Table B.20: Clostridioides *difficile*, Hand Hygiene–Single Studies

Note: Full references are available in the [Section 4.2 reference list](#Section4point2refs).

| Author, Year | Description of Patient Safety Practice | Study Design; Sample Size; Patient Population | Setting: | Outcomes: Benefits | Outcomes: Harms | Implementation Themes/Findings | Risk of Bias (High, Moderate, Low) | Comments |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Al-Tawfiq et al., 201830** | The Joint Commission Centre for Transforming Healthcare’s web-based Targeted Solutions Tool (TST) for improving hand hygiene; hand hygiene compliance | Trained unknown and known observers monitored compliance, and rates of hospital-acquired infections were tracked and correlated against the changes in hand hygiene compliance. In total, the secret observers recorded 5,669 hand hygiene observations; 4-month baseline; 1 year intervention period. | A 30-bed oncology/hematology inpatient unit and a 350-bed community hospital located in eastern Saudi Arabia | The compliance rate increased from 75.4% at baseline (May to August 2014) to 88.6% during the intervention (13 months) and the control periods (p<0.0001; not statistically significant). Reductions in healthcare-associated infection rates were recorded for *Clostridium difficile* infections from 7.95 (95% CI 0.8937 to 28.72) to 1.84 (95% CI 0.0241 to 10.26) infections per 10,000 patient-days (p=0.23). |  | The top contributing factors for noncompliance were improper use of gloves, hands full of supplies or medications, and frequent entry or exit in isolation areas. Researchers concluded that the application of TST allowed healthcare organizations to improve hand hygiene compliance and to identify the factors contributing to noncompliance. An action plan was developed to decrease improper glove use through education and focusing particularly on the primary noncompliant groups. | Low/ moderate—potential for Hawthorne effect; part of an overall quality improvement project. Single site, small. | The researchers identified obstacles to hand hygiene such as inappropriate use of gloves, particularly within the house-keeping department. |
| **Edmonds et al., 20138** | Washing with plain soap and water | Pre/post- experimental study. This two-phase study was conducted to determine whether surrogate organisms were predictive of *C. difficile* spore removal and to compare the efficacy of various hand washing preparations at removing *C. difficile*. Nine subjects completed evaluations for a nonantimicrobial body wash or tap water for removal of spores of *B. atrophaeus*, *C. sporogenes*, and *C. difficile*. In phase 2, three to nine subjects completed evaluations for 10 test products and a tap water control for removal of *C. difficile* spores using a modification of a standard hand wash test method. | Controlled experiment | A peracetic acid and surfactant formulation was the most effective test preparation and achieved significantly greater reductions of *C. difficile* spores than did the tap water control, the 4% chlorhexidine gluconate (CHG) hand wash, 0.5% bleach, 8% hydrogen peroxide, 0.3% triclosan hand wash, nonantimicrobial hand wash, and nonantimicrobial body wash (p<.05). An ink and stain remover (applied with and without a brush) was significantly more effective than the tap water control, nonantimicrobial body wash, and 4% CHG hand wash (p<.05). The sodium tetraborate decahydrate powder was also significantly more effective than tap water (p<.05). The remaining preparations were statistically equivalent and not more effective than tap water alone. |  | Findings demonstrated that existing hand hygiene interventions have limited efficacy against *C. difficile* spores. Therefore, HCWs should continue to follow the recommendations for hand washing with soap and water and emphasize contact precautions (especially gloves) for care of patients with CDI. The lack of readily available *C. difficile* spore suspensions makes it difficult to evaluate the efficacy of hand wash products against *C. difficile*. Surrogate organisms should not be used to predict efficacy of hand hygiene agents against *C. difficile* spores.  The only other products to achieve significantly higher log10 reductions than the tap water were sodium tetraborate decahydrate powder and the ink and stain remover. However, these products also contain harsh ingredients that are unacceptable for routine use in healthcare environments. |  | The peracetic acid and surfactant formulation likely achieved the highest log reduction through a combination of spore removal and inactivation. However, the active concentration or contact time would negatively impact skin tolerability. |
