promotion | Better HCW education regarding the types of patient care activities that can result in hand contamination and cross-transmission<br><br>Develop and implement promotion programmes in pre-graduate courses<br><br>Study the impact of population-based education, religion and culture on hand hygiene behaviour<br><br>Design and conduct studies to determine if frequent glove use should be encouraged or discouraged<br><br>Determine the most important evidence-based indications for hand cleansing (considering that it might be unrealistic to expect HCWs to clean their hands according to every indication, as formulated in recommendations)<br><br>Assess the key determinants of hand hygiene behaviour and promotion among the different populations of HCWs<br><br>Develop methods to obtain top management support<br><br>Implement and evaluate the impact of the different components of multimodal programmes to promote hand hygiene<br><br>Identify effective social models to promote hand hygiene<br><br>Assess impact on hand hygiene compliance and untoward consequences of patient involvement in hand hygiene promotion<br><br>Assess compliance with recommendations of surgical hand preparation | Studies to test the strategies for hand hygiene promotion in developing countries<br><br>Cost-benefit analysis of promotion strategies in developing countries |

***Table I.21.1.***
***Hand hygiene research agenda (Cont.)***

| Area | In both developed and developing countries | More focus on developing countries |
|---|---|---|
| Hand hygiene agents and technique, and hand care | Determine the most suitable hand hygiene agents<br><br>Determine if preparations with sustained antimicrobial activity reduce infection rates more effectively than do preparations whose activity is limited to an immediate effect<br><br>Study the systematic replacement of conventional handwashing by handrubbing<br><br>Develop devices to facilitate the use and optimal application of agents<br><br>Develop hand hygiene agents with low skin irritancy potential<br><br>Study the possible advantages and eventual interaction of hand care lotions, creams, and other barriers to help minimize the potential irritation associated with hand hygiene agents<br><br>Conduct further studies to determine the relative efficacy of alcohol-based solutions and gels in reducing transmission of health care-associated pathogens<br><br>Conduct a survey on available handrub products at country level and their cost<br><br>Determine if bar soap is acceptable; if yes, establish if it is the case to recommend single-use small pieces<br><br>Establish appropriate timing for the surgical scrub with medicated soap | Dermatitis and skin reactions in different ethnic groups and tropical climates |

***Table I.21.1:***
***Hand hygiene research agenda (Cont.)***

| Area | In both developed and developing countries | More focus on developing countries |
|---|---|---|
| Laboratory-based and epidemiological research and development | Develop experimental models for the study of cross-contamination from patient to patient and from environment to patient<br><br>Develop new protocols for evaluating the in vivo efficacy of agents considering, in particular, short application times and volumes that reflect actual use in health-care facilities<br><br>Monitor hand hygiene adherence by using new devices or adequate surrogate markers, allowing frequent individual feedback on performance<br><br>Evaluate the type of surgical hand antisepsis in the different countries with a standardized protocol to define the status quo and compliance with recommendations among surgeons<br><br>Determine the percentage increase in hand hygiene adherence required to achieve a predictable risk reduction in infection rates<br><br>Generate more definitive evidence for the impact on infection rates of improved adherence to recommended hand hygiene practices<br><br>Provide cost–effectiveness evaluation of successful and unsuccessful promotion campaigns<br><br>Conduct further studies to determine the consequences of soap contamination<br><br>Conduct further in vitro and in vivo studies of both alcohol-based formulations and antimicrobial soaps to establish the minimal level of virucidal activity that is required to interrupt direct contact transmission of viruses in health-care settings<br><br>Evaluate the effectiveness of handrubbing or washing to interrupt transmission of pathogens such as noroviruses<br><br>Review evidence on reduced susceptibility to antiseptic agents and evaluate whether or not resistance to antiseptics may influence the prevalence of antibiotic resistant strains<br><br>Evaluate the type of handrub available in the different countries with a standardized protocol to define the status quo<br><br>The number of positive cultures of tap water at the sink for Pseudomonas aeruginosa and the number of positive hand cultures with selective cultures for non-fermenting Gram-negative bacteria | |

