Enhanced performance feedback and patient participation to improve hand hygiene compliance of health-care workers in the setting of established multimodal promotion: a single-centre, cluster randomised controlled trial

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Summary

Background Hand hygiene compliance of health-care workers remains suboptimal despite standard multimodal promotion, and evidence for the effectiveness of novel interventions is urgently needed. We aimed to assess the effect of enhanced performance feedback and patient participation on hand hygiene compliance in the setting of multimodal promotion.

Methods We did a single-centre, cluster randomised controlled trial at University of Geneva Hospitals (Geneva, Switzerland). All wards hosting adult, lucid patients, and all health-care workers and patients in these wards, were eligible. After a 15-month baseline period, eligible wards were assigned by computer-generated block randomisation (1:1:1), stratified by the type of ward, to one of three groups: control, enhanced performance feedback, or enhanced performance feedback plus patient participation. Standard multimodal hand hygiene promotion was done hospital-wide throughout the study. The primary outcome was hand hygiene compliance of health-care workers (according to the WHO Five Moments of Hand Hygiene) at the opportunity level, measured by direct observation (20-min sessions) by 12 validated infection control nurses, with each ward audited at least once every 3 months. This trial is registered with ISRCTN, number ISRCTN43599478.

Findings We randomly assigned 67 wards to the control group (n=21), enhanced performance feedback (n=24), or enhanced performance feedback plus patient participation (n=22) on May 19, 2010. One ward in the control group became a high-dependency unit and was excluded from analysis. During 1367 observation sessions, 12 579 hand hygiene opportunities were recorded. Between the baseline period (April 1, 2009, to June 30, 2010) and the intervention period (July 1, 2010, to June 30, 2012), mean hand hygiene compliance increased from 66% (95% CI 62–70) to 73% (70–77) in the control group (odds ratio [OR] 1·41, 95% CI 1·21–1·63), from 65% (62–69) to 75% (72–77) in the enhanced performance feedback group (1·61, 1·41–1·84), and from 66% (62–70) to 77% (74–80) in the enhanced performance feedback plus patient participation group (1·73, 1·51–1·98). The absolute difference in compliance attributable to interventions was 3 percentage points (95% CI 0–7; p=0·19) for the enhanced performance feedback group and 4 percentage points (1–8; p=0·048) for the enhanced performance feedback plus patient participation group. Hand hygiene compliance remained significantly higher than baseline in all three groups (OR 1·21 [1·00–1·47] *vs* 1·38 [1·19–1·60] *vs* 1·36 [1·18–1·57]) during the post-intervention follow-up (Jan 1, 2013, to Dec 31, 2014).

Interpretation Hand hygiene compliance improved in all study groups, and neither intervention had a clinically significant effect compared with control. Improvement in control wards might reflect cross-contamination, highlighting challenges with randomised trials of behaviour change.

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Introduction

Health-care-associated infections represent a leading preventable adverse event in inpatients.[1] Hand hygiene is widely considered key to prevent such infections and cross-transmission of multidrug-resistant organisms.[2,3] WHO recommends a multimodal approach to hand hygiene promotion that includes provision of alcohol-based handrub at the point of care, education of health-care workers, audit and performance feedback of hand hygiene behaviour, reminders in the workplace, and institutional safety culture. Existing evidence supports the effectiveness of multimodal hand hygiene promotion.[3–7] However, sustaining success remains challenging.

Since hand hygiene compliance remains suboptimal despite standard efforts, effective new interventions that further improve hand hygiene are needed in settings where multimodal promotion is already applied. Performance feedback is a core behaviour improvement strategy in health care and hand hygiene promotion.[3,8,9] Since performance feedback is most effective when it is personalised, immediate, and accompanied by goal setting,[9] we hypothesised that personalised feedback to individual health-care workers coupled with intensified

Research in context

Evidence before this study

Two systematic reviews have assessed interventions to improve hand hygiene in hospital health-care workers. In 2014, Schweizer and colleagues identified six randomised controlled trials and 39 quasi-experimental studies of bundled interventions to improve hand hygiene compliance. They found that such strategies were associated with improved hand hygiene (odds ratio 1·82, 95% CI 1·69–1·97) but concluded that multimodal hand hygiene promotion "should be further studied using high-quality study designs and compared with other interventions". In 2015, Luangasanatip and colleagues reported that the WHO multimodal hand hygiene strategy is effective at increasing compliance in health-care workers. Their network meta-analysis suggested that the addition of goal setting, reward incentives, and accountability strategies might lead to further improvements. We searched PubMed for trials published from Jan 1, 1995, to Feb 1, 2016, assessing the effectiveness of performance feedback and patient participation. We used the search term: "(Hand Hygiene[MeSH]) AND (Feedback, Psychological[MeSH] OR "Feedback" OR Patient Participation [MeSH] OR Patient Engagement [MeSH] OR "Patient Participation")". We did not apply any language restrictions. We found no additional randomised trials and, specifically, we know of no previous randomised controlled trials that have assessed the effectiveness of patient participation in promoting hand hygiene of health-care workers.

Added value of this study

Our study is one of very few randomised controlled trials to assess the addition of well defined interventions to the WHO multimodal hand hygiene strategy. We sought to address the need for randomised controlled trials in this domain and used a clustered randomised controlled trial design to minimise the effect of contamination and take advantage of the team culture of individual hospital wards. Although we were unable to show an effect of the interventions compared with control, we observed an institution-wide improvement in hand hygiene compliance (including in control wards) in the absence of any other intervention. This improvement was partly sustained during a 2-year follow-up period after the specific study intervention ended.

