MAJOR ARTICLE

The Impact of Gown-Use Requirement on Hand Hygiene Compliance

Yoav Golan,[1] Shira Doron,[1] John Griffith,[2] Hesham El Gamal,[3] Maged Tanios,[3] Keri Blunt,[1] Laurie Barefoot,[1] Judy Bloom,[4] Katelyn Gamson,[1] Laura K. Snydman,[1] Karen Hansjosten,[1] Eldad Elnekave,[1] Stanley A. Nasraway,[5] and David R. Snydman[1]

Divisions of [1]Geographic Medicine and Infectious Diseases, [2]Clinical Care Research-Biostatistics, [3]Critical Care and Pulmonary Medicine, [4]Transplant Surgery, and [5]Surgical Intensive Care Unit, Departments of Medicine and Surgery, Tufts–New England Medical Center and Tufts University School of Medicine, Boston, Massachusetts

Background. Hand hygiene compliance remains low, despite its effectiveness in preventing infections. Gowns are routinely used to reduce dissemination of organisms within hospitals. Use of gowns is time consuming and costly, and their effectiveness, compared with that of hand hygiene alone, is debated. Among the arguments supporting a gown-use requirement is the potential to boost awareness of infection control, leading to improved hand hygiene compliance.

Methods. Hand hygiene compliance was recorded in a 14-month crossover trial comparing compliance at 2 intensive care units during periods with and without a gown-use requirement.

Results. During 170 h of observation, 1619 hand hygiene opportunities were recorded. Compliance was 10% before care was given and 36% after care was given. Compliance with glove and gown use was 62% and 63%, respectively. After-care hand hygiene compliance for nurses, physicians, and therapists was 40%, 38%, and 22%, respectively. Compliance after patient contact, body fluid contact, and other in-room activity was 42%, 48%, and 22%, respectively. For periods with and without a gown-use requirement, overall after-care compliance (37% vs. 34%) and rates by personnel and activity type were similar. In the subgroup of patients on contact precautions, hand hygiene compliance during the period with a gown-use requirement versus the period without a gown-use requirement was 11% versus 10% ($P = .85$) before care was given and 45% versus 39% ($P = .09$) after care was given. In this subgroup, after adjustment for type of in-room activity, medical personnel, intensive care unit, and observer, the predicted after-care hand hygiene compliance during periods with and without a gown-use requirement was 48% versus 41% ($P = .02$).

Conclusions. The hypothesis that a gown-use requirement might improve hand hygiene compliance in the intensive care unit could not be confirmed. In the subgroup of patients on contact precautions, improvement in hand hygiene compliance associated with the gown-use requirement was small and did not affect precare rates.

Compliance with hand hygiene requirements can prevent many cases of health care–associated infections that result in substantial morbidity, mortality, and increased cost of care [1–4]. Yet rates of compliance with hand hygiene remain low (30%–60%) in most hospitals [2, 3, 5–10]. According to the recommendations of the Centers for Disease Control and Prevention, gowns are commonly used as part of contact precautions [11]. Two recent studies suggested that gowns are effective barriers, decreasing dissemination of vancomycin-resistant *Enterococcus* (VRE) in an intensive care unit (ICU) [12, 13]. The use of gowns is costly and time consuming, and, as a barrier precaution, gowns were found to be not cost-effective by several studies [14–16]. The practice of contact precautions consists of hand hygiene and the use of gloves and gowns. Gown use is time consuming and interferes with productivity and might serve as a disincentive for health care personnel to enter a room [17], which can have a negative impact on patient care. This phenomenon is especially likely to exist in the ICU, where contact precautions

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Reprints or correspondence: Yoav Golan, Div. of Geographic Medicine and Infectious Diseases, Tufts–New England Medical Center, 750 Washington St., Box 041, Boston, MA 02111 (ygolan@tufts-nemc.org).