***Table I.21.1:***
***Hand hygiene research agenda (Cont.)***

| Area | In both developed and developing countries | More focus on developing countries |
|---|---|---|
| System | Evaluate the influence of "automatic taps/ faucets" on water quality<br><br>Evaluate the frequency of recontamination (when rinsing) after surgical hand scrub and the impact on surgical infection rates<br><br>Conduct a survey on what handrub products are available at country level and their cost | Establish the requisite quality for water for handwashing (drinkable?)<br><br>Establish the most appropriate method to keep water safe for care and hand hygiene purposes when it needs to be stored at point of use (containers)<br><br>Establish the recommended number of sinks per bed<br><br>Evaluate the cost–benefit of glove reuse in settings with limited/ poor resources |

***Table I.21.2:***
***Unsolved issues for research and field testing***

| Area | Outstanding questions to be resolved |
|---|---|
| Water quality and its availability in health care | Should water for handwashing be drinkable or simply the cleanest possible?<br>Should water requirements be differentiated according to the resources available in different settings?<br>– Are the water quality requirements at the tap/faucet in the operating room different from those in the rest of the health-care setting?<br>– Should high-risk populations, who need guaranteed high standards of water quality, be identified (i.e. immunosuppressed)? |
| Soap | What is the potential for actual soap contamination during use?<br>What is the best storage method between uses? |
| Hand drying | What quality of paper should be used for hand hygiene?<br>– What should be the standards for paper? Is there a preferred type of paper?<br>– Could the paper be recycled?<br>– Is there an impact of quality of paper on hand hygiene compliance?<br>What are the best approaches when single-use towels are not possible?<br>Use of recycled paper for hand drying:<br>– What type of in vitro studies may be appropriate to assess the level of contamination of recycled paper?<br>– Could there be an impact of the type of paper (recycled paper vs not recycled paper) on health care-associated infection or colonization rates by multidrug-resistant pathogens?<br>– What is the cost–benefit of using recycling paper? |

***Table I.21.2:***
***Unsolved issues for research and field testing (Cont.)***

| Area | Outstanding questions to be resolved |
|---|---|
| Antimicrobicidal activity of products | When handling Norwalk virus, is handrubbing or handwashing preferred?<br>Is there an impact of resistance to antiseptics on the prevalence of antibiotic- resistant strains? |
| Use of glove | What is the cost–benefit of glove reuse in settings with limited/poor resources?<br>How many times could gloves be reused?<br>What type of gloves could be reused?<br>Could gloves be decontaminated between different patients? How?<br>Should the reuse of gloves definitely be forbidden during outbreaks, if direct contact with blood or body fluids, during care of patients colonized and/or infected with multidrug-resistant pathogens? In other situations? |
| Surgical hand antisepsis | What are the different types of surgical hand antisepsis currently performed in different countries? What elements are to be included in a standardized protocol to define the status quo?<br>What is the appropriate time for the surgical scrub with medicated soap? Either a 5-minute or a 3-minute scrub? Are times < 2 minutes inappropriate? |
| Hand hygiene promotion | Is there a consequential impact of low budget educational interventions on compliance with hand hygiene in limited resourced countries?<br>What are the cognitive determinants of hand hygiene behaviour? |

***Table III.1.1:***
***Advantages and disadvantages of direct and indirect monitoring of hand hygiene compliance***

| | | Advantages | Disadvantages |
|---|---|---|---|
| **Direct monitoring** | Observation | Accurate assessment of compliance | Resource-intensive |
| | Patient assessment | Can give some information on compliance | Patients may be reluctant to carry out this task<br><br>Patients are not trained to observe |
| | Self-assessment | Not resource-intensive | Studies have shown that this is not always accurate |
| **Indirect monitoring** | Monitoring of soap or alcohol use | Less resource-intensive than direct monitoring | Studies have shown that this form of monitoring does not correlate with direct observation |
| | Electronic monitoring | Less resource-intensive than direct monitoring | Does not cover all opportunities for washing hands |