Implications of all the available evidence

Taken with existing evidence, these findings support the central role of performance feedback in promoting and sustaining hand hygiene behaviour in hospital health-care workers, and suggest that patient participation could be cautiously considered by hospitals seeking additional interventions. From a methodological perspective, our experience with this trial highlights the challenges in performing a randomised controlled trial to test a behaviour change intervention even when a clustered design is used—most notably, contamination between study groups and induction of a so-called study effect in the control group. The call for optimally robust study designs to support the effectiveness of behaviour change interventions in infection control should be carefully balanced against the cost required of large multicentre trials.

regular feedback to clinical teams might improve hand hygiene compliance beyond standard multimodal promotion. Patient participation in hand hygiene refers to interventions ranging from patient education to empowering patients to remind health-care workers to perform hand hygiene.[10] This strategy might be useful,[11] but implementation is challenging and its effectiveness has been little researched.[12,13]

We hypothesised that implementation of enhanced performance feedback or enhanced performance feedback plus patient participation in wards with ongoing multimodal hand hygiene promotion would lead to a clinically significant increase (defined a priori as ≥15 percentage points) in hand hygiene compliance compared with multimodal hand hygiene promotion alone. We also aimed to assess, as secondary objectives, the effect of these interventions on hand hygiene compliance before touching patients, requisition of alcohol-based handrub, and hospital-associated colonisation and infection events. We selected a clustered study design because the interventions were to be implemented at the ward level.

Methods

Study design and participants

We did a cluster randomised controlled trial, with the hospital ward as the unit of randomisation, at University of Geneva Hospitals (Geneva, Switzerland), a primary and tertiary care institution with three campuses, 2000 beds, and a long history of multimodal hand hygiene promotion.[14,15] All wards hosting adult, lucid patients were eligible, and we excluded ward types that were unfeasible or inappropriate for patient participation: intensive care and high-dependency wards, paediatric wards, psychiatric wards, palliative care wards, and psychogeriatric wards. All health-care workers and patients in the study wards were eligible to be included in the study.

This trial was approved by the University of Geneva Hospitals institutional review board with a waiver of individual patient consent (protocol 09-299).

Randomisation and masking

After a 15-month baseline period, all participating wards were randomly assigned (1:1:1) to one of three groups—control, enhanced performance feedback alone, or enhanced performance feedback plus patient participation—by a statistician who was masked to study group assignment and outcome assessment. Randomisation was done with a computer-generated sequence and stratified by three types of ward for balanced allocation: surgery, and obstetrics and gynaecology; medicine; and geriatrics and rehabilitation wards. These strata grouped together wards with similar patient characteristics, including length of

stay, which we considered might affect the implementation of patient participation. Within each stratum, block randomisation (block size six) was used to assign wards to study groups. Masking of study participants or observers was not possible because of the nature of the interventions.

Procedures

Standard multimodal hand hygiene promotion activities,[3] including monitoring and feedback, were done hospital-wide throughout the study (appendix p 2). We designed two interventions on the basis of existing evidence and results from 16 focus group sessions (involving 79 health-care workers) about performance feedback and patient participation in early 2010. Interventions were implemented at the ward level.

Enhanced performance feedback included immediate, individualised, and intermittent, aggregated components, with ward-level benchmarking and goal setting. The hand hygiene compliance goal of 80% was established as part of this intervention. At the end of each hand hygiene observation session, observers provided immediate feedback to the health-care workers observed during that session. This consisted of verbal feedback and, where feasible, a card reporting individual hand hygiene compliance and individualised written advice for how to improve, when appropriate (appendix p 10). The card also illustrated the WHO Five Moments for Hand Hygiene and stated the institution-wide hand hygiene compliance goal (≥80%), with the signatures of the medical and nursing directors. This feedback was an opportunity to recognise good hand hygiene behaviour and to provide education when needed.

Systematic feedback consisted of reports and posters, which were distributed every 3 months. A report providing overall and WHO Moment 1 (ie, before touching a patient) hand hygiene compliance for the department benchmarked against hospital-wide results and the target of 80% hand hygiene compliance, along with trends, was emailed by the study team to departmental senior nursing and medical staff, and to the head nurse of wards in the intervention groups. The poster, which was placed in the nursing stations and doctors' offices by infection control professionals, presented a visual representation of hand hygiene compliance for that ward over the previous 3 months and included a space for the clinicians to note their goal for the next 3 months (appendix p 11).

Patient participation was formulated as a health-care worker–patient partnership. On admission, patients were provided with a welcome pack consisting of a brochure (appendix p 12) and an individual pocket-sized bottle of alcohol-based handrub. We developed hand hygiene indications for patients (appendix p 3). Ward staff educated patients about hand hygiene indications for both patients and health-care workers, with a particular emphasis on Moment 1 for health-care workers. Patients were invited to ask health-care workers who did not visibly perform hand hygiene before touching them (Moment 1) to do so, just as health-care workers would remind patients to perform hand hygiene according to patient indications (appendix p 3). Health-care workers were advised to make a pragmatic decision about the capacity of each patient to participate. Patients considered inappropriate because of cognitive impairment, delirium, or illness severity were not involved while their conditions persisted. Posters promoting patient participation were displayed and health-care workers were encouraged to wear promotional badges. Investigators met with health-care workers in patient participation wards for three sessions (15–30 min each) in June, 2010, to explain the intervention and to provide practical examples of how to discuss hand hygiene with patients.

See Online for appendix

We audited process indicators every 3 months. We verified the presence of posters, monitored use of welcome packs, and assessed health-care worker awareness of the allocated intervention groups. During hand hygiene observation sessions, observers recorded feedback card distribution and patient participation events.

To investigate sustainability of the interventions, we recorded hand hygiene compliance and alcohol-based handrub requisition for a 2-year follow-up period. During follow-up, standard multimodal promotion continued and active study interventions ceased.

