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State of the Science Review

Validity of hand hygiene compliance measurement by observation: A systematic review

Annette Jeanes MSc [a,*], Pietro G. Coen PhD [b], Dinah J. Gould PhD [c], Nicolas S. Drey PhD [d]

[a] Infection Control Department, University College London Hospitals, London, United Kingdom
[b] Infection Division, University College London Hospitals NHS Foundation Trust, London, United Kingdom
[c] Cardiff University, Cardiff, United Kingdom
[d] School of Health Sciences, Cardiff, University of London, London, United Kingdom

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Background: Hand hygiene is monitored by direct observation to improve practice, but this approach can potentially cause information, selection, and confounding bias, threatening the validity of findings. The aim of this study was to identify and describe the potential biases in hand hygiene compliance monitoring by direct observation; develop a typology of biases and propose improvements to reduce bias; and increase the validity of compliance measurements.

Methods: This systematic review of hospital-based intervention studies used direct observation to monitor health care workers' hand hygiene compliance.

Results: Seventy-one publications were eligible for review. None was free of bias. Selection bias was present in all studies through lack of data collection on the weekends (n = 61, 86%) and at night (n = 46, 65%) and observations undertaken in single-specialty settings (n = 35, 49%). We observed inconsistency of terminology, definitions of hand hygiene opportunity, criteria, tools, and descriptions of the data collection. Frequency of observation, duration, or both were not described or were unclear in 58 (82%) publications. Observers were trained in 56 (79%) studies. Inter-rater reliability was measured in 26 (37%) studies.

Conclusions: Published research of hand hygiene compliance measured by direct observation lacks validity. Hand hygiene should be measured using methods that produce a valid indication of performance and quality. Standardization of methodology would expedite comparison of hand hygiene compliance between clinical settings and organizations.

Historically, hand hygiene compliance (HHC) in health care settings, despite its ability to reduce infection risk, has been poor.[1-3] Regular HHC monitoring is recommended to improve and sustain compliance.[4] Robust, credible data are required to measure performance and promote and sustain evidence-based practice and quality improvement,[5-7] but there are threats to the validity of data collected by human observation.[8] This concern was part of the rationale for the development of the World Health Organization (WHO) hand hygiene observation method and data collection tool.[9,10]

Monitoring technology, which may improve some validity issues, has been developed and introduced,[11-13] but it is not used widely. Regular HHC monitoring by direct observation continues to be promoted and used[14-16] despite the recognition of the potential to produce inaccurate and unrepresentative data.[17-21] Even with these shortcomings, the observation of infection control practice helps to understand what is happening in practice and to provide meaningful feedback[22]; it provided the impetus for this review.

Bias in hand hygiene monitoring

Direct observation of HHC is regarded as the gold standard[23,24] of assurance, but validity is threatened by the potential for bias arising from human error. Information bias,[25] selection bias,[26,27] and confounding bias[28] have been identified as the main types of bias that

* Address correspondence to Annette Jeanes, Infection Control Department, University College London Hospitals, 3rd Floor East, 250 Euston Rd, London NW1 2PG, United Kingdom.
E-mail address: Annette.jeanes@nhs.net (A. Jeanes).
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can affect validity when this approach is used. The widely documented Hawthorne effect[29] increases productivity in response to scrutiny,[30] which also increases hand hygiene frequency[31] and has been criticized.[18-21] Criticism of HHC data includes observer bias, lack of observer training, limited reliability, absence of corroborative methods of data collection,[14,15,32,33] and sampling bias arising because data collection has taken place primarily during the day and on critical care units.[14,15,32]

Validity related to methodology

Validity is affected by study design, methods, and data collection tools.[34,35] Two possible types exist: internal validity, which is the ability to accurately measure what is required while avoiding bias or error, and external validity, which is the ability to generalize findings.[36,37]