***Table III.2.1:***
***Quality indicators related to hand hygiene in health-care settings***

| **Structure** |
|---|
| Handrub at bedside/point of care<br>– percentage of beds served by handrub<br>– should a benchmark be proposed? |
| Handrub dispensers working |
| Sink adequately placed*<br>– percentage of beds served by sinks<br>– percentage of beds served by sinks adequately equipped (paper towel, liquid soap)<br>– should a benchmark be proposed? |
| Automatic sink |
| Taps/faucets not manipulated by hands |
| Liquid soap available |
| Liquid soap dispensers working |
| No hand-operated liquid soap dispensers |
| Availability of paper towels |
| Availability of gloves at point of care |
| Availability of skin care products |
| Adequate storage of products** |
| Adequate provision of hand hygiene products*** |
| Written hand hygiene guidelines or recommendations available |
| **Process** |
| Promotion of institutional climate (posters, award, etc.) |
| Extensive and complete education programmes |
| A product selection process has been implemented |
| Feedback performance to staff |
| No staff downsizing or understaffing |
| No overcrowding |
| Active participation at individual and institutional level |
| Senior management support |
| Institutional/corporate commitment to the use of alcohol-based handrub and the monitoring of its use |
| **Outcome** |
| Monitor adherence of staff to hand hygiene practices |
| Monitor adherence at time of outbreak |
| Monitor appropriate use of gloves |
| Monitor adherence to nail and artificial nail policies |
| Monitor regular presence of hand hygiene products in the units |
| Monitor the amount of handrub used (surrogate marker) |
| Count used paper hand towels (surrogate marker; value could decrease with time) |
| Reduction in infection rates |
| Reduction in cross-transmission rates (i.e. MRSA, VRE) |
| Reduction in antimicrobial resistance spread |
| Cost implications of hand hygiene promotion |

* = outside the ward: at ward entrance, at the nursing station; inside the unit/ward: at 2 m from the patient.

** = safe storage, concerning contamination risks and security risks.

*** = organized management of provision, with regular provision of products.

***Table V.3.1:***
***Examples of public information campaigns by WHO***

| Campaign | Objectives | Implementing bodies | Target audiences | Country | Significant results |
|---|---|---|---|---|---|
| Public information campaign by the Stop-TB Partnership | Community mobilization<br>1. Mobilizing local communities<br>2. Promoting healthy behaviour<br>3. Mobilizing patients<br>4. Providing training to health officials<br><br>Private sector partnerships<br>5. Involving non-governmental organizations and civil society in Stop-TB<br>6. Involving business<br>7. Enhancing web and electronic information sharing<br><br>Global advocacy<br>8. Branding, marketing and monitoring<br>9. World TB Day and other publicity campaigns<br>10. Involving celebrities<br>11. Increasing media coverage<br>12. Political avocacy | WHO<br><br>Governments of Member States<br><br>International agencies<br><br>Civil society and non-governmental organizations<br><br>Collaborating centres | General public<br><br>Health workers<br><br>Health-care professionals<br><br>TB patients and their families<br><br>Children<br><br>Young adults | Global<br><br>Countries with high TB burden | Increased global and national awareness about TB and DOTS strategy |

TB: tuberculosis
DOTS: Directly Observed Treatment Short-course

***Table V.3.1:***
***Examples of public information campaigns by WHO (Cont.)***

| Campaign | Objectives | Implementing bodies | Target audiences | Country | Significant results |
|---|---|---|---|---|---|
| Public information campaign by the Tobacco-Free Initiative | Anti-tobacco media campaigns<br>1. World No-Tobacco Day on 31 May each year<br>2. Awareness-raising workshops (local, national, regional)<br>3. Awareness-raising of the tobacco industry activities<br>4. Awareness-raising about the WHO FCTC process<br>5. Information through the dissemination of publications dedicated to specific themes<br>6. Web site | WHO HQ and regions<br>Tobacco control programmes or institutes in governments and or administrations (national, state, local)<br>Non-governmental organizations and associations of health professionals<br>Other associations or collaborating centres (universities, institutes, etc.) | Governments and policy-makers<br>Non-governmental organizations<br>General public<br>Others, depending on the issues and the campaign:<br>Youth<br>Parents<br>Women (on some gender-related issues)<br>Health professionals | Global<br>Various countries | Increased awareness of:<br>– harm of tobacco<br>– tobacco industry activities<br>–TFI activities<br>Awareness-raising on the importance of:<br>– behavioural change<br>– policy change |

TFI: Tobacco Free Initiative.
WHO FCTC: WHO Framework Convention on Tobacco Control.