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are required for a larger proportion of patients and the workload is particularly high. Indeed, a recent study showed that attending physicians were approximately one-half as likely to examine patients on contact precautions, compared with patients off contact precautions [18]. A second study showed that patients on contact precautions experienced more preventable adverse events, expressed greater dissatisfaction with their treatment, and had less documented care, compared with control subjects [17].

It has been argued that even if gown use is ineffective as a barrier, it might reduce bacterial dissemination by increasing awareness of other infection control measures, intensifying infection control adherence within a ward as a whole [19–21]. Therefore, the potential of gown use to increase compliance with hand hygiene has been an argument to support its use. This potential has not been studied in a trial, and data from an observational study failed to support it [22]. We tested the hypothesis that a gown-use requirement improves compliance with hand hygiene.

METHODS

Study design, setting, and hypotheses. We conducted a crossover design, interventional study in 2 ICUs—a medical ICU and a surgical ICU—at Tufts–New England Medical Center (Boston, MA), a tertiary care, 421-bed, university-affiliated hospital. The intervention consisted of eliminating the gown-use requirement from the contact precautions protocol for patients infected or colonized with VRE or methicillin-resistant *Staphylococcus aureus* (MRSA) (the requirement for gown use for patients infected with *Clostridium difficile* and other drug-resistant organisms was not changed). The trial had 3 phases. Phase 1 was a 2-month run-in phase during which gown use was required in both units (February and March 2002). In phase 2, the requirement for gown use was discontinued in the surgical ICU and continued in the medical ICU (April 2002–September 2002). In phase 3, the requirement for gown use was discontinued in the medical ICU and reintroduced in the surgical ICU (October 2002–March 2003). Each ICU has 10 private patient rooms. Each room contains a sink and an alcohol-based solution dispenser that is mounted near the room's entrance. Contact precautions consisting of a sign on the door, performance of hand hygiene before and after care was given, gown and glove use, and use of patient-dedicated equipment are implemented in our hospital for all patients who are colonized with MRSA and VRE. The institutional review board approved the study protocol, and the need for informed consent was waived. Our primary goal was to explore the effect of a gown-use requirement on hand hygiene compliance rates. A secondary aim was to explore this effect in the subgroup of patients on contact precautions.

Sample-size calculation. The number of hand hygiene opportunities per intervention arm necessary to demonstrate a 5% difference in hand hygiene compliance was calculated to be 323 ($\alpha = 0.05$; $\beta = 80\%$).

Observations. Ten observers performed 1-h observations of randomly chosen rooms during randomly chosen days and hours in both units. Observers consisted of epidemiology nurses, physicians, and medical students, all of whom were instructed in the method of observation and data recording to ensure consistency and to decrease interobserver variability. Two to three adjacent rooms were observed during each session. Unit directors and nurse managers were notified about the study, but other medical personnel were unaware of the purpose of the observations, and measured compliance rates were not disclosed.

Compliance data were recorded on a previously validated data collection form that was modified for the purpose of this study [7]. Data collected included ICU type, room number, date, hour, precaution status, type of medical personnel, type of in-room activity, and compliance with hand hygiene and glove and gown use. The identity of personnel was not documented. Opportunities for hand hygiene were defined according to published guidelines [3]. In general, hand hygiene was considered indicated before and after contact with patients, their body fluids, or devices inside the patients' rooms. Execution of hand hygiene was defined as any attempt to clean the hands with either soap and water or an alcohol-based antiseptic solution immediately before or after contact. Activity outside the room between patient contact and hand hygiene was regarded as noncompliance.

Compliance rates were calculated as the number of executions divided by the number of opportunities. Rates were calculated for 3 different populations (nurses, physicians, and other types of medical personnel that mostly consisted of therapists) and 3 types of activities (patient contact, body fluid contact, and other activities). When both patient contact and body fluid contact occurred, the activity was considered to be a body fluid contact.

