Title page: A pragmatic randomised controlled trial of 6 step versus 3 step Hand Hygiene technique in acute hospital care

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Abbreviated title: RCT: 6 step v 3 step hand hygiene technique

Abstract

Objective: This study evaluated the microbiological effectiveness of the World Health Organization's (WHO) 6 step and the Center for Disease Control's 3 step hand hygiene techniques using alcohol based handrub (ABHR).

Design: A parallel group randomized controlled trial (RCT).

Setting: An acute care inner city teaching hospital.

Participants: Doctors (n=42) and nurses (n=78) undertaking direct patient care.

Intervention: Random1:1 allocation of the 6 step(n=60)or the 3 step technique(n=60).

Results: The 6 step technique was microbiologically more effective at reducing the median log10 bacterial count ((3.28 (95% CI 3.11, 3.38 cfu/ml) to 2.58 (95% CI 2.08, 2.93) cfu/ml)) than the 3 step ((3.08 (95% CI 2.977, 3.27)to 2.88 (95% CI 2.58, 3.15) cfu/ml)) (p=0.02), but did not increase the total hand coverage area (98.8% versus 99.0%, p=0.15) and required 15% (95% CI: 6%-24%) more time (42.50 seconds vs 35.0 seconds, p=0.002). Total hand coverage was not related to the reduction in bacterial count.

Conclusions: Two techniques for hand hygiene using ABHR are promoted in international guidance; 6 step by the WHO and 3 step by the Center for Disease Control. The study provides the first evidence in a RCT that the 6 step technique is superior, thus these international guidance documents should consider this evidence, as should healthcare organisations using the 3 step technique in practice.

Trial registration numbers: UK Clinical Research Network run by the National Institute Health Research: CSP 16084. Clinical trials.gov number: NCT02396836 and URL: https://clinicaltrials.gov/ct2/show/NCT02396836?term=hand+hygiene&rank=5.

Introduction

Hand hygiene is argued to be the most important intervention in preventing healthcare associated infection.[1] Despite this a recent systematic review[2] identified that there is limited evidence to support hand hygiene techniques, and compliance with hand hygiene remains sub-optimal. It might be argued that there is little point in getting the opportunity, or '5 moments',[1] correct for hand hygiene, if a technique effective in reducing the bacterial load on the hand thereafter is not evident.

There are two main techniques in international guidance on hand hygiene: the first of these is the World Health Organization (WHO) 6 step technique,[1] which involves applying a palmful of alcohol based handrub in a cupped hand, covering all surfaces and rubbing 6 different aspects of the hands. This technique has a limited evidence base for use in clinical practice as it was developed as a standardised technique to test hand hygiene products in a laboratory setting.[3] Furthermore, this technique has no evidence of microbiological effectiveness in clinical settings with alcohol based handrub (ABHR). The second technique is the 3 step technique. This techniqueinvolves 1.applying ABHRto the palm of one hand and rubbing hands together; 2.covering all surfaces; until 3.hands are dry.[4]There is some observational evidence base[5] and one randomized controlled trial (RCT) to support this technique on the basis of shorter duration, although not for ABHR use specifically.[6] Given most hand hygiene opportunities in developed countries uses ABHR and compliance is sub-optimal, this study aimed to evaluate the microbiological effectiveness of the two current techniques used internationally on residual bacterial load.

Methods

Study design

A parallel group RCT with random allocation to either: 1. hand-rubbing with ABHR covering all hand surfaces (3 step technique), or 2. hand-rubbing with ABHR using the 6 step technique. The aim was to compare the microbiological effectiveness of the techniques on hand coverage and reduction of bacterial contamination on the hands of healthcare workers (HCW) in a large university teaching hospital in the UK, where the 6 step technique was current practice. Ethics committee approval was granted from Glasgow Caledonian University (HLS13/03) and access and research approval permissions from NHS Greater Glasgow & Clyde Research &Development committee (GN13MI027). The study protocol is available on line at:https://register.clinicaltrials.gov/prs/app/action/SelectProtocol?selectaction=Edit&uid=U0002B31&ts=2&cx=-ivhvei&sid=S0004T1X.

Participants

Participants were eligible for inclusion if they were a nurse or doctor present on the ward, doing direct patient care not requiring the use of gloves or hand washing with Chlorhexadine, and if theyagreed to participate. There were no ineligible participants and 4 refusals. They were excluded if they had: a self-declared active skin condition at the time of the study, had already taken part in the study, or if their hands became contaminated during the procedure requiring them to wash their hands.