Information bias includes the Hawthorne effect,[29] which has been identified in several HHC studies.[11,38-41] The Hawthorne effect may diminish with time,[42] particularly if observation takes place often.[43] The presence of auditors known to staff and overt observation can prompt improved HHC[11,38,41,44] and inflate HHC performance scores by between 30% and 50%.[11,41] Observers themselves may adopt behavior that results in bias[41,44] by undertaking selective observation,[45] leading to confirmation bias.[11,46,47] Employing a team of auditors may counteract the effect of idiosyncratic bias related to a specific auditor, but this has the effect of increasing interobserver variability.[48] Regular inter-rater testing can reduce variation and improve the validity of the data collection when teams are used. Training, experience, and careful choice of data collection instrument promote inter-rater reliability and may improve with training and practice.[49,50] Recording rapid successive actions and prolonged periods of observation can lead to recording errors.[51,52] Bias may also occur when HHC is linked to rewards.[53]

Selection bias is possible when the sample is limited to specialist units or time periods not representative of all health care settings or the 24-hour period.[1,2,54-61] A wider selection of clinical settings, staffing, and activity and avoiding self-selection of health care workers reduces sampling bias[62,63] and systematic errors in data collection.[64] Ad hoc samples may be unrepresentative compared with regular planned sampling, while continuous sampling may be more reliable than intermittent sampling.[65]

Confounding bias can influence the interpretation of findings,[25] generating misleading outcomes. Avoiding confounding bias requires an a priori study design to identify potential confounding variables or randomization to ensure that they are equally distributed. In the analysis and interpretation of findings, stratification, multivariate analysis, and multi-level analysis can be used to control for known confounding variables.

We undertook a systematic review to document bias in HHC studies. Our aims were to establish biases in studies where HHC was monitored by direct observation, develop a taxonomy of biases, and make recommendations to improve the validity of hand hygiene monitoring.

METHODS

We included publications that reported use of direct observation to monitor health care workers' HHC in health care facilities. All study designs were included. Complex interventions were included if HHC by direct observation was a component. Published peer-reviewed, full-text studies and reports were included. Publications with no published abstract were excluded, as it was impossible to assess them against the inclusion and exclusion criteria. Publications prior to 1970 were excluded because most hand hygiene monitoring associated with improving compliance was established after this date. Publications after 2015 were excluded as well, as we were seeking a sample of publications to produce a taxonomy of bias.

Searches were undertaken with the following databases: PubMed, Scopus, Health Business Elite, BNI, and CINAHL. In addition, the work of key authors in the field was identified, gray literature primarily from National Health Service portals was reviewed, suggestions from other experts were sought, and a hand search of current relevant literature was undertaken.

Initially, the systematic reviews of Haas and Larson,[14] Gould et al,[66] Gould et al,[67] Erasmus et al,[16] and Huis et al[68] were examined, and key terms used from these publications informed terms used in the search strategy.

Medical Subject Headings used in the search included "hand hygiene," "hand hygiene compliance," "staff," "observation," "assurance," "compliance monitoring," "compliance measurement," "performance monitoring," "performance measurement," "quality improvement," "audit," "reporting," "interpreting/interpretation," "direct observation," "feedback," "competence," "knowledge," "5 (five) moments," "behavior," "reliability," "validity," "accuracy," "hand wash/washing," and "clean hands." Terms were used in combination. Subsequently, results were checked to ensure that publications from key authors had been identified in the search.

The following limits were applied: Full Text; Published Date: 01/ 01/ 1989-31/12/ 2014; English Language, Search modes −Boolean/Phrase via Interface of NHS Athens and EBSCOhost Research Databases Health Business Elite, and CINAHL with Full Text.

Studies were included if they assessed health care workers' HHC by direct observation in acute health care settings with sufficient methodological detail to assess validity. Two members of the research team selected studies, with third-party arbitration in cases of disagreement. Sample size and outcome of the intervention/measurement were irrelevant and were not factors in the data collection or selection of the publications.

The Fisher exact test was used to explore trends in publication: country of origin and year of publication. We used the percentage of selected studies in each category of bias to describe the nature of bias. We used Stata version 12 software (Stata Corp., College Station, TX) for data management and statistical analysis.

RESULTS

We identified 5,206 abstracts. Of these, 118 full-text publications potentially met the inclusion criteria, and 71 were described in enough detail to be included (Figure 1). No significant trends were detected according to country of origin ($P = .259$) or year of publication ($P = .188$). Most studies were from Europe or North America. Table 1 and Table 3 summarize bias in publications. Table 4 is a summary of results with references.