***Table V.4.1:***
***Examples of national public information campaigns for hygiene and hand hygiene promotion***

| Campaign | Objectives | Implementing bodies | Target audiences | Country | Significant results |
|---|---|---|---|---|---|
| Central American Hand-washing Initiative (1996–1999)[726]<br><br>Implemented through strong private–public partnerships | 1. Market research and consumer studies<br>2. Campaign materials (posters, advertisements, brochures)<br>3. Banners in fairs<br>4. Radio and television spots<br>5. Promotional materials for children: brochures, colouring books, games<br>6. Corporate advertising: healthy behaviour with soap promotions | Public–private partnership:<br><br>BASICS and EHP for USAID<br>UNICEF<br>World Vision and CARE<br><br>Ministries of health and ministries of education<br><br>Unilever in various countries<br><br>Televison and radio stations | Consumers and the general public<br><br>Women, especially mothers<br><br>Schoolchildren<br><br>Country partners | Guatemala<br>El Salvador<br>Honduras<br>Costa Rica<br>Nicaragua | Handwashing improved among 10% of women from "inadequate handwashing groups"<br><br>Percentage of mothers using the correct technique doubled (in three countries)<br><br>4.5% reduction in overall prevalence of diarrhoea in children under 5 years of age |

BASICS: Basic Support for Institutionalizing Child Survival.
EHP: The Environmental Health Project.
CARE®: humanitarian organization fighting global poverty.

***Table V.4.1:***
***Examples of national public information campaigns for hygiene and hand hygiene promotion (Cont.)***

| Campaign | Objectives | Implementing bodies | Target audiences | Country | Significant results |
|---|---|---|---|---|---|
| Handwashing Initiative in Ghana and Kerala[724]<br><br>(2003 onwards ) | 1. Global advocacy: participation at international level; articles in global press; web site<br>2. Consumer and market research to evaluate most appropriate channels of communication<br>3. Developing and testing a communication package<br>4. Sketching and testing advertisements for radio, television, promotional materials, posters, support materials<br>5. Mobilizing champions<br>6. Using direct contacts with target audiences to communicate information | Public–private partnership:<br>The World Bank<br>London School of Hygiene and Tropical Medicine<br>UNICEF<br>USAID, AED,<br>Ministries of health, education, works and housing, women's and children's affairs in Ghana and India<br>Unilever in various countries<br>Gettrade<br>PZ Cussons<br>Indian Soap and Toiletries Makers' Association<br>Khadi and Cottage Industry Board<br>Others | Consumers and the general public<br><br>Women, especially mothers<br><br>Schoolchildren<br><br>Country partners | Ghana<br><br>India (Kerala State) | No data generated so far |

AED: Academy for Educational Development.

***Table V.4.1:***
***Examples of national public information campaigns for hygiene and hand hygiene promotion (Cont.)***

| Campaign | Objectives | Implementing bodies | Target audiences | Country | Significant results |
|---|---|---|---|---|---|
| Sanitation and hygiene promotion[751] | 1. Development of communication and social mobilization strategies including identification of communication channels<br>2. Utilization of the mass media to disseminate hand hygiene messages<br>3. Organization of workshops<br>4. Community activities, training sessions and house-to-house visits to raise awareness<br>5. Activity-based school sanitation and hygiene education | Ministry of health<br>Ministry of education<br>UNICEF | General public<br>Women, especially mothers<br>Schoolchildren | Myanmar | Handwashing with soap and water after defecation has increased from 18% in 1996 to 43% in 2001 |

***Table V.5.1:***
***The public information component of two national campaigns focusing on the prevention of health care-associated infection***

