

Quantitative assessment of risk reduction from hand washing with antibacterial soaps

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1. SUMMARY

The Centers for Disease Control and Prevention have estimated that there are 3 713 000 cases of infectious disease associated with day care facilities each year. The objective of this study was to examine the risk reduction achieved from using different soap formulations after diaper changing using a microbial quantitative risk assessment approach. To achieve this, a probability of infection model and an exposure assessment based on micro-organism transfer were used to evaluate the efficacy of different soap formulations in reducing the probability of disease following hand contact with an enteric pathogen. Based on this model, it was determined that the probability of infection ranged from 24/100 to 91/100 for those changing diapers of babies with symptomatic shigellosis who used a control product (soap without an antibacterial ingredient), 22/100 to 91/100 for those who used an antibacterial soap (chlorohexadine 4%), and 15/100 to 90/100 for those who used a triclosan (1.5%) antibacterial soap. Those with asymptomatic shigellosis who used a non-antibacterial control soap had a risk between 49/1 000 00 and 53/100, those who used the 4% chlorohexadine-containing soap had a risk between 43/100 000 and 51/100, and for those who used a 1.5% triclosan soap had a risk between 21/100 000 and 43/100. The adequate washing of hands after diapering reduces risk

and can be further reduced by a factor of 20% by the use of an antibacterial soap. Quantitative risk assessment is a valuable tool in the evaluation of household sanitizing agents and low risk outcomes.

2. INTRODUCTION

Hand washing has long been known to be a beneficial public health practice for preventing the spread of infectious disease. Since the advent of antibacterial or disinfecting soaps, hand washing has been shown to be more effective in interrupting the cycle of disease transmission (Daschner 1988). The risk reduction of bacterial disease afforded by hand washing in hospital settings and day care centres has been demonstrated a number of times (Black *et al.* 1981; Khan 1982; Garner *et al.* 1985; Butz *et al.* 1990; Simmons *et al.* 1990; Larson 1999). Table 1 is a summary of other studies of the disease-preventing efficacy of various soap formulations. However, the Centers for Disease Control and Prevention have estimated that there are 3 713 000 cases of infectious disease associated with day care facilities each year (Bennett *et al.* 1987).

Table 2 shows the major bacterial agents responsible for illnesses in day care facilities. For bacteria such as *Shigella*, approximately 300 000 cases occur each year in the US, of which 25% are estimated to be associated with day care centres. It is the bacterium most frequently associated with outbreaks of infectious intestinal disease in day care settings (Van *et al.* 1991). Several studies of environmental surfaces in day care settings have shown that faecal contamination is

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Table 1 Effectiveness of hand disinfection for the reduction of disease. In some cases, more than one control measure was taken

Population	Type of disease	Type of disinfectant/approach	Reduction (reference)
Military	Cutaneous infections	2% 3,5 dibromosalicylanilide and 3,4,5 tribromosalicylanilide, 3,4,4 trichlorocarbanilide, 4,4 dichloro-3-(trifluoromethyl) carbanilide	44% (Leonard 1967)
Military	Cutaneous infections	0.75% hexachlorophene 0.75% triclocarban	44% (MacKenzie 1970)
Babies-newborn nursery	Skin colonization- <i>Staph. Aureus</i>	Hand washing	42% (Mortimer <i>et al.</i> 1962)
Babies-newborn nursery	Skin colonization- <i>Staph. aureus</i>	Hexachlorophene	67% (Mortimer <i>et al.</i> 1966)
Babies-ICU	Colonization/sepsis- <i>Enterococcus</i>	Education, cohorting of babies, separation of hospital supplies, gloves, hand washing	89% (Malik <i>et al.</i> 1999)
Patients	Colonized/infected- <i>Klebsiella</i>	Chlorhexidine	End of outbreak (Casewell and Phillips 1977)
ICU	Nosocomial infections	4% chlorhexidine (Hibiclens), 7.5% povidone-iodine ((Betadyne), plain soap	39% (Maki and Hecht 1982)
Children-hospital	Enteric cross-infection	Ordinary soap or chlorhexidine	100% (Taylor <i>et al.</i> 1979)
Cardiac ICU	Nosocomial infection	Unknown	Significant decrease (Dandalides <i>et al.</i> 1974)
ICU	Nosocomial infection	4% chlorhexidine gluconate solution	74% (Conly <i>et al.</i> 1989)
Surgical patients	Wound infections	Soap or hexachlorophene	38% (Cruse <i>et al.</i> 1973)
Day care occupants	Diarrhoea	Regular soap	74% (Black <i>et al.</i> 1981)
Day care occupants	Viral meningitis	Hand washing frequency	Significant decrease (Mohle-Boetani <i>et al.</i> 1999)
School children	Gastrointestinal disease	Hand washing frequency	Significant decrease (Master <i>et al.</i> 1997)
Prison farm	Skin infection	2% 3,4,5 tribromosalicylaniline, 3,4,4 trichlorocarbanilide, and 4,4 dichloro-3 (trifluoromethyl)carbanilide	> 82% (Duncan <i>et al.</i> 1969)