| **Isaacson et al., 201537** | Hand washing using friction, that is, sand and water | Experimental comparison between different hand washing methods. Fourteen HCW subjects completed six study arms in randomized order: (1) no hand washing; (2) negative hand washing control: 30 seconds of rubbing with 5 mL of water and 30 seconds of tap water rinsing; (3) 30 seconds of rubbing with 5 mL of 0.3% triclosan soap and 30 seconds of rinsing; (4) 30 seconds of rubbing with a paste consisting of 15 mL of sand mixed with 15 mL of tap water and 30 seconds of rinsing; (5) 15 seconds of rubbing with 5 mL of a 50% baking soda and 50% vegetable oil mix, and 15 seconds of rubbing with 5 mL of liquid dish detergent, followed by 30 seconds of rinsing; and (6) 60 seconds of rinsing. Contamination was measured after each method. | Controlled experiment | Hand washing with sand resulted in an additional 0.5 log reduction in spore recovery compared with the current standard of soap and water.  Sand was the only intervention statistically superior to water, removing an additional 0.36 log of spores (p=.019). Compared with triclosan soap/water, sand removed 0.5 log more spores (p=.003), and oil/baking soda followed by dish detergent removed 0.37 log more spores (p<.001). |  | Although the sand used in this study was well tolerated by participants and resulted in no irritation after a single use, abrasives might not be suitable for routine hand washing. This study did not find a significant difference in residual spore counts after washing with triclosan soap versus tap water, consistent with findings from previous studies. This finding may occur because triclosan soap is not sporicidal and confers no additional friction. | Moderate—small sample—potential variation in technique across participants. Spores left over from the prior intervention. Did not use a “wash out” period, although they found that they did not necessarily need that. | Study was based on the idea that augmenting the friction of hand washing would result in a reduction in contamina-tion. |
| **Kirkland et al., 201229** | Hand hygiene compliance using (1) leadership/ accountability; (2) measurement/ feedback; (3) hand sanitizer availability; (4) education/ training; and (5) marketing/ communication. | Three-year interrupted time series with multiple sequential interventions and 1-year post-intervention followup. Tracked two primary outcomes monthly: (1) HH compliance rates and (2) healthcare-associated infection rates. Between 2006 and 2008, HH observations increased from 244 to 498 average monthly observations. | 383-bed teaching hospital, rural New Hampshire | HH compliance increased significantly from 41% to 87% (p<0.01) during the initiative and improved further to 91% (p<0.01) the following year. Nurses achieved higher HH compliance (93%) than physicians (78%). There was a significant, sustained decline in the healthcare-associated infection rate, from 4.8 to 3.3 (p<0.01) per 1,000 patient-days. Refills for wall-mounted dispensers increased 37%.  In the final year, overall HAIs declined; and the CDI rate stayed the same (0.9 to 0.6 per 1,000 patient-days, p=0.1). The rates of *S. aureus* infection (2.5 to 1.6 per 1,000 patient-days, p<0.001) and bloodstream infection (2.1 to 1.4 per 1,000 patient-days, p=0.004) fell significantly. | Not provided | Monthly data show that the single biggest improvement in HH overall, and in physician HH specifically, occurred after a year of measurement and monthly feedback citing poor performance. Physicians reported that, for them, regularly seeing data linking HH performance to healthcare- associated infections was important. Intervention built on the work of Goldmann, which framed the need for both system and personal accountability for HH.  Routine HH audits on all units, with monthly unit-specific data, were published on an intranet site available to all staff, as were strategies to optimize availability of hand sanitizer (Purell, 62% ethyl alcohol formulation). | Low/ moderate—cannot precisely measure each intervention; single site, small; potential participant bias.  Strength: covert observation; use of tracer condition—in comparison with OR (where intervention would not have made an impact), HAI rates decreased overall. | When this initiative began, the culture was one in which autonomy was valued and enthusiasm for quality improvement activities varied; such efforts typically attracted small groups of committed nurses. Infection rate reduction lags behind HH improvement. |