Information bias

The Hawthorne effect[29] was identified in 12 (17%) studies. Attempts were made to control for it in 31 (44%) studies through covert or inconspicuous observation. One study was halted when staff became suspicious of observers.[135] The purpose of data collection is likely to have become clear in studies in which health care workers were shadowed,[93,97,101] received feedback,[132] were sited in patient rooms,[85,87] were exposed to prolonged observation periods,[118] or were subjected to intense observation. In 1 study, each individual was observed for 2 hours per shift on 3 occasions,[77] whereas in another, simultaneous observation of the same individual by 2 observers occurred.[78] Obtaining ethical

approval is likely to have resulted in awareness of the purpose of the study. Informed consent was required in 11 (15%) studies, and in 41 (58%) studies ethical approval was necessary. In 1 study, compliance increased the longer the auditors remained in the clinical area.[20]

The number of observers present during the audit process was not stated in 31 (44%) publications. In the remainder, 1-2 people were usually present. Observers were trained in 56 (77%) studies. Training varied and included written instructions, DVD/video, lectures, workshops, scenarios, simulations, familiarization and concurrent pilot, and trial observations. In 9 (13%) studies, observers had previously received training. The method of training was specified clearly in only 23 (32%) studies. Validation of scoring within training was undertaken in 28 (39%) studies. In 15 (21%) studies, observers were internal to the organization and could have been known to staff. In 11 (16%) studies, observers were external; in 45 (63%) studies, the origin of observers was not stated or was unclear; and in 12 (17%) studies, the authors themselves were the observers.

In 47 (66%) studies, study duration was less than 12 months; in 18 (25%) studies, duration was longer than 12 months. In 18 (25%) studies, observation was less than 1 hour; in 16 (23%) studies, observation was more than 1 hour; and in other studies, observation took place continuously with 20-minute audits every 24 hours.[118,119] Audit frequency, study length, or both were not stated or were unclear in 58 (82%) studies. The frequency of observation measurement was clearly stated in only 16 (23%) studies. Inter-rater reliability was checked in 26 (37%) studies, and in 16 this took place only during training. Six (8%) studies reported ongoing tests for inter-rater reliability with use of the kappa statistic. In many studies, assessment of information bias was hampered by lack of details of the methods used.

Selection bias

Sampling bias because of timing of observation, the setting in which observation was conducted, or both was evident in all studies. In 35 (49%) studies, observations were restricted to single-specialty wards such as adult or neonatal critical or pediatrics. In 11 (16%) studies, monitoring took place in more than 1 hospital. Fifty-four (76%) studies reported the time of day when observations were conducted. Fifty (70%) studies reported that observation occurred partly or entirely during the day. Observation at night was undertaken in 25 (35%) studies. Weekend observation was undertaken in only 10 (14%) studies. Those observed were primarily doctors and nurses. In 16 (23%) studies, occupational group was not specified. In 33 (46%) studies, occupational group of the observers was not specified. In the others, observation was conducted by students, infection control staff, nurses, researchers, or doctors.