Table 2 Estimated cases of bacterial infections in the US associated with various transmission routes (Van *et al.* 1991)

Microbe	Number of cases per year	% Associated with day care centres
<i>Escherichia coli</i>	200 000	5
<i>Salmonella</i>	2 000 000	1
<i>Shigella</i>	300 000	25

widespread. Approximately 30% and 20% of the hands of both children and care-givers, respectively, were shown to be contaminated (Ekanem *et al.* 1983; Weniger *et al.* 1983; Van *et al.* 1991). The relationship between the presence of faecal coliforms and disease outcome was confirmed in a study by Laborde *et al.* (1993), during which diarrhoeal illness without respiratory symptoms was monitored in 221 children less than 3 years old.

While the role of contaminated hands in the transmission of disease has been elucidated, described qualitatively and evaluated through epidemiological studies, it has been

difficult to examine quantitatively the effectiveness of various soap formulations in reducing exposure to pathogens. A few investigations have shown that antibacterial soaps are more effective than plain soaps in reducing bacterial numbers on skin and hands (Finkey *et al.* 1984; Jungermann *et al.* 1967; Voss 1975). However, these have not quantified the health benefit that may be achieved by utilizing more effective soap formulations.

Risk assessment is an approach that can be used to evaluate exposure scenarios associated with hazards, and elicits an estimate of the probability of various risk outcomes. Risk assessment has become a valuable tool for evaluating a variety of human health hazards associated with contamination of the environment. Risk estimation can provide a useful means for decision makers in the development of standards, treatment requirements for risk management and risk/benefit analysis. The risk assessment approach is divided into four basic steps: (i) hazard identification; (ii) exposure assessment; (iii) dose-response modelling; and finally, using these to develop an overall (iv) risk characterization.

2.1. Objectives

The objective of this exercise was to examine the risk reduction achieved, based on exposure to bacteria from the contamination of hands after diaper changing with and without antibacterial soaps during hand washing, using a microbial quantitative risk assessment approach. The objectives were to assess the reduction in bacteria remaining on the hands immediately after washing with an antibacterial soap compared with a control agent, and the associated reduction in exposure and risk.

A simplified conceptual framework for the transmission of infectious agents via contact with dirty diapers is shown in Fig. 1. The types of data necessary to build this framework are the amount of faeces in an average diaper, the levels of bacteria per gram of faeces, the transference of bacteria from one soiled diaper to the hands, the reduction in bacterial counts by hand washing, hand-to-mouth transfer rates and dose-response estimates.

3. MATERIAL AND METHODS

3.1. *Shigella* concentration in diaper

The exposure scenario was associated with diaper changing activities with subsequent contamination of the hands. The excretion levels of *Shigella* in the faeces of infected children have been reported to range from 10^5 and 10^9 cfu g^{-1} faeces for those with a symptomatic infection, and from 10^2 to 10^6 cfu g^{-1} faeces for those with an asymptomatic infection

(Feacham *et al.* 1993). Asymptomatic infection with *Shigella* among children in day care centres has been reported (O’Ryan-Matson 1990; Pickering 1990; Van *et al.* 1991).