Outcomes

The primary outcome was overall hand hygiene compliance of health-care workers in the participating wards, measured by direct observation according to the WHO Five Moments of Hand Hygiene, which defines an opportunity as the occurrence of any indication during observed care sequences.[16] Hand hygiene compliance was recorded and analysed at the opportunity level but summarised by dividing the number of actions (rubbing or washing) during opportunities by the total number of opportunities (presented as a percentage). 12 validated infection control nurses did the observations during 20-min sessions, with each ward audited at least once every 3 months during the baseline and intervention periods, and once every 4 months during the follow-up period. At University of Geneva Hospitals, infection control nurses are assigned to medical specialty departments for all infection prevention and control responsibilities, including hand hygiene observations. They therefore audited the same wards (including wards in each group) allocated to them for daily routine throughout the study period.

The predefined secondary outcomes were considered in four categories and were recorded monthly at the ward level (except Moment 1 compliance). The first category was hand hygiene behaviour. Hand hygiene compliance at WHO Moment 1 (ie, before patient contact) was selected because we expected it to be most amenable to patient participation. Alcohol-based handrub requisition,

monitored by dividing monthly ward-specific requisition of alcohol-based handrub by 1000 patient-days, was included to provide a complementary measure of hand hygiene behaviour.[17] Only 100 mL bottles of alcohol-based handrub carried by health-care workers for their personal use were included in the measure, because these bottles are the predominant means of hand hygiene among health-care workers and are not used in corridors or by visitors.

The second category of secondary outcomes was health-care-associated infections. Primary and secondary bloodstream infections were defined as a first positive blood culture result from any sample type collected at least 48 h after hospital admission. Incidence of bloodstream infections was recorded prospectively,[18,19] and health-care-associated infections period prevalence surveys were done every 3 months using definitions of the National Healthcare Safety Network.[19,20]

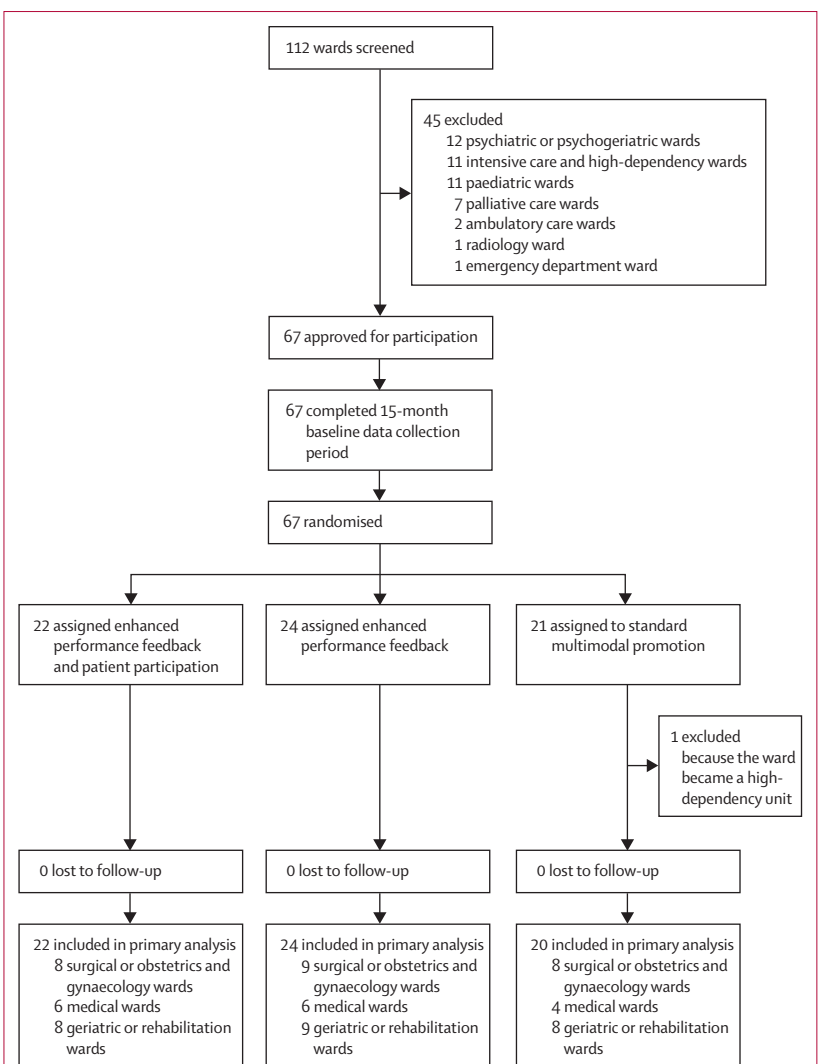

Figure 1: **Trial profile**

The third category was hospital pathogen clinical isolates. Positive results from clinical samples were extracted retrospectively from the microbiology database for the following pathogens: meticillin-resistant *Staphylococcus aureus* (MRSA), extended-spectrum β-lactamase-producing Enterobacteriaceae (ESBL-PE), and *Clostridium difficile* toxin. For MRSA and ESBL-PE, screening samples were excluded. Antibiotic resistance was screened with antibiogramme and confirmed by the detection of *mec*A for MRSA, and with the double-disk method according to Clinical and Laboratory Standards Institute guidelines for ESBL-PE. *C difficile* infection was diagnosed by McCoy cell culture cytotoxicity assay before 2010, then by BD GeneOhm Cdiff assay (BD Diagnostics, Quebec City, QC, Canada). Only the first positive result per patient and study period was included. The result was attributed to the patient location at time of sample collection.

The fourth category was acquisition of multidrug-resistant organisms, defined as the identification of MRSA or ESBL-PE, or both, in any sample (clinical or screening) at least 48 h after hospital admission in patients who were not known to be colonised. Antibiotic resistance was determined as above.

Statistical analysis

Pre-study observations indicated a hand hygiene performance of 60%. We nominated a priori a 15 percentage-point increase to 75% as a clinically significant target, which corresponded to a standardised effect size of roughly 0·33. We anticipated that an equal cluster size of 22 wards per group would give rise to at least ten hand hygiene opportunities every 3 months per ward, with an assumed intracluster correlation coefficient of 0·06 (based on pre-study data). This assumption translated to a total of 220 opportunities per group to assess the difference in the compliance between groups (α=5%) with 80% power. We accounted for correlation of opportunities within each ward, but hand hygiene compliance would also be likely to be correlated with patient and health-care worker, which is more challenging to account for because of anonymisation. Thus, we inflated the number of opportunities by five, leading to a total of 1100 opportunities per group per study period.