| Campaign | Interventions and tools | Target audiences | Implementing bodies | Country | Significant results |
|---|---|---|---|---|---|
| "clean***your***hands"<br><br>United Kingdom<br><br>(September 2004 to date) | Development of:<br>1. A series of three posters: the core campaign posters; the staff champion posters; the patient posters<br>2. Patient leaflets, badges, stickers<br>3. Printed information materials and video to HCWs<br>4. A media kit<br>5. A campaign web site<br>6. Media launches of the campaign involving local celebrities<br>7. Conferences<br>8. National televised debate | Health-care providers<br><br>Hospital visitors<br><br>Patients<br><br>Partner organizations | National Patient Safety Agency<br><br>National Health Service Trusts<br><br>Department of Health | United Kingdom | No data generated to date |
| "100 000 Lives"<br><br>USA[598]<br><br>(December 2004 to date) | 1. Information calls on the campaign and on each intervention<br>2. Campaign brochure<br>3. Sign-up process: system, state and regional events<br>4. Media kits, media events<br>5. "Getting started" kits<br>6. Campaign web site<br>7. Information to existing partners on enrolling new partners<br>8. Publicity of the successes of participating hospitals in implementing the campaign | Health-care providers<br><br>Partner organizations<br><br>Patients | Institute of Health Care Improvement<br><br>Hospitals<br><br>Systems | USA | No data generated to date |

## WHO GUIDELINES ON HAND HYGIENE IN HEALTH CARE (ADVANCED DRAFT)

# APPENDICES

## GLOBAL PATIENT SAFETY CHALLENGE 2005–2006: "CLEAN CARE IS SAFER CARE"

# APPENDIX 1. DEFINITIONS OF HEALTH-CARE SETTINGS AND OTHER RELATED TERMS

**HEALTH SYSTEM**: all the activities whose primary purpose is to promote, restore or maintain health (*The World Health Report 2000 – Health systems: improving performance*)

**DEFINITIONS FROM THE WHO GLOSSARY OF TERMS** (Available at: http://www.wpro.who.int/chips/chip04/definitions.htm)

## HEALTH INFRASTRUCTURE:

- **General hospital**. A hospital which provides a range of different services for patients of various age groups and with varying disease conditions.
- **Specialized hospital**. A hospital admitting primarily patients suffering from a specific disease or affection of one system, or reserved for the diagnosis and treatment of conditions affecting a specific age group or of a long-term nature.
- **District/first level referral hospital**. A hospital at the first referral level that is responsible for a district or a defined geographical area containing a defined population and governed by a politico-administrative organization such as a district health management team. The role of district hospitals in primary health care has been expanded beyond being dominantly curative and rehabilitative to include promotional, preventive and educational roles as part of a primary health-care approach. The district hospital has the following functions:
  1) it is an important support for other health services and for health care in general in the district;
  2) it provides wide-ranging technical and administrative support and education and training for primary health care;
  3) it provides an effective, affordable health-care service for a defined population, with their full participation, in cooperation with agencies in the district that have similar concerns.
- **Primary health-care centre**. A centre that provides services which are usually the first point of contact with a health professional. They include services provided by general practitioners, dentists, community nurses, pharmacists and midwives, among others.

## HEALTH WORKFORCE:

- **Physicians/doctors**. All graduates of any faculty or school of medicine, actually working in the country in any medical field (practice, teaching, administration, research, laboratory, etc.).
- **Midwives**. All persons who have completed a programme of midwifery education, and have acquired the requisite qualifications to be registered and/or legally

licensed to practise midwifery, and are actually working in the country. The person may or may not have prior nursing education.

- **Nurses**. All persons who have completed a programme of basic nursing education and are qualified and registered or authorized to provide responsible and competent service for the promotion of health, prevention of illness, the care of the sick, and rehabilitation, and are actually working in the country.
- **Pharmacists**. All graduates of any faculty or school of pharmacy, actually working in the country in pharmacies, hospitals, laboratories, industry, etc.
- **Dentists**. All graduates of any faculty or school of dentistry, odontology or stomatology, actually working in the country in any dental field.
- **Other health-care providers (including community health workers)**. All workers who respond to the national definition of health-care providers and are neither physicians, midwives, nurses, dentists, or pharmacists.

**Inpatient**. A person who is formally admitted to a health-care facility and who is discharged after one or more days.

**Outpatient**. A person who goes to a health-care facility for a consultation, and who leaves the facility within three hours of the start of consultation. An outpatient is not formally admitted to the facility.