All wards in the hospital were included and a random order was used to determine which wards to study on a particular day. Participants were informed about the study via email and

posters in advance of data collection, and in person on the day by the researchers. Verbal consent was taken from participants to protect their identity and anonymity.

Randomisation and masking

To avoid staff knowing in advance randomization was not disclosed until the day of data collection. Pre-prepared sealed opaque envelopes were used to randomly allocate participants into hand hygiene protocols (1) 3 step or (2) 6 step technique. An infection control practitioner, experienced in hand hygiene audit, and a research nurse collected the data. A study number was assigned to each participant using pre-numbered data collection forms.The data collectors had no involvement in the analyses or writing up. The specimens were processed and reported by a microbiologist (KS), blinded to the group allocations. The microbiology interpretation and analyses were conducted by SL and CR respectively who were both blinded to the allocation of groups.

Procedures and Interventions

The data collectors were trained in the study protocol and to use glove juice technique.[7] They observed the patient care activities in the ward, and identified activities involving direct patient contact. Staff who had agreed to participate were then approached for data collection. To standardise the techniques each participating HCW was shown a diagram on an instruction card demonstrating the allocated technique and 3 ml.of "Softcare Med©" ABHR,which contained a blend of isopropyl alcoholand n-propanol, was used via a pump dispenser.

After the patient interaction, a glove juice sample[7] was taken by the data collector from the dominant hand of the participant. Participants then used the ABHR, with the respective allocated technique, after which a second glove juice sample was taken. One data collector

recorded the duration of the technique with an electronic stop watch and collected the glove juice technique specimen.[7] Hands were then rinsed and dried and Spirigel©, a handrub with a fluorescent dye, applied to evaluate adherence to the allocated techniqueand hand coverage. Hand coverage was determined by observation of the hands for any areas not covered with fluorescent dye. To identify these areas hands were evaluated under ultraviolet light following application of the dye. The location and size of areas not covered by dye were documented on a standard hand drawing. The total area not covered for each participant was determined by the investigator based on the drawings, and placed in one of four categories: 0%, up to 5%, 5% – 15%, and > 15%[5].To standardise data collection one data collector observed and recorded if each step of the technique was completed during application of the Spirigel©and coverage of the hands.

Outcomes

The primary outcome measure was residual bacterial load on the hands of the HCW after using the hand hygiene technique. Secondary outcomes included compliance with the technique (%), hand coverage and sites missed, andduration (seconds). There were no adverse events recorded and the ABHR used was that of the study hospital so no risk to safety was anticipated with the study.

Statistical analysis

A sample of 120 clinical participants was required to detect differences, at 90% power, with a bacterial load of at least 0·38 in mean log10 CFU.[6] It was anticipated that due to the lower number of doctors available on the wards that randomization would be done in a manner to allow more nurses to be recruited, if required, but to maintain the 1:1 allocation of both nursing and medical participants in each arm of the trial. The data were analysed by one of the authors (CR).

To rule out the influence from the prior-hand hygiene practice we used ratios of the post-hand hygiene bacterial colony counts over the prior-hand hygiene counts. A linear regression model was fitted to identify significant difference in the ratios between these two hand hygiene techniques, using a log transformation. A quantile-quantile plot was produced to check the validity of the normal assumption and a Wilcoxon Rank-Sum test was used if there was a significant deviation from normality. This test was used to examine the difference of the time taken for hand hygiene and the percentage of the hand area not covered between the techniques. Detailed hand part comparisons of coverage between the two techniques were carried out using contingency tables. A Chi-square test was applied to examine the difference in coverage and Fisher's Exact Test was applied if the counts in the table were small. The same procedure was applied to the observation data for duration of applying the ABHR. The 95% confidence limits for the medians were obtained from 10,000 boot strap samples. All analysis was conducted using R© version 3·0·3.