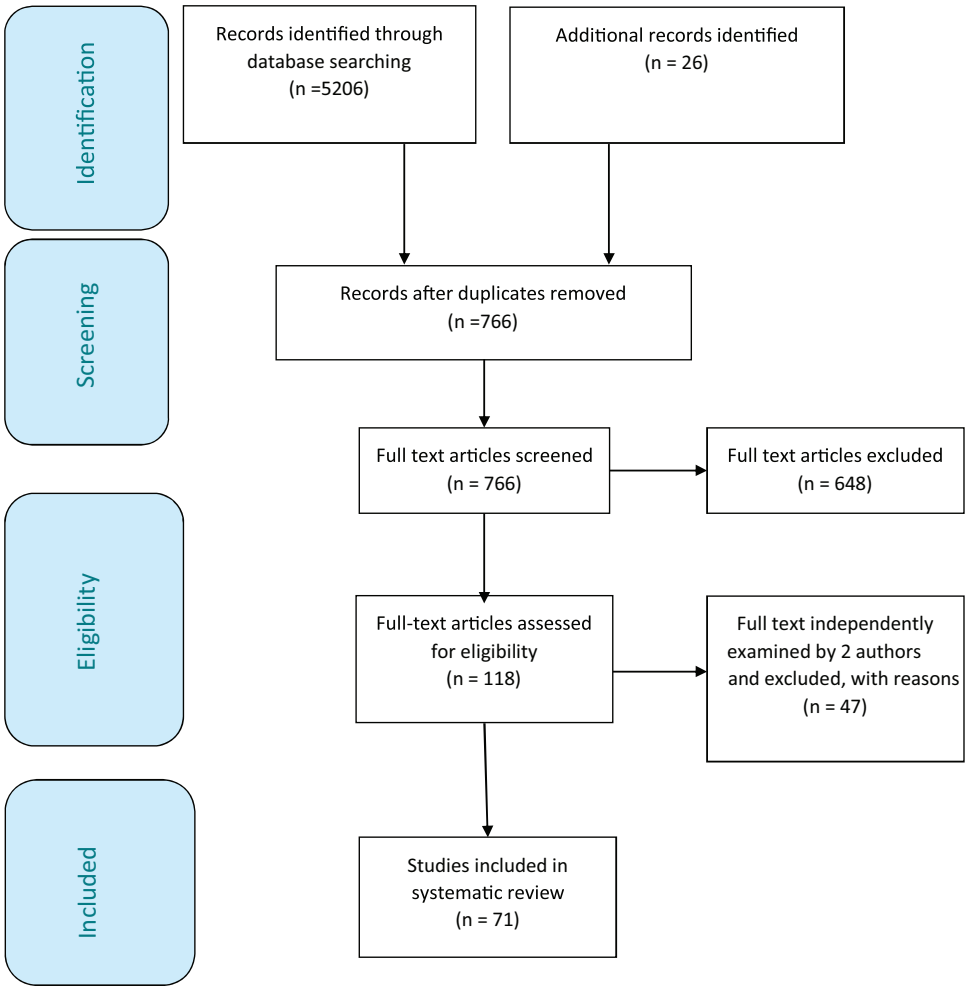

Figure 1. Search flow diagram (based on Moher et al[147]).

Confounding

Twenty-seven (38.0%) studies attempted to control for confounding by measuring confounding variables, and these were used to undertake a multivariate analysis.

Comparability of studies

Data from the different studies were not comparable, as the definitions of hand hygiene and HHC; measurement criteria, including hand hygiene opportunities; and methodologies, including overt and covert observation, varied. In describing hand hygiene measurement, at least 60 different terms were used; alcohol hand decontaminants alone accounted for 7 different terms.

Most studies did not specify in detail how observation was undertaken. The number of observations undertaken or other outcome measures was not reported or was unclear in 12 studies. The periods of time observed and the number of areas observed during the observation varied considerably and were not comparable across studies.

In 32 (45%) studies, standard hand hygiene observation tools, such as the WHO compliance tool, were used. In 17 (24%) studies, the authors used a tool developed especially for the study. In 15 (21%) studies, the data collection tool was modified or adapted—for example, modifying the WHO guidelines to capture data in relation to 4 of the recommended Five Moments for Hand Hygiene.[77,78,112] In 7 studies, the nature of the data collection tool was not apparent.

These variations and adjustment in the tools used in studies made summarizing and comparing the criteria used for measurement difficult. For example, Boscart et al[77] used the Ontario Tool, which combines the WHO Moments of "after-patient-contact" and "after contact with patient environment" and "before patient contact" and "before contact with patient environment."

Hand hygiene expectation associated with glove use was inconsistent across studies as well. According to the criteria adopted in some data collection tools, failure to perform hand hygiene after removing gloves was considered noncompliant,[79,80,137] whereas in others, glove use was not included as part of HHC monitoring.