| **Knight et al., 201027** | Hospital-wide alcohol-based hand rub (AHBR) policy | A retrospective chart review analysis to compare incidence rates of CDAD before and after implementation of the ABHR policy. Population: inpatient status between January 1, 2001, and June 30, 2008. Full implementation of the ABHR policy was completed by May 1, 2003. A total of 766 patients with healthcare facility-onset, healthcare facility-associated CDAD were identified. | A 795-bed community teaching hospital | The incidence rate of CDAD was 3.98 per 10,000 patient- days after implementation of the ABHR policy, compared with 4.96 per 10,000 patient days before implementation (p=.0036). The crude mortality rate in patients diagnosed with CDAD was 10.7% after implementation, compared with 13.3% before implementation (p=.275). After implementation of the ABHR policy, compliance with hand hygiene, including both ABHR and soap and water, rose dramatically. | The rate of sepsis in patients diagnosed with CDAD was 19.6% after implemen-tation, compared with 5.2% before implement-tation (p<.0001). | Before implementation, only a 2% chlorhexidine-based soap product was available in the hospital. At the time of implementation, all existing antimicrobial products were removed and replaced with the alcohol-based hand foam. The only soap product available was a lotion soap with no antimicrobial activity. During a cluster, outbreak, or evidence of nosocomial transmission of *C. difficile*, the authors recommend switching to soap and water only for hand hygiene. | Low/ moderate; single site. Possible other IPC improve-ments during period.  Strengths: relatively long study period; controlled for doses of antibiotics as a potential confounder. | None |
| **Oughton et al., 20092** | Hand washing with soap and water (vs. alcohol-based hand rubs) | Randomized crossover comparison among 10 volunteers with hands experimentally contaminated by nontoxigenic *C. difficile* (no hand washing training was conducted). A crossover format was used so that all volunteers would be exposed to all interventions once for each contamination protocol during the observation period of June–July 2007. Minimum of 24 hours between interventions; 318 observations; included use of control group. | Controlled experiment | Under the whole-hand protocol, the greatest adjusted mean reductions were achieved by warm water with plain soap (2.14 log10 CFU/mL [95% credible interval (CrI), 1.74 to 2.54 log10 CFU/mL]); cold water with plain soap (1.88 log10 CFU/mL [95% CrI, 1.48 to 2.28 log10 CFU/mL]); and warm water with antibacterial soap (1.51 log10 CFU/mL [95% CrI, 1.12 to 1.91 log10 CFU/mL]), followed by antiseptic hand wipes (0.57 log10 CFU/mL [95% CrI, 0.17 to 0.96 log10 CFU/mL]). Alcohol-based hand rub (0.06 log10 CFU/mL [95% CrI, 0.34 to 0.45 log10 CFU/mL]) was equivalent to no intervention. Hypothenar (odds ratio, 10.98 [95% CrI, 1.96 to 37.65]) and the fingertips (odds ratio, 6.99 [95% CrI, 1.25 to 23.41]) were less likely to remain heavily contaminated after hand washing. | Not provided | Alcohol-based hand rub produced a significant reduction in contamination, although of a lesser magnitude than was seen with the other hand hygiene interventions. The reason that antibacterial soap seems slightly inferior to plain soap according to the whole-hand protocol but not according to the palmar surface protocol is uncertain. It may be due to a higher concentration of organic matter present in the whole-hand protocol, which interferes with the activity of chlorhexidine. | Low/ moderate—in vitro study, no gloving, small sample, single site. | Study included surface (i.e., palms) and whole-hand contami-nation. With 10 paired assessments for each product, a power of more than 99% to detect a 1.0 log10 difference was calculated. All of the hand washing interventions studied were performed for less time than recommended by the manufacturers of the products. |
| **Pokrywka et al., 201735** | Patient hand hygiene (PHH) | A biphasic, quasi-experimental study was performed to increase PHH through education for staff and to provide education, assistance, and opportunities to the patient for hand cleaning. PHH practice was assessed by patient surveys and analyzed by Chi squared test. Phase 1: four medical-surgical nursing units: pre/post-intervention patient surveys; Phase 2: whole hospital pre/post-intervention patient surveys. | A 495-bed university-affiliated medical center in a large healthcare system | Patient-reported HH opportunities and frequency improved for patients in Phase 1 and 2, although the improvement was greater for Phase 1. CD SIRs for the study period showed a decrease in the number of observed hospital-onset (HO) LabID events in the first two quarters (Qs) after the implementation of PHH in March 2015, and a corresponding decrease