### DEFINITIONS FROM THE EUROPEAN OBSERVATORY ON HEALTH SYSTEMS AND POLICIES

(Available at http://www.euro.who.int/observatory/Glossary/TopPage?phrase=D)

**Ambulatory care**. All types of health services provided to patients who are not confined to an institutional bed as inpatients during the time services are rendered (USAID, 1999). Ambulatory care delivered in institutions which also deliver inpatient care is usually called "outpatient care". Ambulatory care services are provided in many settings ranging from physicians' offices to freestanding ambulatory surgical facilities to cardiac catheterization centres. In some applications, the term does not include emergency services provided in tertiary hospitals (USAID, 1999).

**Day care**. Medical and paramedical services delivered to patients who are formally admitted for diagnosis, treatment or other types of health care with the intention of discharging the patient the same day.

**Long-term care**. Long-term care encompasses a broad range of help with daily activities that chronically disabled individuals need for a prolonged period of time. Long-term care is primarily concerned with maintaining or improving the ability of elderly people with disabilities to function as independently as possible for as long as possible; it also encompasses social and environmental needs and is therefore broader than the medical model that dominates acute care; it is primarily low-tech, although it has become more complicated as elderly persons with complex medical needs are discharged to, or remain in, traditional long-term care settings, including their own homes; services and housing are both essential to the development of long-term care policy and systems. Nursing homes, visiting nurses, home intravenous and other services provided to chronically ill or disabled persons.

**Social care**. Services related to long-term inpatient care plus community care services, such as day care centres and social services for the chronically ill, the elderly and other groups with special needs such as the mentally ill, mentally handicapped and the physically handicapped. The borderline between health care and social care varies from country to country, especially regarding social services which involve a significant, but not dominant health-care component such as, for example, long-term care for dependent older people.

# APPENDIX 2. HAND AND SKIN SELF-ASSESSMENT TOOL

| On a scale of 1–7, rate the current condition of the skin on your hands | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Appearance**<br>Abnormal:<br>red, blotchy, rash | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Normal:<br>No redness blotching, rash |
| **Intactness**<br>Many abrasions or fissures | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Completely intact.<br>No abrasions or fissures |
| **Moisture content**<br>Extremely dry | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Normal amount of moisture |
| **Sensation**<br>Extreme itching, burning or soreness | 1 | 2 | 3 | 4 | 5 | 6 | 7 | No itching, burning, or soreness |

Adapted from:[155,426].

# APPENDIX 3. EXAMPLE OF A SPREADSHEET TO ESTIMATE COSTS

A spreadsheet for self-completion by an individual health-care institution allows the input of local data and will indicate likely cost savings over time. The example below is used in the United Kingdom "clean***your***hands" campaign. Values are for example purposes.

| Data in coloured cells can be changed | |
|---|---|
| | |
| **Upfront costs** | |
| This is the estimated additional upfront cost of | £2 351 |
| equipping each bed in your Trust with alcohol rub | |
| | |
| **Trust information** | |
| Number of general and acute care beds | 500 |
| Occupancy rate | 85.4% |
| Total general and acute care admissions | 20 000 |
| | |
| **Procurement** | |
| Do you intend to use PASA? (choose Yes or No) | Yes |
| | |
| **Hand hygiene compliance** | |
| Initial handwashing compliance rate | 28.4% |
| Target handwashing compliance rate (after 5 years) | 76.2% |
| | |
| **Current usage and spending** | |
| Current annual alcohol rub usage (litres) | 100 |
| Current annual alcohol rub spend (£) | 810 |
| Current annual alcohol unit cost (£ per litre) | 8.10 |
| Current volume per 1000 patient-days (litres) | 0.64 |
| Current cost per 1000 patient-days (£) | 5.20 |
| | |
| **PASA unit costs** | |
| £ per litre | 6.40 |