Other differences included only stipulating hand hygiene after contact with a contaminated environment or objects rather than after contact with all patient environments.[81,96] This extended to applying a risk assessment to criteria in some studies.[108,110]

Three studies adopted very specific actions and expectations[105,121,134] for hand hygiene opportunities, whereas others referred to standard criteria such as the WHO Five Moments for Hand Hygiene. Others were specific but neglected to explain if the expectation was before or after contact.[128] Other adjustments included excluding the first patient contact because observers were waiting outside the patient room and could not see if the health care worker had cleaned their hands in the previous

Table 1
Data collection of bias and rational for inclusion

Information extracted	Rationale
When was the study published?	Provides context, particularly as in earlier studies; hand hygiene compliance monitoring was not well established
Where was it undertaken?	Generalizability and external validity [25] and to identify sample selection bias[65]
Ethical or equivalent approval and or consent for participation (health care worker)	Requirement for consent for participation may lead to self-selection[14] (eg, for poorly performing staff to opt out or high-performing staff to opt in), which would create selection bias[65] and could impede efforts of covert observation in addition, consent for participation would increase awareness of staff of observation[44] and the remit of the study
Who was observing and how many people were involved in measurement?	To identify observer bias,[70] interobserver variability,[50] and reactive effect of observation[44]
Internal or external observers	Observer bias due to allegiance[11,45] or knowledge of people and or area, reactive effect of observation[44]
Preparation and training of observers	Interobserver variability,[50] observer drift,[51] and observer bias[70]; measurement bias (errors)[51] may occur if observers are not prepared[52]
Overall time period in the duration of the study that observation was undertaken	Observer drift[51] may occur over a long period; measurement bias may occur with variations in observers or clinical practices over a long period; interobserver variability[50] related to numerous observers
How long were observers observing on each occasion?	The novelty effect of being observed may diminish with time[46]; observer drift or fatigue[51] and measurement bias may occur in long sessions
How frequently did they undertake observations?	Reactive effect of observation may reduce if it is a routine,[46] and measurement bias may occur if observers are rarely undertaking measurement; very limited measurements may not be generalizable[25]
Who was being observed?	To identify sample selection bias[65]
Monitoring tool used (identity of tool)	Reliability of tool
Was the tool used validated?	Validity of tool
Origin of the tool and if adapted	Validity of tool, comparability of data and definitions
Was a pilot study done?	Undertaking a pilot affects the quality of study as it informs feasibility and modifications[71]
Covert or overt observation (obtrusive/unobtrusive)	Reactive effect of observation[44]
Reason for monitoring/measuring	Confirmation and other bias related to influence,[42,48,72] selection bias
Definitions of hand hygiene opportunity and hand hygiene	Comparability of results
Quality of hand hygiene compliance recorded; was it measured?	Complexity of measurement
Number of observations or other criteria such as hand hygiene opportunities	Comparability of results
Reliability tests used	Reliability
Product measured	Confirmatory
Was author of the publication an observer?	Confirmation bias[42,48,72]
Time of day, nights, and weekends	Sample selection bias and comparability
What did they actually do?	Validity related to replication

Table 2
Publications selected for systematic review—detail of origin and type of potential bias identified