Analyses. The outcome variable for all analyses was compliance with hand hygiene, modeled as a binary variable. Explanatory variables included gown-use requirement status of the unit (intervention, i.e., gown-use was not required; control, i.e., gown-use was required), patient's contact precautions status ("on" or "off" precautions), type of ICU, type of personnel, type of in-room activity, and observer. The χ^2 test was used for univariate analyses. Two multivariate logistic regression models were used: a stratified model (by contact precautions status) and a nonstratified model. All explanatory variables were forced into the multivariate models. A P value of $<.05$ was determined to be statistically significant. A logistic regression

Table 1. Number of opportunities for hand hygiene stratified by gown-use requirement.

Variable	No. (%) of opportunities during 16 unit months in which gown use was required[a,b] (n = 998)	No. (%) of opportunities during 12 unit months in which gown use was not required[c] (n = 621)
Intensive care unit		
Medical	531 (53)	353 (57)
Surgical	467 (47)	262 (43)
Contact precautions		
Required	498 (50)	332 (53)
Not required	500 (50)	289 (47)
Medical personnel		
Nurses	590 (59)	375 (60)
Physicians	161 (16)	112 (18)
Other[d]	247 (25)	134 (22)
In-room activity		
Patient contact	457 (46)	308 (50)
Body fluid contact	148 (15)	69 (11)
Other	391 (39)	244 (39)

[a] Gown use was required in the surgical and medical intensive care units during February and March 2002, in the medical intensive care unit from April to September 2002, and in the surgical intensive care unit from October 2002 to March 2003.
[b] Data on in-room activity were missing for 2 hand hygiene opportunities.
[c] Data on type of intensive care unit were missing for 7 hand hygiene opportunities.
[d] Other types of medical personnel mostly consisted of respiratory therapists and technicians.

model was used to predict adjusted rates of hand hygiene compliance after care was given to patients on contact precautions. All analyses were performed using SAS software, version 8.1 (SAS Institute).

Approximately 100 health care providers participated in this study, and most were observed multiple times. Because some health care providers tend to execute hand hygiene more often than others, an individual's execution of hand hygiene can be predicted by his past compliance rates. As a result, each health care provider acts as a cluster, and dependence exists between observations made of his compliance. Ignoring such dependence could lead to underestimation of the standard error and result in a smaller P value, and thus lead to an overestimation of the statistical significance of the effect of a gown-use requirement on hand hygiene compliance. Because the identity of personnel observed in our study was not recorded, a full hierarchical analysis adjusting for medical staff–level clustering could not be conducted. Instead, we used sensitivity analysis to estimate the potential effect of clustering on the statistical significance of our results. First, we performed the analysis and ignored the effect of clustering. If the resulting P value was <.05, a threshold analysis was performed to investigate how large the clustering effect, represented as the inflation factor (IF), would have to be to render the P value nonsignificant and whether this degree of clustering is plausible. This IF is often approximated by the following: $IF = 1 + \rho(\overline{m} - 1)$, where ρ is the interclass correlation, or the proportion of the variance attributable to clustering, and m is the average sample size per individual.

RESULTS

In 170 h between February 2002 and March 2003, a total of 1619 opportunities for hand hygiene were observed, as shown in table 1. A larger proportion of the observations were performed during the control phase than during the intervention phase. More than one-half of the observations were performed in the medical ICU. During both the intervention and control phases, in both units, nearly an equal number of observations were of interactions with patients on and off contact precautions. The majority of observations were of nurses, followed by physicians and other types of medical personnel. The largest proportion of observations was of patient contact. Approximately 60% of observations were of direct contact with patients or body fluids. Observations of different types of medical personnel and in-room activities were well balanced between the units and between the intervention and control phases.

Overall hand hygiene compliance rates were 10.1% before patient care and 35.6% after patient care (table 2). Only 5% of patient care episodes resulted in execution of hand hygiene

Table 2. Hand hygiene compliance rates before and after patient care.