3.2. Transfer to hands

Based on several studies, anywhere from 10 to 100% of the bacteria present on contaminated cloth was transferred to the hands of study volunteers when handling fabric contaminated with a known amount of bacteria (Marples and Towers 1979; Scott and Bloomfield 1990). The actual level of contamination of hands is not known. For the purposes of this analysis, it was assumed that 0.1 g of faecal material may be picked up by the changer’s hand.

3.3. Reduction of *Shigella* by hand washing

To describe the microbial reduction (of *Shigella*) on hands, results from a study of 24 volunteers whose hands were contaminated with *Serratia marscescens* (Bartzokas *et al.* 1987) were used. In this study, hands were contaminated, washed, and rinsed 10 consecutive times. Two pre- and four post-disinfection samples were taken: a pre-disinfection baseline, a control baseline, and after the first, fourth, seventh and tenth sequences with the disinfecting product. In the experiments with *S. marscescens*, the reduction in bacterial loads (of inoculated organisms) following hand washing with a non-medicated natural bar soap without antimicrobials, a 4% chlorhexidine gluconate in a non-ionic detergent base and a 1.5% weight-to-volume ratio triclosan

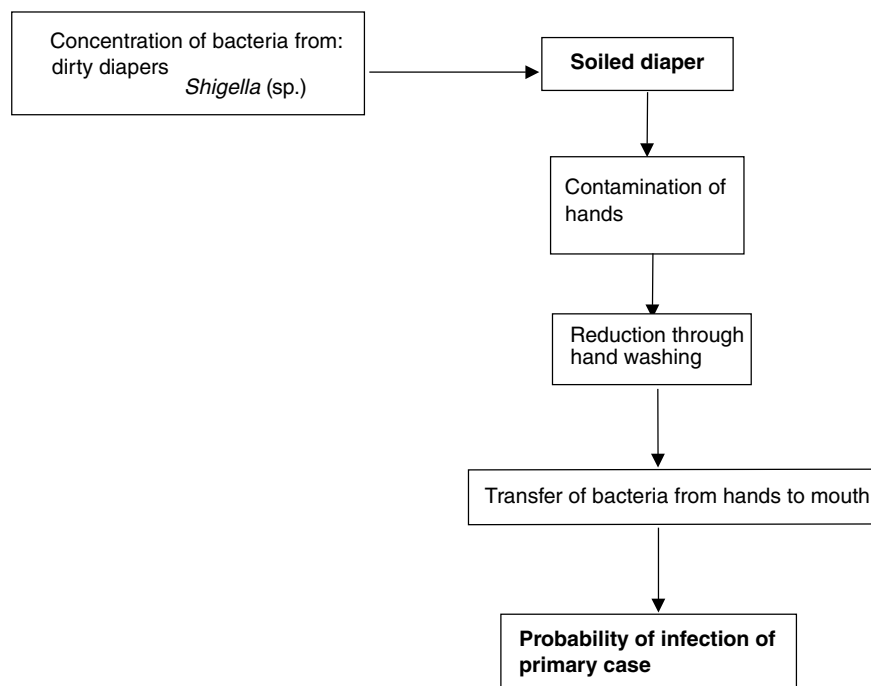


Fig. 1 Framework for the transmission of microbial pathogens through contaminated diapers

Table 3 Reduction of *Serratia* levels by hand washing (Bartzokas *et al.* 1987)

Test condition	Mean log ₁₀ cfu reduction	Standard deviation	Number of subjects
Control	2.56	0.20	24
4% Chlorhexidine	2.61	0.33	24
1.5% Triclosan	2.91	0.42	24

formulation in a liquid potassium soap, was compared. The results are shown in Table 3. These represent the reductions after the first wash with the antibacterial product. These data, which appear to be central to the conclusion that antimicrobial soaps reduce the probability of infection, suggest that there are no differences because the mean log reductions do not appear to be statistically significantly different.