Reference in text	Publication	Year of publication	Country	Type of potential bias identified
70	Abela N, Borg MA	2012	Malta	S, I, C
71	Aboumatar H, Ristaino P, Davis RO, et al	2012	USA	S, I, C
72	Allegranzi B, Sax H, Bengaly L, et al	2010	Mali	S, I, C
73	Allegranzi B, Gayet-Ageron A, Damani N, et al	2013	Costa Rica, Italy, Mali, Pakistan, Saudi Arabia	S, I
74	Al-Wazzan B, Salmeen Y, Al-Amiri E, et al	2011	Kuwait	S, I, C
75	Biddle C, Shah J.	2012	USA	S, I, C
76	Bischoff WE, Reynolds TM, Sessler CN, et al	2000	USA	S, I, C
77	Boscart VM, Levchenko AI, Fernie GR	2010	Canada	S, I, C
78	Boscart VM, Lee JH, Márquez-Chin C, et al	2011	Canada	S, I, C
79	Brown SM, Lubimova AV, Khrustalyeva NM, et al	2003	Russia	S, I, C
80	Chau JP, Thompson DR, Twinn S, et al	2011	Hong Kong	S, I, C
20	Chen LF, Carriker C, Staheli R, et al	2013	USA	S, I, C
81	Creedon SA.	2006	Ireland	S, I, C
82	Dedrick RE, Sinkowitz-Cochran RL, Cunningham C	2007	USA	S, I, C
83	di Martino P, Ban KM, Bartoloni A	2011	Italy	S, I, C
84	Duggan JM, Hensley S, Khuder S	2008	USA	S, I, C
39	Eckmanns T, Bessert J, Behnke M, et al	2006	Germany	S, I, C
85	Eveillard M, Hitoto H, Raymond F, et al	2009	France	S, I, C
86	Eveillard M, Pradelle MT, Lefrancq B, et al	2011	France	S, I, C
87	Eveillard M, Raymond F, Guilloteau V, et al	2011	France	S, I, C
88	Fuller C, Savage J, Besser S, et al	2011	UK	S, I, C
89	Golan Y, Doron S, Griffith J, et al	2006	USA	S, I, C
90	Harbarth S, Pittet D, Grady L, et al	2001	USA	S, I, C
91	Harne-Britner S, Allen M, Fowler KA, et al	2011	USA	S, I, C
92	Helder OK, Brug J, Looman CW, et al	2010	The Netherlands	S, I, C
93	Huis A, Schoonhoven L, Grol R, et al	2013	The Netherlands	S, I
94	Johnson PD, Martin R, Burrell LJ, et al	2005	Australia	S, I, C
95	Korniewicz DM, El-Masri M	2010	USA	S, I, C
96	Lam BC, Lee J, Lau YL	2004	Hong Kong	S, I, C
97	Lankford MG, Zembower TR, Trick WE, et al	2003	USA	S, I, C
98	Larson EL, Albrecht S, O'Keefe M	2005	USA	S, I, C
99	Laustsen S, Lund E, Bibby BM, et al	2009	Denmark	S, I, C
100	Linam WM, Margolis PA, Atherton H, et al	2011	USA	S, I, C
101	Luke MM, Alavosius M	2011	USA	S, I, C
102	Marra AR, Moura DF Jr, Paes AT, et al	2010	Brazil	S, I, C
103	Mathai AS, George SE, Abraham J	2011	India	S, I, C
104	Mayer J, Mooney B, Gundlapalli A, et al	2011	USA	S, I
105	McArdle FI, Lee RJ, Gibb AP, et al	2006	UK	S, I, C
106	McAteer J, Stone S, Fuller C, et al	2008	UK	S, I, C
107	McLaws ML, Pantle AC, Fitzpatrick KR, et al	2009	Australia	S, I, C
108	Meengs MR, Giles BK, Chisholm CD, et al	1994	USA	S, I, C
109	Mertz D, Dafoe N, Walter SD, et al	2010	Canada	S, I, C
110	Mestre G, Berbel C, Tortajada P, et al,.	2012	Spain	S, I, C
111	Monistrol O, Calbo E, Riera M, et al	2011	Spain	S, I, C
112	Mukerji A, Narciso J, Moore C, et al	2013	Canada	S, I, C
113	Novoa AM, Pi-Sunyer T, Sala M	2007	Spain	S, I, C
114	Pan A, Mondello P, Posfay-Barbe K, et al	2007	Italy	S, I, C
115	Pessoa-Silva CL, Hugonnet S, Pfister R, et al	2007	Switzerland	S, I, C
2	Pittet D, Hugonnet S, Harbarth S, et al	2000	Switzerland	S, I, C
116	Pittet D, Mourouga P, Perneger TV	1999	Switzerland	S, I, C
117	Pittet D, Stéphan F, Hugonnet S, et al	2003	Switzerland	S, I, C
118	Randle J, Arthur A, Vaughan N, et al	2014	UK	S, I, C
119	Randle J, Arthur A, Vaughan N	2010	UK	S, I, C
120	Rosenthal T, Erbeznik M, Padilla T, et al	2009	USA	S, I, C
121	Sahay S, Panja S, Ray S, et al	2010	India	S, I, C
122	Saint S, Bartoloni A, Virgili G, et al	2009	Italy	S, I, C
123	Saint S, Conti A, Bartoloni A, et al	2009	Italy	S, I, C
124	Scheithauer S, Haefner H, Schwanz T, et al	2009	Germany	S, I, C
125	Scheithauer S, Oberröhrmann A, Haefner H, et al	2010	Germany	S, I, C
126	Scheithauer S, Oude-Aost J, Heimann K, et al	2011	Germany	S, I, C
127	Scheithauer S, Kamerseder V, Petersen P, et al	2013	Germany	S, I, C
128	Smith SJ, Young V, Robertson C, et al	2012	UK	S, I, C
129	Son C, Chuck T, Childers T, et al	2011	USA	S, I, C
130	Steed C, Kelly JW, Blackhurst D, et al	2011	USA	I, C
131	Tromp M, Huis A, de Guchteneire I, et al	2012	The Netherlands	S, I, C
132	van den Hoogen A, Brouwer AJ, Verboon-Maciolek MA, et al	2011	The Netherlands	S, I, C
133	Venkatesh AK, Pallin DJ, Kayden S, et al	2011	USA	S, I, C
134	Wendt C, Knautz D, von Baum H	2004	Germany	S, I, C
135	Whitby M, McLaws ML	2004	Australia	S, I, C
136	White CM, Statile AM, Conway PH, et al	2012	USA	S, I, C
137	Won SP, Chou HC, Hsieh WS, et al	2004	Taiwan	S, I, C