Variable	Compliance before patient care	Compliance after patient care
Overall	10	35
Medical personnel		
Nurses	12	39
Physicians	8	38
Others[a]	8	22
In-room activity		
Patient contact	12	42
Body fluid contact	16	48
Other	5	22
Intensive care unit		
Medical	11	37
Surgical	9	35
Contact precautions		
Required	11	43
Not required	10	28

NOTE. Hand hygiene compliance appears as a percentage and was calculated as the number of hand hygiene executions/ the number of opportunities × 100.
[a] Other types of medical personnel mostly consisted of respiratory therapists and technicians.

both before and after care was given. Given the low before-care compliance rate, further analyses focused mostly on after-care compliance rates. Personnel types differed significantly in their compliance rates, with nurses having the best after-care rates (39.9%), followed by physicians (38.4%) and other medical personnel (22.3%). Compliance rates differed between in-room activity categories, being highest after body fluid contact (48%), followed by compliance after patient contact (42%) and other in-room activity (22%). Hand hygiene compliance was significantly better after care was given to patients on contact precautions were required than after care was given to patients off contact precautions (43% vs. 28%; $P < .001$) (table 3). This trend was found for encounters of all subgroups except that of other medical personnel types and after body fluid contact. Compliance rates before care was given to patients on contact precautions were as low as rates before care was given to patients off contact precautions (11% vs. 10%).

As presented in table 4, hand hygiene compliance did not differ between the intervention and control phases, except for 3 subgroups for whom hand hygiene compliance significantly decreased after use of gowns was no longer required for contact precautions: physicians, after caring for patients on contact precautions (39% compliance with a gown-use requirement [83 opportunities] vs. 57% compliance without a gown-use requirement [70 opportunities]; $P = .026$); any medical personnel, after exposure to body fluids of patients on contact precautions (39% [94 opportunities] vs. 59% [46 opportunities]; $P = .031$); and any medical personnel, after activity that did not include patient or body fluid contact in the rooms of patients off contact precautions (19% [201 opportunities] vs. 10% [127 opportunities]; $P = .031$).

The overall compliance with glove and gown use, when required, was 62% and 63%, respectively. Compliance with 1 of the 3 infection control measures monitored (hand hygiene, glove use, and gown use) was associated with higher rates of compliance with the other 2 measures. Among medical personnel who were compliant with hand hygiene, compared with personnel who were noncompliant with hand hygiene, rates of compliance with use of gloves (when it was required) were 85% versus 44% ($P < .001$), and rates of compliance with use of gowns (when required) were 81% versus 48% ($P < .001$). Among medical personnel who were compliant with glove use (when required), compared with personnel who were noncompliant with glove use, rates of compliance with hand hygiene were 56% versus 21% ($P < .001$), and rates of compliance with use of gowns (when required) were 87% versus 15% ($P < .001$). Among medical personnel who were compliant with gown use (when required), compared with personnel who were noncompliant with gown use, rates of compliance with hand hygiene were 61% versus 18% ($P < .001$), and rates of compliance with use of gloves were 92% versus 23% ($P < .001$). No hand hygiene or glove use was observed after treatment of patients on contact precautions in 36% of episodes. Compliance with glove use, when required, was higher during the intervention phase (57% vs. 66%; $P = .005$).

Multivariate analysis. Results of multivariate analyses are

Table 3. Hand hygiene compliance after patient care according to status of contact precautions.

Variable	Compliance while interacting with patients for whom contact precautions were required ($n = 830$)	Compliance while interacting with patients for whom contact precautions were not required ($n = 789$)	P
Overall	43	28	<.001
Intensive care unit			
Medical	41	32	.009
Surgical	47	26	<.001
Medical personnel			
Nurses	48	32	<.001
Physicians	48	26	<.001
Others[a]	26	18	.061
Type of in-room activity			
Patient contact	51	35	<.001
Body fluid contact	52	42	.160
Other	28	16	<.001

NOTE. Hand hygiene compliance appears as a percentage and was calculated as the number of hand hygiene executions/the number of opportunities × 100.

[a] Other types of medical personnel mostly consisted of respiratory therapists and technicians.

Table 4. Hand hygiene compliance according to gown-use requirement and status of contact precautions.