To describe the study outcomes, we present overall and Moment 1 hand hygiene compliance for each group and study period and patient-level secondary outcomes as mean incidence per 1000 patients-days, both with 95% CI.

To assess the effect of the two interventions compared with control, we constructed generalised linear mixed-effects models with ward as a random effect to account for the clustered study design at the ward level. For hand hygiene compliance, the level of analysis was each hand hygiene opportunity, and we used generalised linear mixed-effects models with a logit link function. An interaction term between the study period and the study group was used to test the effect of the interventions in

each group and to assess whether the effect was different in intervention groups compared with the control group. We also assessed the intracluster correlation (95% CI). Hand hygiene compliance was also derived from the mixed-effects logistic regression model for each group at each study period. The 95% CI for hand hygiene compliance was obtained with simulations based on parameter estimates and their covariance matrix, taking the 2·5 and 97·5 percentile of these simulated proportions.

	Baseline period			Intervention period		
	Enhanced performance feedback plus patient participation	Enhanced performance feedback	Control	Enhanced performance feedback plus patient participation	Enhanced performance feedback	Control
Session-level characteristics						
n	164	165	146	297	331	264
Day						
Monday	56 (34%)	48 (29%)	44 (30%)	51 (17%)	53 (16%)	47 (18%)
Tuesday	27 (16%)	34 (21%)	32 (22%)	72 (24%)	66 (20%)	44 (17%)
Wednesday	33 (20%)	28 (17%)	27 (18%)	54 (18%)	66 (20%)	70 (27%)
Thursday	7 (4%)	10 (6%)	5 (3%)	27 (9%)	29 (9%)	35 (13%)
Friday	41 (25%)	45 (27%)	38 (26%)	93 (31%)	117 (35%)	68 (26%)
Time of day						
Morning	119 (73%)	136 (82%)	131 (90%)	246 (83%)	286 (86%)	230 (87%)
Afternoon	45 (27%)	29 (18%)	15 (10%)	51 (17%)	45 (14%)	34 (13%)
Season						
Spring	62 (38%)	71 (43%)	58 (40%)	85 (29%)	95 (29%)	64 (24%)
Summer	28 (17%)	30 (18%)	34 (23%)	73 (25%)	68 (21%)	54 (20%)
Autumn	46 (28%)	36 (22%)	31 (21%)	81 (27%)	94 (28%)	78 (30%)
Winter	28 (17%)	28 (17%)	23 (16%)	58 (20%)	74 (22%)	68 (26%)
Activity index*						
≤20	46 (28%)	47 (28%)	41 (28%)	80 (27%)	118 (36%)	82 (31%)
21–40	93 (57%)	93 (56%)	80 (55%)	177 (60%)	168 (51%)	148 (56%)
41–60	21 (13%)	21 (13%)	23 (16%)	37 (12%)	38 (11%)	28 (11%)
>60	4 (2%)	4 (2%)	2 (1%)	3 (1%)	7 (2%)	6 (2%)
Opportunity-level characteristics						
n	1594	1629	1430	2767	2920	2239
WHO Moment						
1—before touching a patient	432 (27%)	494 (30%)	424 (30%)	743 (27%)	750 (26%)	604 (27%)
2—before clean or aseptic procedure	198 (12%)	168 (10%)	170 (12%)	285 (10%)	341 (12%)	248 (11%)
3—after body fluid exposure risk	182 (11%)	133 (8%)	165 (12%)	244 (9%)	236 (8%)	210 (9%)
4—after touching a patient	520 (33%)	570 (35%)	478 (33%)	980 (35%)	1056 (36%)	775 (35%)
5—after touching patient surroundings	262 (16%)	264 (16%)	193 (13%)	515 (19%)	537 (18%)	402 (18%)
Profession						
Nurses	802 (50%)	901 (55%)	807 (56%)	1532 (55%)	1806 (62%)	1273 (57%)
Doctors	371 (23%)	363 (22%)	271 (19%)	565 (20%)	376 (13%)	298 (13%)
Nursing assistants	365 (23%)	311 (19%)	310 (22%)	605 (22%)	650 (22%)	597 (27%)
Other	56 (4%)	54 (3%)	42 (3%)	65 (2%)	88 (3%)	71 (3%)
Action						
None	570 (36%)	589 (36%)	495 (35%)	660 (24%)	760 (26%)	608 (27%)
Alcohol-based handrub	1014 (64%)	1026 (63%)	915 (64%)	2075 (75%)	2127 (73%)	1610 (72%)
Soap and water	9 (1%)	11 (1%)	14 (1%)	29 (1%)	30 (1%)	17 (1%)
Both	1 (<1%)	3 (<1%)	6 (<1%)	3 (<1%)	3 (<1%)	4 (<1%)

Data are n (%), unless indicated otherwise. *Number of hand hygiene opportunities per hour of care.

Table 1: **Hand hygiene observations, by study group and period**

We used a linear mixed-effects model to test whether alcohol-based handrub use (after logarithmic transformation) varied by time (months) between the intervention and baseline periods (time variable set at zero for all baseline months and from 1 to 24 for each intervention month) in the study groups by using an interaction term between the group and the time of the intervention period (in months). We also tested whether the change in alcohol-based handrub requisition started before the intervention period by using a continuous time variable centred on the start of the intervention period. A similar approach was used to compare monthly change during the follow-up period, adjusting for previous change in alcohol-based handrub requisition.

For patient-level (ie, secondary) outcomes, incidence rate ratios were calculated to compare month-specific infection rates between the intervention and baseline periods, using a mixed-effects Poisson regression model with an interaction term between study periods and groups as described previously.