C, confounding bias; *I*, information bias; *S*, selection bias.

room,[109] whereas others focused only on hand hygiene before contact with the patient, as it was perceived to be important and simplified the observers' task.[122]

Other measurements

Hand hygiene product usage was measured in 14 (20%) studies, although the method varied and was mostly limited to staff members assessing how much product was left in individual dispensers.[79] Only 15 (20%) studies assessed the hand hygiene method, which variously included time taken, coverage of hands, drying, and turning off taps.

Taxonomy of bias

The rationale for the potential bias extracted in the 71 studies is summarized in Table 1; the potential bias for each publication is identified in Table 2. The extent of bias identified in this review is summarized in Table 3. Types of bias identified reflect those reported in earlier narrative reviews.[14-16,32,33] The most frequent forms of selection bias found were associated with limiting the number of hospitals studied and not monitoring weekends. Internal rather than external observers and the frequently of observation were the most frequent forms of information bias identified.

Although a constant threat to the validity of the data collected, the Hawthorne effect could be viewed as a systematic error in the observational methodology, which is relatively constant, and error tolerance could be applied. The data collected are a sample of behavior that can be affected by several variables. Though potentially inaccurate, if the methods, conditions, and degree of error are relatively constant, the results of observation may be a pragmatic indicator of performance for inspection of trends. However, this could also apply to other forms of bias.

Limitations

The main limitation of this review was inability to identify all possible sources of bias, especially those arising from the Hawthorne effect, because hand hygiene data collection was incompletely described in many published studies. Hand hygiene is assessed as part of a complex intervention in many infection prevention studies, and our search strategy, although comprehensive, may not have identified all potentially eligible reports. In studies in which hand hygiene was not the main outcome measure, it is unlikely that hand hygiene methodology would have been described in enough detail to permit extraction of information required for this review.

In conclusion, multiple sources of bias were detected in all studies in which HHC was monitored by direct observation, reducing the validity of findings and challenging current opinion that direct observation of HHC is the gold standard approach. The use of the taxonomy of bias could improve the design and use of HHC monitoring tools and improve confidence in data produced.

There are benefits in observing practice, including improving practice.[138] Observation is used to assess clinical competence[139] and gain insights into what happens in practice. Acquiring insight may lead to the rejection or modification of established assumptions and the development of a new approach to issues.[140] This may also lead to the challenging of gold standards, such as measuring hand hygiene compliance by observation, and other potential solutions or ideas may be generated.

A structured and systematic approach to observation would be more rigorous and reproducible than random observations. However, limiting or restricting observations to a predetermined and rigid format may miss important serendipitous findings. Repeatedly just observing HHC may inadvertently create blindness to other significant events, since attention may be highly selective.[141] Even experienced observers may be subject to unintentional blindness when focused on a single process that is familiar and predictable.[142]

However, experienced observers may be more successful than a novice at detecting patterns and anomalies.[143] Expertise and preparedness create a "search image," which, combined with situational awareness, filters out irrelevant information that may overwhelm the analytical skills of a novice.[144] Therefore, observation by someone with relevant experience, training, and education could be beneficial in identifying deviations from the expected norm.