Variable, by time of hygiene opportunity	All Patients			Patients for whom contact precautions are required			Patients for whom contact precautions are not required		
	Gown required	Gown not required	*P*	Gown required	Gown not required	*P*	Gown required	Gown not required	*P*
Before care was given	10	11	.535	11	10	.846	9	11	.173
After care was given									
Overall	37	34	.324	45	39	.090	28	28	.935
Medical personnel									
Nurses	41	39	.598	50	46	.426	33	32	.866
Physicians	42	35	.257	57	39	.026	26	29	.729
Others[a]	23	20	.456	28	22	.304	18	18	.931
In-room activity									
Patient contact	43	45	.659	55	47	.140	33	41	.090
Body fluid contact	52	43	.241	59	39	.031	41	52	.355
Other	24	19	.165	28	28	.953	19	10	.027

NOTE. Hand hygiene compliance appears as a percentage and was calculated as the number of hand hygiene executions/the number of opportunities × 100.

[a] Other types of medical personnel mostly consisted of respiratory therapists and technicians.

presented in table 5. For the whole cohort, after adjustment for potential confounding introduced by in-room activity, type of medical personnel, type of unit, and observer, hand hygiene compliance before or after care was given was similar during intervention and control periods (OR for compliance before care was given, 0.81 [$P = .269$]; OR for compliance after care was given, 1.12 [$P = .369$]).

The association between contact precaution status and improved hand hygiene remained significant, despite adjustment for potential confounders, including gown status (OR, 2.38; $P < .001$). The predicted probability of hand hygiene compliance after care was given to patients on contact precautions was 42%, compared with 26% after care was given to patients off contact precautions.

In a subgroup analysis that included only patients on contact precautions, hand hygiene compliance after care was given, but not before care was given, was significantly higher during the period of control, compared with compliance during the intervention period (OR, 1.46; $P = .024$). The predicted probability of hand hygiene compliance was 48% during the control period versus 41% during the intervention period.

In a subgroup analysis that included only patients off contact precautions, compliance with hand hygiene was similar during the intervention and control phases both before and after care was given to patients off contact precautions.

The potential effect of clustering. In the primary analysis, because differences in hand hygiene compliance rates during phases of intervention and control were not statistically sig-

Table 5. Results of multivariate analyses: the association between the gown-use requirement and hand hygiene compliance adjusted for type of medical personnel, type of in-room activity, intensive care unit, and observer.

Variable, by patient class	OR (95% CI) for hand hygiene compliance when gowns required vs. not required	*P*
Overall		
Before care was given	0.81 (0.56–1.12)	.269
After care was given	1.12 (0.88–1.42)	.369
Patients for whom contact precautions were not required		
Before care was given	1.00 (0.58–1.75)	.989
After care was given	1.11 (0.76–1.63)	.582
Patients for whom contact precautions were required		
Before care was given	0.92 (0.54–1.57)	.734
After care was given	1.46 (1.05–2.04)	.024

nificant, no adjustment of clustering was needed (such adjustment would render the P value even less significant).

In the secondary analysis of the subset of patients on contact precautions, the adjusted association of a gown-use requirement with improved hand hygiene compliance was statistically significant ($P = .024$). An inflation factor of 1.3 would be necessary to reduce the level of association to $P = .05$. Given an average cluster size of 8, the corresponding interclass correlation would have to be 0.04. This would mean that 4% of the variance observed in the data is related to individual patterns of hand hygiene (i.e., a clustering effect), rather than to the circumstances (the requirement for gown use). On the basis of clinical knowledge and previous reports [10, 23], such a small degree of interclass correlation cannot be excluded, suggesting that the statistical association between hand hygiene compliance and gown use requirement in the subset of patients on contact precautions might be insignificant.

DISCUSSION

This is the first intervention trial evaluating the impact of a gown-use requirement on hand hygiene compliance. We found that rates of compliance were similar during the intervention and control periods, demonstrating that the use of gowns does not improve compliance with hand hygiene. In a subgroup analysis, we did find, however, that the requirement of gown use was associated with a small increase in the likelihood of hand hygiene compliance when treating patients on contact precautions (45% when gowns required vs. 39% when not required). This increase was observed only after patient care was given, and its statistical significance is doubtful, given the potential impact of clustering.