All p values were based on two-tailed tests, with significance defined as p less than 0·05. Analyses were done with Stata IC version 13.0 (StataCorp, College Station, TX, USA).

This trial is registered with the ISRCTN registry, number ISRCTN43599478.

	Number of hand hygiene actions	Number of hand hygiene opportunities	Mean compliance* (95% CI)	Absolute change*† (95% CI)	Odds ratio* (95% CI)
Overall hand hygiene					
Control					
Baseline	935	1430	66% (62–70)	..	1
Intervention	1631	2239	73% (70–77)	7% (4–10)	1·41 (1·21–1·63)
Follow-up	631	949	70% (66–75)	4% (0–8)	1·21 (1·00–1·47)
Enhanced performance feedback					
Baseline	1040	1629	65% (62–69)	..	1
Intervention	2160	2920	75% (72–77)	10% (7–13)	1·61 (1·41–1·84)
Follow-up	1356	1956	72% (68–75)	7% (4–10)	1·38 (1·19–1·60)
Enhanced performance feedback plus patient participation					
Baseline	1024	1594	66% (62–70)	..	1
Intervention	2107	2767	77% (74–80)	11% (8–14)	1·73 (1·51–1·98)
Follow-up	1485	2100	72% (69–76)	6% (4–10)	1·36 (1·18–1·57)
WHO Moment 1—before patient contact					
Control					
Baseline	216	424	54% (46–61)	..	1
Intervention	355	604	61% (54–67)	7% (1–14)	1·34 (1·03–1·75)
Follow-up	135	236	63% (54–71)	9% (0–17)	1·45 (1·02–2·06)
Enhanced performance feedback					
Baseline	244	494	51% (44–58)	..	1
Intervention	473	750	65% (59–71)	14% (8–20)	1·81 (1·43–2·31)
Follow-up	301	481	65% (58–71)	14% (9–20)	1·79 (1·35–2·37)
Enhanced performance feedback plus patient participation					
Baseline	199	432	48% (41–55)	..	1
Intervention	470	743	65% (59–70)	17% (11–23)	1·99 (1·55–2·55)
Follow-up	325	543	62% (56–68)	14% (7–20)	1·75 (1·34–2·30)

*Obtained from a generalised linear mixed-effects model with ward included as a random effect. †Absolute percentage point difference between baseline and intervention period, and from baseline to follow-up.

Table 2: **Hand hygiene compliance overall and with WHO Moment 1**

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, writing of the report, or the decision to submit the paper for publication. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between Jan 1 and March 31, 2009, we screened 112 wards and excluded 45 that were considered inappropriate for patient participation (figure 1). Data were collected from all 67 participating wards during the baseline period (April 1, 2009, to June 30, 2010). On May 19, 2010, we randomly assigned 22 wards to receive enhanced performance feedback plus patient participation, 24 to receive enhanced performance feedback, and 21 to receive standard multimodal promotion, of which one medical acute care ward became a high-dependency unit during the baseline period and was therefore excluded from analysis. 12 579 hand hygiene opportunities were recorded during 1367 observation sessions in the baseline period and the intervention period (July 1, 2010, to June 30, 2012; table 1). Inter-observer agreement between the 12 infection control nurses who did the direct observations was 0·94 (range 0·83–1·00), and a median of three (IQR 2–4) health-care workers were observed per session.

Overall hand hygiene compliance increased in the intervention period compared with the baseline period in all three groups (p<0·0001 for all groups; table 2). The absolute difference in compliance attributable to the interventions was 3 percentage points (95% CI 0–7; p=0·19) for enhanced performance feedback and 4 percentage points (1–8; p=0·048) for the combined intervention. The absolute difference in compliance between the two intervention groups was not significant (p=0·46). The intracluster correlation was very low (0·027, 95% CI 0·018–0·042). For overall hand hygiene compliance stratified by health-care worker profession and indication, see appendix pp 4–7.

Hand hygiene at WHO Moment 1 (ie, before patient contact) increased significantly between the baseline and intervention periods for all three groups (p<0·0001 for the two intervention groups and p=0·03 for the control group). The absolute difference attributable to the interventions was 7 percentage points (95% CI 0–16; p=0·099) for enhanced performance feedback and 10 percentage points (0–18; p=0·035) for the combined intervention. The absolute difference in Moment 1 compliance between the two intervention groups was not significant (p=0·61). The intracluster correlation was again very low (0·064, 95% CI 0·041–0·097). For Moment 1 hand

hygiene compliance stratified by health-care worker profession, see appendix p 4.

Mean monthly requisition of alcohol-based handrub per 1000 patient-days changed from 31·8 L (SD 7·4) in the baseline period to 27·8 L (2·6) in the intervention period in the control group, from 30·4 L (4·6) to 29·8 L (2·9) in the enhanced performance feedback group, and from 27·9 L (5·1) to 30·5 L (2·8) in the enhanced performance feedback plus patient participation group. Monthly alcohol-based handrub requisition did not change considerably from baseline to the intervention period (p=0·54; table 3). However, during the baseline period, requisition peaked in 2009 because of the pandemic influenza A (H1N1) epidemic (appendix p 13). During the intervention period, a monthly increase in alcohol-based handrub requisition (roughly 1 L per 1000 patient-days) was seen only in the enhanced performance feedback plus patient participation group.

Patient-level outcomes are summarised in table 4. For causative organisms of primary bloodstream infections see appendix p 8.

In the intervention period, feedback cards were provided to 331 (36%) of 908 audited health-care workers in the enhanced performance feedback group and to 280 (32%) of 884 audited health-care workers in the enhanced performance feedback plus patient participation group. During the intervention period, wards in the combined intervention group distributed a median of 33 (IQR 21–47) welcome packs per 100 admissions. During audits every 3 months, 209 (38%, 95% CI 34–42) of 553 audited health-care workers in the enhanced performance feedback group and 213 (68%, 63–74) of 311 in the enhanced performance feedback plus patient participation group were aware of their intervention allocation (appendix p 9). Nurses and nursing assistants were more frequently aware of the intervention than were physicians (appendix p 9). Observers witnessed no episodes of patients reminding health-care workers to perform hand hygiene during hand hygiene opportunities before patient contact.