3.4. Transfer from fingertip to lip

In order to estimate the transfer of bacteria from fingers to lips, a controlled study was undertaken. The study partic-

ipants had approximately 6 logs of pooled *Serratia rubidea* and *Micrococcus roseus* dosed onto the assigned fingertip of one hand using 5 µl of inoculum. The fingertip was allowed to air dry for 30 s. The subject was instructed to place the fingertip to the middle of the lower lip for 10 s. To determine the transfer rate of organisms to the mouth, the fingertip was sampled by moistening a Dacron swab in 3 ml Letheen broth and swabbing the surface of the fingertip. The swab was replaced in the tube and analysed. Also, the area of the lip where the organisms were transferred was sampled with a Dacron swab as described above. Six of the 20 subjects had a control fingertip sampled. The control fingertip (without touching the lip) was sampled by placing 5 µl pooled inoculum onto an assigned fingertip. The fingertip was allowed to air dry for 30 s. The fingertip was sampled by a Dacron swab moistened in 3 ml Letheen broth. The swab was replaced in the tube and analysed. Each sampling was repeated. The number of bacteria recovered from the lip was divided by the number recovered from the control finger to determine percentage transfer from finger to lip, which was 24.6% (S.D. = 29.18) from this sample. Only those with the control fingertip sampled were included in the analysis. The study results are reported in Table 4.

Table 4 Results of fingertip to lip transfer study

Case initials	Organism	Number of organisms recovered from control fingertip	Number of organisms recovered from lip	Lip/control (% transfer)
AO	<i>S. rubidea</i>	20 400 000	1 740 000	8.5
		16 800 000	1 560 000	9.3
	<i>M. luteus</i>	19 200 000	2 640 000	13.8
		21 600 000	2 940 000	13.6
PMW	<i>S. rubidea</i>	37 200 000	26 000 000	70.2
		36 000 000	19 000 000	53.3
	<i>M. luteus</i>	26 100 000	2 460 000	9.4
CE	<i>S. rubidea</i>	19 200 000	3 120 000	16.3
		810 000	9900	1.2
	<i>M. luteus</i>	780 000	11 400	1.5
		1 020 000	102 000	10.0
JT	<i>S. rubidea</i>	2 580 000	120 000	4.7
		393 000	25 500	6.5
	<i>M. luteus</i>	381 000	25 800	6.8
		2 880 000	750 000	26.0
PO-C	<i>S. rubidea</i>	2 460 000	60 000	2.4
		870 000	99 000	11.4
	<i>M. luteus</i>	810 000	108 000	13.3
		8 400 000	540 000	6.4
FV	<i>S. rubidea</i>	9 300 000	492 000	5.3
		315 000	228 000	72.4
	<i>M. luteus</i>	327 000	216 000	66.1
		3 990 000	1 890 000	47.4
		2 220 000	2 550 000	114.9
				24.6

Bacteria used: *Serratia rubidea* and *Micrococcus luteus*.

3.5. Dose–response/probability of infection model

Risk assessment models have been used on a limited scale for judging the risks associated with infectious micro-organisms (Haas 1983; Regli *et al.* 1991; Rose *et al.* 1991; Rose and Gerba 1991). The model itself is microbe-specific based on human feeding studies. For *Shigella*, this model was derived from Crockett *et al.* (1996). Once the hazard was determined and the exposure estimated, this was placed into the model. Risk outcomes were determined and uncertainties and assumptions evaluated.

3.6. The *Shigella* dose–response model

A specific dose–response model was developed and evaluated for *Shigella* (Crockett *et al.* 1996). The dose–response model used in this study arises from the best-fit beta-Poisson dose–response model. In previous work, this was found to describe the infectivity of the organism. The model depicts the probability of infection (P_i or π) following a single dose (d) of *Shigella* to be given by:

$$4S \pi = 1 - \left[1 + \frac{d}{N_{50}} (2^{1/\alpha} - 1) \right]^{-\alpha}$$

From examination of infectivity data, the best fit model parameters were found to be α equal to 0.2099, and N_{50} (the median infective dose, as cfu) equal to 1120 organisms, equivalent to the dose required to illicit 50% infection in the population exposed.