in the HO SIRs from 0.834 to 0.572 and 0.497, respectively. SIR p-values for Q2 and Q3 (0.0157 and 0.0103, respectively) were significantly lower than expected (p ≤0.05). The Q4 SIR, however, showed an increase to 0.3844 over the two preceding quarters. | The average frequency of PHH the patients reported did not change (average 2.4 before the initiative vs. 2.6 times after). | PHH may be a potentially underused preventive measure for CDI. Hospitalized patients are often not provided the opportunity to clean their hands. Limited patient mobility and acuity along with a lack of education present obstacles. Surveys of patients at the institution showed a need for increased PHH opportunities. Staff provided encouragement for PHH. Laminated signs were posted in each patient room with reminders for staff to assist patients in washing their hands throughout the day. This practice was augmented with screensavers and signage in staff areas. The increase in CDI in Q4 may show need for continued support and education. | Low/ moderate:  surveys collected data from patients and were therefore susceptible to social desirability bias.  CDI rates—small sample/ single site. Increased staff HH could have impact.  Strength: no IPC changes were made during Phase 2. | None |
| **Schweon et al., 201331** | Multimodal hand hygiene program | Quasi-experimental pre/post. Data were collected for 22 months (May 2009 through February 2011). In March 2010, a comprehensive hand hygiene program was implemented, including increased product availability, education for healthcare personnel (HCP) and residents, and an observation tool to monitor compliance. | A 174-bed skilled nursing facility, in Stroudsburg, PA | CDI rate decrease 0.08 to 0.04, p=.36 (insignificant). Infection rates for LRTIs were reduced from 0.97 to 0.53 infections per 1,000 resident-days (p=.01) following the intervention, a statistically significant decline. Infection rates for SSTIs were reduced from 0.30 to 0.25 infections per 1,000 resident-days (p=.65). A 54% compliance rate was observed among HCP. | Not provided | Not provided | Low/ moderate—resident compliance not monitored; single site. | None |
| **Sickbert-Bennett et al., 201632** | Clean In, Clean Out, cleaning hands before/after working with patient, covert observation, audit and feedback | Quasi-experimental: compared hand hygiene compliance data from the last quarter of the covert observations by infection preventionists and designated nursing staff with compliance data from the first month of the new program. Study used a Chi squared to compare the average historical HAI rate from January 2013 until the implementation of the new program in October 2013 with the average HAI rate during the study period of October 2013 to February 2015, after implementation of the new program. More than 4,000 unique observers made more than 140,000 observations. | 853-bed hospital, North Carolina | The researchers found that a 10% improvement in hand hygiene was associated with a 14% reduction in HA-CDI (p=0.070). They found a significant increase in the overall hand hygiene compliance rate (p<0.001) and a significantly decreased overall HAI rate (p=0.0066), supported by 197 fewer infections and an estimated 22 fewer deaths. These reductions resulted in an overall savings of approximately U.S. $5 million. | Not provided | Engaging all hospital staff in measuring hand hygiene compliance created a Hawthorne effect. A key feature of the intervention was that the focus for observation was simply on cleaning hands upon entering and leaving patient rooms. | Low—single site.  Strength: no other formal IPC efforts were being implemented at the same time. | None |
| **Stone et al., 201226** | National “Cleanyour-hands” campaign in England and Wales, which included installation of bedside alcohol hand rub, materials promoting hand hygiene and institutional engagement, and regular hand hygiene audit. | Prospective, ecological, interrupted time series study of 187 trusts from July 1, 2004, to June 30, 2008 (4 years). Assessed associations between procurement and infection rates by a mixed effect Poisson regression model (accounting for bed occupancy, length of stay, hospital type, and timing of other national interventions targeting these infections). | Regional: 187 acute hospital trusts in England and Wales | Combined procurement of soap and alcohol hand rub tripled from 21.8 to 59.8 mL per patient bed-day; procurement rose in association with each phase of the campaign. Rates fell for MRSA bacteremia (1.88 to 0.91 cases per 10,000 bed-days) and CDI (16.75 to 9.49 cases). MSSA bacteremia rates did not fall. Increased procurement of soap was independently