During the 2-year follow-up period (Jan 1, 2013, to Dec 31, 2014), 5005 hand hygiene opportunities were recorded during 507 sessions, with a median of three (IQR 2–4) health-care workers per session (figure 2). Hand hygiene compliance declined in the follow-up period compared with the intervention period in the enhanced performance feedback group and the combined intervention group, but remained higher than baseline in all groups (table 2). Hand hygiene compliance at Moment 1 (ie, before touching a patient) also remained significantly higher in the follow-up period than during baseline in all three groups, and no significant difference was seen between the follow-up and intervention periods in the three groups (table 2).

Requisition of alcohol-based handrub continued to increase during the follow-up period in all three groups (appendix p 13). A monthly increase in alcohol-based handrub requisition was seen in the control group (5·8 mL per 1000 patient-days; p=0·02) and in the enhanced performance feedback plus patient participation group (1·1 mL per 1000 patient-days; p<0·0001); such requisition was slightly increased in the enhanced performance feedback group (4·3 mL per 1000 patient-days per month; p=0·06). This increase was equivalent to roughly 1·01 L per 1000 patient-days per month in the enhanced performance feedback plus patient participation group and 1·00 L per 1000 patient-days in the control group.

	Coefficient (95% CI), L per 1000 patient-days	p value
Change in monthly requisition of alcohol-based handrub during the intervention period		
Control	0·0003 (–0·0064 to 0·0070)	0·93
Enhanced performance feedback	0·0025 (–0·0040 to 0·0091)	0·45
Enhanced performance feedback plus patient participation	0·0079 (0·00013 to 0·0140)	0·02
Change in monthly requisition of alcohol-based handrub explained by the interventions		
Enhanced performance feedback alone *vs* control	0·0022 (–0·0025 to 0·0070)	0·35
Enhanced performance feedback plus patient participation *vs* control	0·0076 (0·0028 to 0·0123)	0·002
Patient participation *vs* enhanced performance feedback	0·0053 (0·0008 to 0·0099)	0·02
Change in monthly requisition of alcohol-based handrub between baseline and intervention periods*	–0·0014 (–0·0057 to 0·003)	0·54

*Centred on the start of the intervention period.

Table 3: **Effect of the intervention on monthly requisition of alcohol-based handrub**

Discussion

In this cluster randomised controlled trial on the effect of two additional interventions in the context of long-standing multimodal hand hygiene promotion, we found an overall increase in hand hygiene compliance of health-care workers from 65% to 74%. Although this increase between the baseline and intervention periods was significantly larger in wards exposed to both enhanced performance feedback and patient participation than in the control wards, the improvement attributable to the combined intervention did not reach our a-priori threshold for clinical significance (15 percentage-point increase) because hand hygiene compliance also increased substantially in the control group. Hand hygiene compliance remained higher than baseline in all three groups during a 2-year follow-up period after the interventions ended.

The most important deviation from our pre-study expectations was the significant increase in hand hygiene compliance in the control wards. We identified two potential explanations. First, although we attempted to minimise cross-contamination between study groups by using a cluster randomised design, such cross-contamination was difficult to avoid because of the movement of health-care workers between wards (particularly physicians, allied health-care professionals, and pool nurses) and the clustering of multiple wards by