Hand hygiene compliance rates observed in our study were low and consistent with results of previous studies [2, 7, 24–26]. Similar to other reports, nurses in our study had the best compliance rates [10, 14, 27]. "Other" medical staff, who consisted mostly of respiratory therapists and technicians, performed poorly. Hand hygiene compliance rates also varied by the type of in-room activity. Rates after exposure to patients' body fluids were consistently better than rates after patient contact without body fluid contact or other in-room activities, confirming that medical personnel can identify a "high-risk" exposure. However, even exposure to such "high-risk" sources did not result in compliance rates >48%. Rates after an in-room activity not involving direct patient or body fluid contact were very low, possibly reflecting a belief that contamination of hands is unlikely to occur in this circumstance. Such a belief contrasts with results of several studies that have documented contamination of the ICU environment with pathogenic antibiotic-resistant bacteria and demonstrated the role of such contamination in the spread of pathogens within the ICU [28, 29]. Thus, the particularly low rate of compliance with hand hygiene after exposure to the ICU environment could further contribute to the dissemination of organisms in the ICU.

The markedly higher compliance rate observed after care was given to patients on contact precautions, compared with the compliance rate observed after care was given to patients off contact precautions, was observed during both the intervention and control periods. Such compliance would appear, therefore, to be independent of the intervention. These data suggest that health care personnel are more likely to adhere to infection control practices when contact is perceived to be a "high risk" for pathogen contamination. Among the possible reasons for such improved compliance might be knowledge that a particular patient is colonized with an antibiotic-resistant pathogen that might spread to other patients or to the employee himself or the formality of the requirement of practicing contact precautions, implying that intensified infection control is mandatory.

Hand hygiene compliance rates before care was given to patients were very low, presumably reflecting a widespread belief among medical staff that hand hygiene before care is given is not as important as it is after care. Such an approach could be justified only in an environment where after-care hand hygiene compliance is perfect. However, the rate of compliance after care was given that was observed in our study was imperfect, allowing potential spread of organisms.

Hand hygiene was not better during the period of gown-use requirement. Several reasons might account for this lack of association. Our data suggest that personnel who are noncompliant with gown use are less compliant with hand hygiene. For these personnel, the requirement for gown use would not be expected to have a positive impact on hand hygiene compliance. In circumstances when compliance with gown use is good, gown use might result in false reassurance that the appropriate measures have been taken, thereby undermining the importance of hand hygiene. Finally, there may be no effect of gown use on the general infection control attitude within a unit, because people might view each of the infection control requirements as separate entities rather than as a single concept.

This study's findings are limited in several ways. The absence of documentation of health care providers' identities resulted in the inability to optimally adjust for a potential clustering effect. Presumably, better adjustment would have only resulted in a decrease in statistical significance of our findings. Since the results of our primary analysis were not statistically significant, better adjustment for clustering would not have changed our conclusions. An additional potential weakness was the relatively large number of observers involved, which could have resulted in a lack of consistency in data recording. To address this potential inconsistency, each observer was assigned to observe in both units and during both the control and intervention phases. The large average number of observations

per observer (160 observations) allowed for appropriate adjustment for potential confounding introduced by observers. In the current study, we only included ICUs, thus our conclusions should only be generalized to this type of unit. This study evaluated the association between hand hygiene compliance and the gown-use component of contact precautions. The practice of contact precautions, as a whole, was shown to be effective in reducing dissemination of hospital pathogens and was not evaluated in this study [11, 30].

In conclusion, given the unclear role of gowns as a barrier precaution and our inability to show that gown-use requirement is associated with a substantial impact on hand hygiene compliance, we believe that further research to support the use of gowns as part of contact precautions is warranted. Furthermore, measures to increase hand hygiene compliance to the level observed among interactions with patients on contact precautions need to be understood and implemented.

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