Results

A total of 120 participants were recruited into this studyon week days (1st February to 31st March 2014), inclusive of 78 nurses and 42 doctors from 15 acute wards including intensive care units and a range of medical and surgical specialities. For the 6 step technique, the median log10 bacterial colony counts prior to hand hygiene were 3.28(95% CI 3.11, 3.38) cfu/ml, which reduced significantly to 2.58(95% CI 2.08, 2.93) cfu/ml (Table 1) after hand hygiene. While for the 3 step technique, there was a smaller reduction ((3.08(95% CI 2.97, 3.27) cfu/ml to 2.88(95% CI 2.58, 3.15) cfu/ml)). The ratios of the post-handrub bacterial counts over the pre-handrub counts weresignificantly lower (p =0·02) for the 6 step technique; the median ratio of pre to post cleaning bacterial load for those using the 6 step technique was 0.51 (95% CI 0.30, 0.89) times the ratio for those using the 3 step (median post to pre-ratios were 0.33, 6 step and 0.65, 3 step). For the 6 step, the time taken was

generally longer (Table 1) with a median value of 42.5 (95% CI 39·0, 45·0) seconds compared to 35·0 (95% CI 33·0, 37·0) seconds for the 3 step technique (Table 1). The regression results showed that the time taken was 15% (95% CI: 6%-24%) longer for the 6 step technique (p=0·002).

Table 1 shows that for both techniques, the magnitude of the area covered during hand hygiene was not related to a greater reduction in bacterial loads. The detailed observation data for hand coverage are summarized in Figure 1; the 6 step technique generally covered more parts of the hands. Only 39 of 60 (65%) participants were fully compliant, i.e. followed the instructions entirely for the 6 step technique. When the subgroup of those who performed the technique correctly were compared with those who had not; a significant difference was found in the reduction in bacterial load, p=0.01, in favour of those who complied 100% with the technique. Among those fully compliant the median bacterial load goes from 3.18 (before) to 2.08 (after hand hygiene) log10(cfu/ml,) compared to3.36 (before) to 2.55(after hand hygiene) log10(cfu/ml)among those not fully compliant; the median ratio of post-handrubbing to pre-handrubbing bacterial load for thosefully compliant was 0.31 (95% CI 0.14, 0.75) times that of those who were partially compliant. There was no difference in time taken to perform technique (p=0·51) or total surface coverage (p=0·14) between these subgroups.

The vast proportion of the colonies which constituted the total aerobic bacterial counts were phenotypically identified as staphylococci. With the exception of one sample, aerobic bacteria were recovered from all pre-hand hygiene samples and the vast majority (86 %, 103/120) also had these organisms present post-hand hygiene. There was no significant difference between technique used and aerobic bacteria being detected; 82% having detectable bacteria on the hand surface after the 6 step, and 90 % after the 3 step.

The percentage of the hand area covered by the ABHR did not differ on average between the two techniques. The detailed coverage data are summarised in Figure2 which illustrates that the back of the hands and the fingers were generally less likely to be covered in full compared to the palm of the hands and the fingers for both techniques. The back of the hands, the back of the thumbs and the back of the index fingers were most frequently missed regardless of the techniques used. There was no significant difference between the techniques for hand coverage, except with the 6 step technique, when there were significantly more participants with their back of the hands not fully covered (p=0·002), but there were fewer participants with their back of the index (p= 0·01) and the middle finger (p =0·002) of the right hand not fully covered (Figure 2) compared with the 3 step technique.

There was no significant difference between participants groups (doctors versus nurses) in terms of changes in bacterial counts irrespective of technique used. The reduction in bacterial load was 55% (median of 0.45, interquartile range (0·19 to 1·00)) in doctors and 63% (median of 0·37, interquartile range (0·08 to 1·06) in nurses s i.e. nurses had a 14·1% (95% CI -61%, 54·3%) greater reduction relative to doctors but this was not significant (p=0·64). Both doctors and nurses achieved a comparable level of hand coverage with similar areas of the hands not covered; a median of 1·2% for doctors and 1·1% for nurses.

Discussion

This pragmatic RCT with 90% power evaluated the microbiological effectiveness of 6 step versus 3 step ABHR hand hygiene technique in terms of: residual microbial load, hand surface coverage and duration of application. Our results demonstrate that, contrary to the findings from a systematic review,[2] the 6 step technique with ABHR was more effective than the 3 step hand hygiene technique, in terms of residual bacterial load.

Contrary to earlier observational studies on hand washing,[5, 8-12]larger coverage area of the hand was not related to a larger reduction in bacterial loads.This may because the 6 step technique took a longer time due to the greater number of maneuvres required compared to the 3 step technique. Other authors[9] have identified that a reduction in bacterial load can also be influenced by the amount of ABHR applied to the hands. However, in this study the amount used was the same for both techniques.