	Enhanced performance feedback plus patient participation				Enhanced performance feedback				Control				p value‡
	Number of events	Patient-days	Mean rate (95% CI)*	IRR (95% CI)†	Number of events	Patient-days	Mean rate (95% CI)*	IRR (95% CI)†	Number of events	Patient-days	Mean rate (95% CI)*	IRR (95% CI)†	
Acquisition of multidrug-resistant organisms													
MRSA													
Baseline	201	152 861	1·3 (1·1–1·5)	..	180	162 266	1·1 (1·0–1·3)	..	150	131 509	1·1 (1·0–1·3)	..	..
Intervention	259	250 679	1·0 (0·9–1·2)	0·79 (0·66–0·95)	243	262 729	0·9 (0·8–1·0)	0·82 (0·67–0·99)	223	209 523	1·1 (0·9–1·2)	0·92 (0·75–1·13)	0·56
ESBL-PE													
Baseline	67	152 861	0·4 (0·3–0·6)	..	46	162 266	0·3 (0·2–0·4)	..	49	131 509	0·4 (0·3–0·5)	..	..
Intervention	123	250 679	0·5 (0·4–0·6)	1·13 (0·84–1·52)	117	262 729	0·4 (0·4–0·5)	1·56 (1·11–2·19)	95	209 523	0·5 (0·4–0·6)	1·21 (0·86–1·71)	0·36
Hospital-acquired infections													
Primary bloodstream infection													
Baseline	86	152 861	0·6 (0·5–0·7)	..	81	162 266	0·5 (0·4–0·6)	..	68	131 509	0·5 (0·4–0·7)	..	..
Intervention	102	250 679	0·4 (0·3–0·5)	0·71 (0·54–0·95)	141	262 729	0·5 (0·5–0·6)	1·02 (0·78–1·34)	63	209 523	0·3 (0·2–0·4)	0·57 (0·40–0·80)	0·02
Secondary bloodstream infection													
Baseline	86	152 861	0·6 (0·5–0·7)	..	76	162 266	0·5 (0·4–0·6)	..	62	131 509	0·5 (0·4–0·6)	..	..
Intervention	102	250 679	0·4 (0·3–0·5)	0·98 (0·73–1·31)	113	262 729	0·4 (0·4–0·5)	0·91 (0·68–1·22)	100	209 523	0·5 (0·4–0·6)	1·00 (0·73–1·38)	0·90
Period prevalence													
Baseline	55	718	7·66 (5·7–9·6)	..	58	768	7·6 (5·8–9·7)	..	38	612	6·2 (4·3–8·1)	..	..
Intervention	196	2822	6·9 (6·0–7·9)	0·91 (0·68–1·23)	220	2770	7·9 (7·0–9·0)	1·05 (0·78–1·40)	191	2375	8·0 (7·0–9·2)	1·33 (0·94–1·88)	0·28
Clinical isolates													
MRSA													
Baseline	85	152 861	0·6 (0·4–0·7)	..	81	162 266	0·5 (0·4–0·6)	..	102	131 509	0·8 (0·6–0·9)	..	..
Intervention	132	250 679	0·5 (0·4–0·6)	0·95 (0·72–1·24)	111	262 729	0·4 (0·3–0·5)	0·82 (0·62–1·10)	100	209 523	0·5 (0·4–0·6)	0·63 (0·48–0·83)	0·11
ESBL-PE (*Escherichia coli*)													
Baseline	42	152 861	0·3 (0·2–0·4)	..	29	162 266	0·2 (0·1–0·3)	..	29	131 509	0·2 (0·1–0·3)	..	..
Intervention	55	250 679	0·2 (0·2–0·3)	0·80 (0·54–1·20)	72	262 729	0·3 (0·2–0·3)	1·53 (0·99–2·35)	67	209 523	0·3 (0·2–0·4)	1·45 (0·94–2·24)	0·06
ESBL-PE (non-*E coli*)													
Baseline	14	152 861	0·1 (0·1–0·2)	..	14	162 266	0·1 (0·0–0·1)	..	14	131 509	0·1 (0·1–0·2)	..	..
Intervention	32	250 679	0·1 (0·1–0·2)	1·39 (0·74–2·60)	23	262 729	0·1 (0·1–0·1)	1·02 (0·52–1·98)	23	209 523	0·1 (0·1–0·2)	1·03 (0·53–1·99)	0·75
Clostridium difficile													
Baseline	28	152 861	0·2 (0·1–0·3)	..	26	162 266	0·2 (0·1–0·2)	..	48	131 509	0·4 (0·3–0·5)	..	..
Intervention	98	250 679	0·4 (0·3–0·5)	2·11 (1·39–3·22)	93	262 729	0·3 (0·3–0·4)	2·14 (1·39–3·31)	78	209 523	0·4 (0·3–0·5)	1·01 (0·71–1·45)	0·01

IRR=incidence rate ratio. MRSA=meticillin-resistant *Staphylococcus aureus*. ESBL-PE=extended-spectrum β-lactamase-producing Enterobacteriaceae. *Per 1000 patient-days, except for prevalence of hospital-acquired infections, where units are per 100 patients observed. †From mixed-effects regression model, accounting for ward-level clustering. ‡From mixed-effects regression model, testing the null hypothesis that the change in outcome rate from the baseline period to the intervention period was the same in all three study groups.

Table 4: **Patient-level outcomes**

shared institutional leadership. Second, exclusion from intervention groups motivated some control wards to develop their own hand hygiene initiatives, including patient participation. Although this so-called study effect in the control group was a success from a patient safety perspective, it undermined the study design. An alternative would have been a stepped-wedge design. However, we reasoned that such a design would not have prevented contamination but would have complicated implementation and data analysis and interpretation, and would also have required a longer intervention period. For these reasons, we considered a simple cluster randomised design to be preferable.

We sought to test the effectiveness of patient participation, which was a challenging intervention involving culture change. The feasibility and ethics of

inviting patients, who are in a position of vulnerability, to remind health-care workers to perform hand hygiene have been questioned and the potential negative effects on health-care worker–patient relationship flagged.[21] Results from a previous patient survey[22] at our institution identified an explicit invitation from health-care workers to ask about hand hygiene as a key enabler, so we incorporated this invitation into our intervention. We expected that participation of a small number of patients could have a disproportionately large effect, as shown by a statewide hand hygiene campaign in Australia,[23] in which 392 (62%) of 629 health-care workers reported enquiries from patients and visitors despite only 106 (27%) of 397 patients and visitors expressing a willingness to do so. Moreover, we hypothesised that patient participation could improve patient care through several ways beyond explicit patient reminders: first, teaching patients about hand hygiene would raise awareness and a sense of responsibility in health-care workers; second, potential patient reminders would increase hand hygiene compliance of health-care workers through creating a social norm; third, improved hand hygiene of patients could reduce cross-transmission; and fourth, facilitating a dialogue between health-care workers and patients about patient safety would result in other positive behaviour changes.

Results of patient-level outcomes should be interpreted with caution. Our sample size estimation was based on the primary outcome (hand hygiene compliance) only. Moreover, hand hygiene compliance also increased in the control wards during the intervention period. In view of the large number of secondary outcomes (and therefore statistical tests), the low observed infection and colonisation rates, and the high baseline level of hand hygiene compliance and relatively modest difference in the magnitude of change in compliance between the three study groups, we preferred not to interpret observed differences in infection and colonisation rates. The increase in *C difficile* tests between study periods was likely to result from a change in test method from cell culture cytotoxicity assay to PCR shortly before the start of the intervention period.