4. RESULTS

4.1. *Shigella*: the hazard

Shigella causes bacillary dysentery, and the symptoms range from mild diarrhoea to severe disease with fever, vomiting, cramps and tenesmus, with blood, mucus and pus in the

stool. The primary species infecting humans are *Sh. dysenteriae*, *Sh. sonnei*, *Sh. flexneri* and *Sh. boydii*. The latter three occur most frequently in developing countries. *Shigella* is a Gram-negative Enterobacteriaceae, and humans are the primary reservoir. Although the average duration of disease is a week, one study suggested that 7% of infected individuals may shed the organism for over a year (DuPont *et al.* 1972). The mean duration of 572 diarrhoeal illnesses detected in children in 12 day care centres studied over a 15 month period in Houston, Texas, was 3.4 days (Staat *et al.* 1991).

Shigella is one of the most common causes of diarrhoea found in day care centres. In one study, it was determined that of 37 children, half touched the toilet seat when using the toilet and 1/3 of these children either touched their face or mouth, or sucked their fingers. On their skin, *Sh. sonnei* remained alive for over 3 h. In addition, it has been noted that *Sh. sonnei* can survive for 7–10 days on cotton threads at cool temperatures (Spicer 1959). In September 1994, the Council for Agricultural Science and Technology estimated the incidence of shigellosis in the US population to be 33/100 000 (Mackintosh and Hoffman 1984). The incidence among children in day care centres has been estimated at 1.02 per child per year (Bartlett *et al.* 1985).

4.2. The exposure assessment and risk estimation

Table 5 summarizes the estimates and ranges of concentrations of bacteria that went into the exposures to produce estimates of infection rates. High numbers of cfu are presumed to be on the hands, even with low levels of faecal contamination (0.1 g) during diaper changing of a baby who has symptomatic shigellosis. Concentrations ranged from 10^5 to 10^8 cfu. With asymptomatic excretion levels, the concentrations on the hands ranged from 10^1 to 10^4 with 0.1 g faeces. Hand washing was found to be effective

Table 5 Exposure estimates and probability of due to excretion of *Shigella* from an infected infant during diaper changing with various hand washing scenarios

Scenario	Concentration cfu g ⁻¹ faeces	cfu transfer of 0.1 g faeces	Reduction by hand washing	24.6% finger-to-mouth transfer rate	Probability of infection given infant <i>Shigella</i> carrier‡ during diapering
Handwashing with control product	10^5 to 10^{9*} 10^2 to $10^{6†}$	10^4 – 10^8 10^1 to 10^5	27.54 to $2.75 \times 10^5*$ $2.75 \times 10^{-2*}$ to $2.75 \times 10^{2*}$	6.78 to $6.78 \times 10^4*$ $6.78 \times 10^{-3*}$ to 67.78	24/100 to 91/100 49/100 000 to 53/100
Handwashing with 4% chlorhexidine gluconate	10^5 to 10^{9*} 10^2 to $10^{6†}$	10^4 to 10^8 10^1 to 10^5	24.54 to 2.45×10^5 2.45×10^{-2} to $2.45 \times 10^{2*}$	6.04 to $6.04 \times 10^4*$ $6.04 \times 10^{-3*}$ to 60.41	22/100 to 91/100 43/100 000 to 51/100
Handwashing with 1.5% triclosan	10^5 to 10^{9*} 10^2 to $10^{6†}$	10^4 to 10^8 10^1 to 10^5	12.30 to 1.23×10^5 $1.23 \times 10^{-2*}$ to 123.03	3.03 to $3.03 \times 10^4*$ 3.03×10^{-3} to 30.28	15/100 to 90/100 21/100 000 to 43/100

*Symptomatic infection.

†Asymptomatic infection.