Nine out of 59 (15%) of those participants performing the 3 step covered all areas of the hand as defined in the 6 steps. This indicates that specific site coverage, rather than overall coverage, was much less effective in 3 step. For the 6 step technique, the back of hands were more frequently missed, while the back of the index and the middle finger of the right hand were less frequently missed compared to 3 step. Only one other study[6] compared these two techniques to date and this study examined hand washing with Chlorhexidinerather than ABHR specifically and did not address sites missed, thus the evidence arising from this part of our study is novel. Other studies examining the 6 step technique compliance found dorsal and palmar aspects were most frequently missed (24% and 18% respectively) and 3·5% of fingertips.[9-10]

Others have examined compliance with the WHO 6 step technique specifically rather than compared with another approach.[5,8-12] In these studies, compliance with the technique varied from 7·9%[5] to 8.5% [13]to 31%[14] to47%.[12]Our study found that even during observation by two researchers and use of a printed instruction card demonstrating the technique, compliance with the 6 step technique was only 65%, compared to 100% compliance with 3 step technique. Those participants with 100% compliance with 6 step technique had a significantly greater log reduction in bacterial load with no additional time or difference in coverage compared to those with 65% compliance with 6 step technique (p=0·01). This finding is reinforced by previous studies,[9] which have indicated that compliance, after

training, with the 6 step technique rose from 31% to 74% in HCW. Studies have indicated that this reduces over time, emphasising the need for on-going re-enforcement, education and training.[11]Unlike other studies to date[11] we found no difference in compliance between doctors and nurses. Other studies have found higher compliance with technique amongst nurses compared to doctors.[11] Our result may have arisen by the use of an instruction card on the technique to minimize potential for confounding from variation in prior training in hand hygiene technique.

For the 6 step technique, the time taken for hand hygiene was longer compared to the 3 step technique. This finding is supported by previous work,[6] wherein the 3 step was found to be significantly quicker (26 vs 38·5 seconds p=0·04). Kampf et al (2008)[5] similarly demonstrated a median time of 25 seconds with 3 step technique. Time taken for hand hygiene is an important consideration but microbiological effectiveness is more important. Whilst both of the techniques reduce the bacterial load what is not known is whether the reduction with 3 step is sufficient to stop transmission of healthcare-associated infections. If it was, then efficiency in time taken may make this a preferable option.

Our study had several strengths. It was a RCT in a clinical setting[5], very few of which are seen in infection prevention and control studies.[15] It had a high recruitment rate with 120 out 124 (97%) agreeing to participate in the study. There were no withdrawals from the study. The hand sites missed as well as time taken and bacterial residual were measured; this is the first time all of these have been accounted for in an RCT in practice. We used the accepted gold standard in microbiology of glove juice technique,[16] hence providing an accurate assessment of bacterial burden that can be transferred via hand contact. The blinding of the microbiologist to the assigned protocols also strengthens our study as detection bias was minimized.

There were some limitations. The glove juice technique sampling potentially removed a large amount of the bacteria present on participants' hands before ABHR application, thus overestimating the bacterial reduction. Compliance with the technique may have been influenced by the Hawthorne effectas hand hygiene was directly observed and assessed.[17] Despite this compliance with the 6 step technique was only 65%.However, as stated earlier compliance was higher than other studies and probably higher than routine practice as HCW were given instructions on performing the hand hygiene techniques. Alternatively, 100% compliance with hand hygiene technique may be unachievable in practice. There were separate procedures for cleaning the hands and using the fluorescent dye; thus, we cannot be certain that participants did exactly the same technique in these two different procedures, limiting the attempt to correlate bacterial reduction with the hand surface coverage.

This study provides the first evidence of applied research from a RCT that the 6 step technique is superior to the 3 step technique in reducing the residual bacterial load after ABHR hand hygiene. The reduction was not related to coverage, type of organism or staff group. Duration was longer for the 6 step technique and areas missed differed for the two techniques. A potentially simpler, more time efficient 3 step technique was not better or equivalent to the 6 step technique in reducing bacterial load.