Although this trial expands on a substantial body of previous work regarding performance feedback and patient participation for the promotion of hand hygiene in health care,[3,4,10] we are aware that few randomised trials have been done. Mertz and colleagues[24] did a cluster randomised controlled trial in three hospitals, with 15 wards allocated to performance feedback, small-group teaching seminars, and posters (intervention group), and 15 wards to usual practice (control group). In the 11-month intervention phase, compliance was modestly higher in the intervention group (48% [3812/7901]) than in the control group (43% [3205/7526]; p<0·001). Huis and colleagues[25] did a cluster randomised controlled trial targeting nurses, with 37 wards randomised to a strategy including alcohol-based handrub availability,

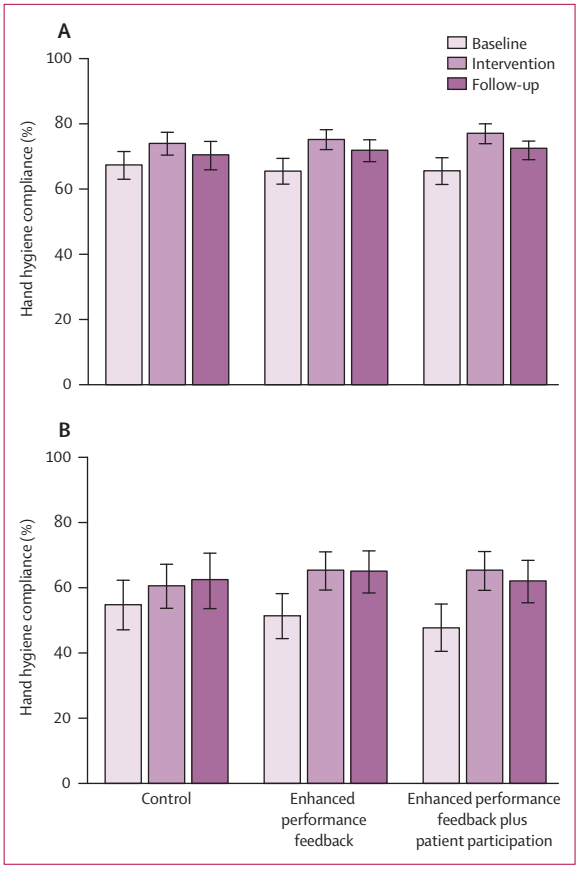

Figure 2: **Overall hand hygiene compliance (A) and hand hygiene compliance before touching a patient (WHO Moment 1; B)**
Error bars indicate 95% CIs.

education, reminders, and feedback (control group) and 30 wards to the strategy plus concurrent social influence and leadership activities (intervention group). Improvement in the intervention group (from 20% to 53%) was greater than that in the control group (from 23% to 42%; odds ratio [OR] 1·64, 95% CI 1·33–2·02). Fuller and colleagues[26] did a stepped-wedge cluster randomised controlled trial to assess the effect of performance feedback coupled with personalised action planning performance in 16 hospitals. Hand hygiene compliance improved in intensive therapy units (OR 1·44, 95% CI 1·18–1·76; equivalent to a 7–9 percentage-point increase) but not in acute geriatric wards (OR 1·06, 95% CI 0·87–1·27; equivalent to a non-significant 1 percentage-point increase). None of these trials monitored hand hygiene compliance higher than 50% with the WHO Five Moments, thus limiting data comparison. However, a consistent finding is that improvement in compliance in randomised trials of hand hygiene interventions is modest compared with that in quasi-experimental studies.

Surveyed patients expressed an appreciation for the importance of hand hygiene and a willingness to remind health-care workers to perform hand hygiene if requested

to do so.[27,28] A potentially beneficial effect of improved hand hygiene practices in patients has also been suggested.[29] Hand hygiene of health-care workers increased significantly in a quasi-experimental study of patient participation (n=98).[30] Using a retrospective before-and-after design, Gagne and colleagues[31] showed a 51% decrease in the rate of health-care-associated MRSA infections with the implementation of a programme promoting hand hygiene of patients and visitors.

The hand hygiene promotion campaign developed at University of Geneva Hospitals was used as the model for the WHO Multimodal Hand Hygiene Promotion Strategy, and hospitals worldwide have therefore implemented similar programmes with demonstrated impact.[5,7] Findings from a network meta-analysis[7] confirm the key role of the WHO multimodal approach and emphasised the need for evidence regarding additional promotional strategies. The fact that many hospitals worldwide have implemented the same multimodal strategy used during the baseline period of this trial suggests that our findings might be generalisable to other centres, which is a particular strength of this trial. However, local cultural and social norms are likely to affect the acceptance of patient participation programmes and, to a lesser extent, performance feedback. The unique and long-standing focus on hand hygiene at University of Geneva Hospitals might also have affected the effectiveness of new interventions, and replication elsewhere is therefore required. Finally, our findings cannot necessarily be generalised to night and weekend staff, since hand hygiene observations occurred on weekday mornings and afternoons.

This study has limitations. First, hand hygiene auditors could not be masked from ward allocation, and we therefore could not exclude information bias. We addressed this issue by using validated auditors and a standardised audit tool, and by collecting alcohol-based handrub requisition data as a corroborating measure. Second, although direct observation is considered the standard method to assess hand hygiene compliance, its limitations include the fact that only a small proportion of total activity is sampled and the possibility of inducing improved compliance during the period of observation (ie, the Hawthorne effect). Third, our definition of hospital pathogen acquisition did not require admission screening, which could have resulted in misclassification of some community acquisitions as nosocomial. Finally, we did not include intensive care and high-dependency wards and paediatric, psychiatric, palliative care, and psychogeriatric wards in this trial because patient participation, as formulated in our trial, was either unfeasible or inappropriate in these settings. Thus, some hospital settings with a high burden of health-care-associated infections were excluded.

To conclude, hand hygiene compliance improved hospital-wide after the introduction of enhanced performance feedback with or without patient participation. This improvement was partly sustained during a 2-year follow-up period after the specific study intervention ended. The fact that compliance improved in all study groups, including the control group, meant that we were unable to detect a clinically significant effect for either intervention. However, we postulate that the hospital-wide changes were attributable to the intervention, and contamination and study effect were seen in the control group. Therefore, further investigation of these interventions with a different study design is warranted.

Contributors

All authors designed the study. AJS and ST obtained the data. AG-A did the statistical analysis. AJS, HS, AG-A, WZ, and DP analysed and interpreted the data. AJS, HS, and AG-A drafted the report. All authors critically reviewed the report for important intellectual content and approved the final version.

Declaration of interests

We declare no competing interests.

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