| Data in coloured cells can be changed | |
|---|---|
| | |
| **Prospective** | |
| New alcohol gel unit cost | 6.40 |
| Volume per 1000 patient-days | 6.49 |
| Final annual alcohol gel usage (litres) | 1 011 |
| Final annual alcohol gel cost (£, at current unit costs) | 8 193 |
| Final annual alcohol gel cost (£) | 6 474 |
| | |
| **Central campaign costs** | |
| Costs of posters, etc. – average cost per bed (£) | 2.56 |
| | |
| **HCAI information** | |
| Rate of HCAI (in-patient phase) | 7.8% |
| Achievable reduction in HCAI | 9.0% |
| Target reduction in HCAI | 9.0% |
| Current annual deaths | 18 |
| Excess in-patient cost for those with HCAI | 3 777 |
| Current estimated HCAIs | 1 560 |
| Average QALYs lost (fatal infection) | 7 |
| Average QALYs lost (non-fatal infection) | 0.007 |
| Additional costs incurred by patients (£) | 6.9 |
| Average additional primary care costs (£) | 23.5 |
| Average costs of additional informal care (£) | 149 |
| Average production gains (£) | 408 |
| | |
| **Discount rates** | |
| Discount rate – financial costs and benefits | 3.5% |
| Discount rate – QALYs | 1.5% |
| | |
| **Perspective** | |
| Perspective for evaluation (choose hospital or society) | Hospital |
| | |

PASA = Purchasing and Supply Agency;
QALY = quality-adjusted life year.

# ABBREVIATIONS

| | |
|---|---|
| **AED** | Academy for Educational Development |
| **AIDS** | acquired immunodeficiency syndrome |
| **ASTM** | American Society for Testing and Materials |
| **BASICS** | Basic Support for Institutionalizing Child Survival |
| **CDC** | Centers for Disease Control and Prevention |
| **CEN** | Comité Européen de Normalisation / European Committee for Standardization |
| **CEO** | chief executive officer |
| **CFU** | colony forming unit |
| **CHG** | chlorhexidine gluconate |
| **CTICU** | cardiothoracic intensive care unit |
| **DOTS** | directly observed treatment short-course |
| **EA** | ethanol |
| **EN / prEN** | European norm / European norm in preparation (prenorm) |
| **EDTA** | ethylene-diaminetetraacetic acid |
| **EHP** | The Environmental Health Project |
| **ESBL** | extended-spectrum beta-lactamase |
| **FDA** | Food and Drug Administration |
| **HAV** | hepatitis A virus |
| **HBV** | hepatitis B virus |
| **HCAI** | health care-associated infection |
| **HCP** | hexachlorophene soap/detergent |
| **HCW** | health-care worker |
| **HICPAC** | Healthcare Infection Control Practices Advisory Committee |
| **HIV** | human immunodeficiency virus |
| **HSV** | herpes simplex virus |
| **ICU** | intensive care unit |
| **IPA** | isopropanol |
| **IPA-H** | isopropanol + humectants |
| **JCAHO** | Joint Commission on Accreditation of Healthcare Organizations |
| **JHPIEGO** | Johns Hopkins Program for International Education on Gynecology and Obstetrics (international health organization affiliated to Johns Hopkins University) |
| **KAAMC** | King Abdul Aziz Medical Center |
| **LR** | log reduction |
| **MIC** | minimum inhibitory concentration |
| **MICU** | medical intensive care unit |
| **MRSA** | methicillin-resistant *Staphylococcus aureus* |

| | |
|---|---|
| **NHS** | National Health Service |
| **NICU** | neonatal intensive care unit |
| **n-P** | n-propanol |
| **NPSA** | National Patient Safety Agency |
| **NA** | not available |
| **NS** | not stated |
| **OPD** | out-patient department |
| **PACU** | post-anaesthesia care unit |
| **PASA** | Purchasing and Supply Agency |
| **PCMX** | para-chloro-meta-xylenol |
| **P-I** | povidone-iodine detergent |
| **PICU** | paediatric intensive care unit |
| **QAC** | quaternary ammonium compound |
| **QUALY** | quality-adjusted life year |
| **RSV** | respiratory syncytial virus |
| **SICU** | surgical intensive care unit |
| **SWIFT** | structure "what-if" technique |
| **TB** | tuberculosis |
| **TFI** | Tobacco Free Initiative |
| **TFM** | Tentative Final Monograph |
| **UNICEF** | United Nations Children's Fund |
| **USA** | United States of America |
| **USAID** | United States Agency for International Development |
| **VRE** | vancomycin-resistant enterococci |
| **V/V** | volume/volume |
| **WHO** | World Health Organization |
| **WHO FCTC** | WHO Framework Convention on Tobacco Control |

## WHO GUIDELINES ON HAND HYGIENE IN HEALTH CARE (ADVANCED DRAFT)

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