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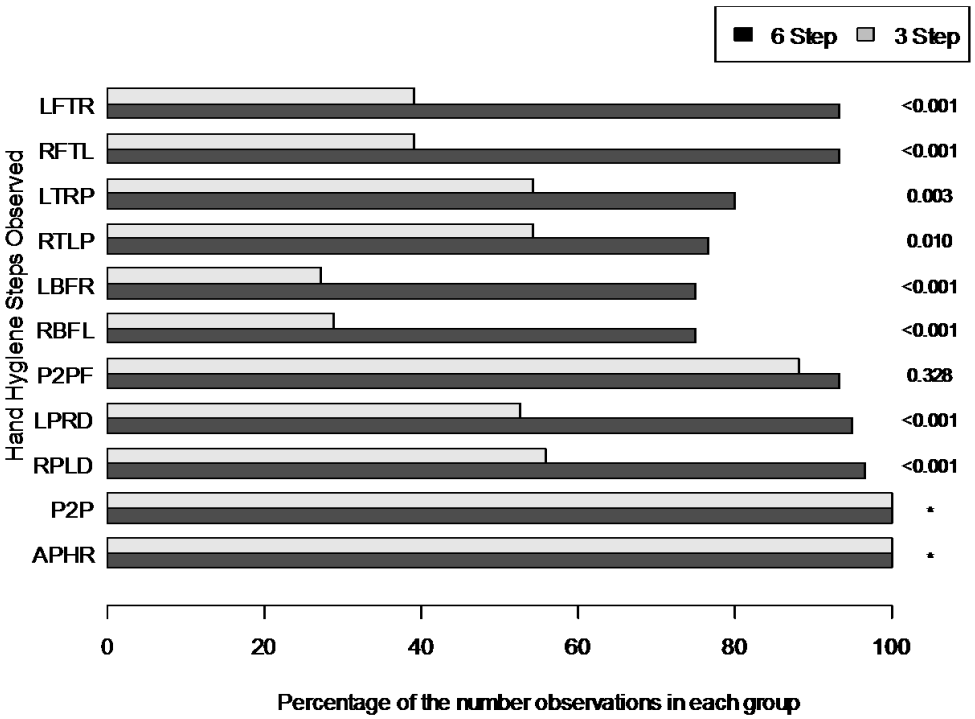
Table 1: Comparison between the 3 and 6 step hand hygiene techniques in terms of the time taken in hand hygiene, the percentage of the hand area not covered and the total bacterial colony counts before and after hand hygiene

	Hand Hygiene Techniques						
	6 step (N=60)			3 step (N=60)*			
	M	Q1	Q3	M	Q1	Q3	P
Time taken (seconds)	42·50	35·00	48·25	35·00	30·00	43·00	0.002
Percentage of hand area not covered	1·20	0·50	2·14	1·02	0·32	1·59	0.097
Pre handrub - total cfu/ml (Blood agar)	1900	595	3100	1200	520	2700	0.296
Post handrub - total cfu/ml (Blood agar)	380	60	1500	750	130	2100	0.157
Pre handrub - log10(total cfu/ml) (Blood agar)	3.28	2.77	3.49	3.08	2.72	3.43	0.296
Post handrub Note some sites where there was zero percent not fully covered are excluded for the plot - log10(total cfu/ml((Blood agar)	2.58	1.78	3.18	2.88	2.11	3.32	0.157
Post.Pre.Ratio	0·31	0·07	0·69	0·65	0·18	1·31	0.016

M Median, Q1 Lower Quartile, Q3 Upper Quartile, P – P value for the Mann Whitney test,

* There was one missing time in the 3step group for time taken.

Figure 1: The percentage of participants in the 6 step (60 observations) and 3 step (59 observations) arms who were compliant with the specific components of the hand hygiene techniques.



Numbers beside the bars are the p values from the Chi Square test of association

* No test carried out as there was 100% compliance in each arm

APHR - Applied a palmful of hand rub; P2P - Palm to palm;RPLD - Right palm over left dorsum fingers interlaced; LPRD - Left palm over right dorsum fingers interlaced; P2PF - Palm to palm fingers interlaced; RBFL - Right back of fingers in left palm; LBFR - Left back of fingers in right palm; RTLP - Right thumb in left palm; LTRP - Left thumb in right palm; RFTL - Right finger tips in left palm; LFTR - Left finger tips in right palm;

Figure 2: The percentage of participants in the 6 step (60 observations) and 3 step (59 observations) arms who did not fully cover the specified areas of the hands.

Numbers beside the bars are the p values from the Chi Square test of association (+ Fisher's Exact Test)

TLB - Thumb LH Back; IFLB - Index finger LH Back; MFLB - Middle finger LH Back; RFLB - Ring finger LH Back; LFLB - Little finger LH Back; BHLB - Back of hand LH Back; TRB - Thumb RH Back; IFRB - Index finger RH Back; MFRB - Middle finger RH Back; RFRB - Ring finger RH Back; LFRB - Little finger RH Back; BHRB - Back of hand RH Back; TLP - Thumb LH Palm; PLP - Palm LH Palm; TRP - Thumb RH Palm; IFRP - Index finger RH Palm; PRP - Palm RH Palm.