‡Indicates the value of N for input into the P_i model.

at reducing the bacteria on the hands. However, with higher excretion, it was shown that large numbers of up to 10^5 cfu could remain on the hands. It was assumed during this analysis that the reductions achieved for *Serratia* were translatable to *Shigella*. Based on an average of 24.6% transfer of bacteria from the fingers to mouth, the self-doses of *Shigella* were estimated to range from a minimal 3×10^{-3} (that is, only 3/1000 changes have one bacterial cell which is ingested and which arrives the intestinal tract) to 10^4 cfu (that is, with each change 10 000 cfu were dosed). The probability of infection is based on a non-linear model, and only at low doses is there a linear relationship. At doses above 6 cfu due to the low infectivity of *Shigella*, the risk is high and begins to plateau out. The resultant probability of infection after 24.6% of the bacteria contacted were transferred to the lip ranged from 24 to 91/100 for those with babies with symptomatic shigellosis who used the control product, 22/100 to 91/100 for those who used chlorhexidine gluconate, and 15 to 90/100 for those who used triclosan. For those changing diapers of babies with asymptomatic shigellosis, those who used the control soap had a risk between 49/100 000 and 53/100, those who used triclosan had a risk between 21/100 000 and 43/100, and those using chlorhexidine had a risk between 43/100 000 and 51/100.

5. DISCUSSION

The application of risk assessment for the evaluation of personal hygiene products has been demonstrated in this and a previous study (Gibson *et al.* 1999). Although there are data gaps in these studies, both have shown that although a reasonable reduction of micro-organisms is offered through the use of regular soap formulations, a slightly greater reduction of bacteria and subsequent reduced probability of disease results from using antibacterial formulations.

Recently, more attention has been focused on household sanitizing agents. As the technology develops to further reduce the possibility of illness resulting from exposure to microbial pathogens in the home, these products can be evaluated through a risk assessment process to estimate the number of cases of disease they could truly prevent. In this example, an approximately 1.63-fold reduction in the probability of disease via contaminated hands during diaper changing, given the presence of an infant shedding *Shigella*, was demonstrated with the use of a soap with a sanitizing agent compared with a control of soap alone.

More data on the transference to/from and the survival of micro-organisms on hands are needed. The use of surrogate micro-organisms such as *Serratia* may be advantageous because of the ease of assay, but may also over-estimate or under-estimate the risk as it may or may not be represen-

tative of the greatest survival, greatest resistance and greatest transfer potential.

Various uncertainties exist when undertaking this type of risk assessment. Excretion rates can be highly variable and have the greatest impact on the risk outcome. To obtain a more complete estimate of risk, multiple pathogens would need to be considered and the excretion distribution, including diaper changing rates over the course of an infection, could be factored into the exposure. This estimate was based on a single diaper changing exposure event. The risk would be increased based on the number of times an individual was exposed (y).

$$P_y = (P_{\text{single}})^y$$

In this study, a comparison was made between two antiseptic hand-wash formulations: 4% chlorhexidine gluconate and a 1.5% weight-to-volume ratio triclosan in a natural liquid potassium soap, pH 9. A number of studies have evaluated the efficacy of chlorhexidine and triclosan in removing bacteria from human hands (Lowbury and Lilly 1973, 1974; Ayliffe *et al.* 1987; Casewell *et al.* 1988; Namura *et al.* 1992) using different methods. Importantly, many do not evaluate the efficacy of a control formulation or the use of water alone in bacterial removal. They also use different methods to evaluate the number of bacteria remaining on the hands: wash, touch or glove. The reduction in micro-organisms on the hands by soaps may be due to many factors including: immediate and time-dependent die-off; physical removal; decreasing adherence if the hands come into contact with a contaminated source post-washing; decreased transference. The available data for examining these various mechanisms are not well developed.

The amount of faeces, distribution of bacteria on the hands before and after washing, number of diapers used, type of diaper and contamination of the changing table would contribute to the multiple exposures which are expected to occur. The transfer of the bacteria from diaper to hands, and hands to mouth, needs to be better characterized. In addition, the frequency of hand-to-mouth contact and the frequency of using antimicrobial products should be evaluated to better characterize the probability of infection.

While the consumer may believe that hand washing with soap results in 'clean' hands, they may not be microbiologically clean. The proper washing of hands after diapering is a practice in the home or day care facility that could readily reduce, or practically eliminate, the risk of disease transmission. The models suggest that with the use of an antimicrobial formulation, this risk is slightly reduced, but this needs further evaluation. The risk assessment approach allows for comparative evaluation of products and protocols that may provide increased public health protection.

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