associated with reduced CDI throughout the study. The adjusted incidence rate ratio for 1mL increase per patient bed-day was 0.993 (95% CI 0.990 to 0.996; p<0.0001). Publication of the Health Act 2006 and visits by DPH improvement teams reduced CDI for at least two quarters after the visit. | Not provided | The campaign took place in the context of a high-profile political drive and other national interventions to reduce MRSA bacteremia and CDI. It received central sustained funding and coordination. The World Health Organization currently offers a very similar intervention as part of its Save Lives initiative. Although caution should be exercised when extrapolating from these results, the campaign could offer a model for other countries to adopt or adapt. | Low/ moderate—large scope, controlled for confounders (although these are not listed), except antibiotics—which potentially would be a big confounder. | None |
| **Tomas et al., 201615** | A sporicidal formulation of ethanol for glove decontami-nation (to use before glove removal) to prevent CDI | Experiment and quasi-experiment: (1) Blind comparison of intervention versus bleach, 70% ethanol, and no cleaning. Gloves were contaminated with spores and then cleaned (the three ways listed); then samples were taken. (2) Study was repeated on gloved hands of personnel after caring for CDI patients. Sample size not given for artificially contaminated gloves. For personnel caring for *C. difficile* patients: 159 patient care episodes (67 by nurses, 52 by physicians, and 40 by allied health providers) involving 24 CDI patients. | Experiment at the Cleveland Veterans Affairs Medical Center | The reduction achieved by the sporicidal ethanol solution was equivalent to the 1:100 dilution of bleach (1.87 vs 1.69 logs; p=.97). A further reduction occurred when the solution was applied as a wipe. No personnel noted that the sporicidal ethanol solution had an adverse odor or caused respiratory irritation or staining of clothing (compared with bleach, which caused discoloration). | Use of a specific formulation of ethanol only for glove disinfection after care of CDI patients may be impractical to implement and might add to the cost of care. Although the sporicidal ethanol solution was not associated with adverse effects, the formulation tested has an acidic pH. | In the study, bleach wipes were effective in reducing spore contamination on gloves, but discoloration of clothing due to inadvertent spills, and aversion to the odor of bleach, were common complaints by personnel.  Findings suggest that the sporicidal ethanol solution could be useful for glove disinfection before removal when caring for CDI patients. Glove disinfection might be useful but it would not replace the need for hand washing after glove removal when caring for CDI patients. | High | Study measures **glove contami-nation**, not impact on CDI rates. |
| **Tomas et al., 201512** | Education on glove and PPE removal and use of bleach wipes for glove decontami-nation | Quasi-experimental study. Pre/post; 28 healthcare workers. Comparison of *C. difficile* hand contamination before and after education intervention and glove contamination intervention. | Cleveland VA Medical Center | After phase 1 (education and practice on PPE removal), acquisition of *C. difficile* on hands occurred in 2 of 27 (7%) episodes of care. After phase 2 (disinfection of gloves with bleach wipes), contamination was significantly reduced compared with the pre-intervention period (0% vs. 16%; p=.04). | Although there were no reported adverse effects attributed to the use of bleach wipes, several personnel complained about the strong odor of bleach. In addition, some participants expressed a concern that staining of clothing or respiratory irritation would be a problem if bleach wipes were used routinely. | In this study, researchers found that despite PPE use, healthcare personnel frequently acquired *C. difficile* spores on their hands while caring for patients with CDI. In a quasi-experimental intervention, improving PPE technique with education led to a nonsignificant reduction in contamination. Adding glove disinfection significantly reduced contamination, with no acquisition of spores detected during 30 episodes of patient care. The researchers postulate that the findings suggest that simple interventions may be effective in decreasing the risk for hand contamination while providing care to patients with CDI.  Results are consistent with previous studies demonstrating that simulations using fluorescent lotions can be useful in improving infection control techniques, including PPE removal. | Low—small sample is reflected by p-values | None |