The identification of barriers to compliance, such as availability of hand hygiene product and the use of improvement opportunities, could add value to the observation monitoring process. Other significant factors that influence compliance may include ambiguity[145] and lack of self-efficacy,[146] when there is a lack of clarity about expectations of compliance, particularly in specialist or complex areas of practice. In addition, the context and conditions in practice are important factors to consider, and understanding the limitations may make expectations of compliance more realistic.

Continuous human observation of HHC would not be valid and is unlikely to be affordable.[13] Automated options are available, but these replace human error with machine error and may have limitations including cost-effectiveness, feasibility,[13] inability to distinguish between users (including patients and visitors), and inability to assess hand hygiene techniques.[24] Alternative methods for regular monitoring of infection control practice performance, which reduce data

Table 3
Summary of bias components across the 71 included studies (components not mutually exclusive)

Bias component	Bias class	N biased	% biased
Who was observed?	Selection	7	9.86
Specialties	Selection	35	49.3
More hospitals?	Selection	60	84.5
Did they also monitor nights?	Selection	46	64.8
Cluster analysis	Selection	56	78.9
Did they also monitor weekends?	Selection	61	85.9
Informed consent	Information	11	15.5
Author observer	Information	12	16.9
Number of auditors	Information	24	33.8
Trained observers	Information	16	22.5
Frequency of observation	Information	54	76.1
Interobserver variation measured?	Information	45	63.4
External vs internal observers	Information	60	84.5
Multivariate analysis	Confounding	44	62

Table 4
Summary of results with references

Bias	No. of publications (%)	References
Information		
Number of observers in each audit not stated	31 (43.7)	2, 72, 74, 75, 80, 82, 84, 85, 87–89, 91, 92, 94, 95, 9, 102, 104, 107, 108, 111, 112, 114, 118, 120, 129, 131–134, 136
1-2 people were involved in each audit	33 (46.5)	39, 70, 71, 73, 76–79, 81, 86, 90, 93, 96, 98, 99, 101, 103, 105, 106, 110, 113, 115, 116, 11, 121, 124–128, 130, 135, 137
Observers were trained	56 (78.9)	20, 39, 41, 70, 71, 74, 75, 77–80, 82–84, 86–91, 93, 95–100, 102, 104, 106, 107, 109–124, 127–132, 134
Observers had received training previously	9 (12.7)	88, 111, 115, 117–119, 123, 124, 127
Method of training was specified clearly	23 (32.4)	71, 74, 75, 78, 80, 84, 88, 91, 93, 97, 100, 102, 104, 107, 110, 112, 120, 122, 123, 130–132, 137
Validation of scoring within training was undertaken	28 (39.4)	2, 39, 74, 75, 78, 80, 88–90, 92, 98, 104, 110, 112, 115, 116, 127, 130, 132
Observers were internal to the organization	15 (21.1)	39, 76, 89, 94, 100, 104, 105, 107, 110, 128, 129, 132, 134, 136, 137
Observers were external to the organization	11 (15.5)	75, 79, 83, 85–87, 99, 120, 122, 123, 135
Origin of the observers was not stated or was unclear	45 (63.4)	2, 20, 70–74, 77, 78, 80–82, 84, 88, 90–93, 95–98, 101–103, 106, 108, 109, 111–119, 121, 124–127, 130, 131, 133
Authors are observers	12 (16.9)	2, 71, 76, 77, 81, 94, 99, 105, 106, 115, 122, 123
Duration of the study was less than 12 months	47 (65.3)	2, 39, 70, 73–75, 78, 79, 82–84, 86–88, 90, 91, 94–98, 101–103, 106–108, 111–113, 115–119, 121–124126-128, 130–132, 134, 135
Duration of the study was more than 12 months	18 (25.4)	20, 69, 70, 72, 77, 88, 92, 93, 99, 100, 104, 109, 110, 120, 129, 133, 136, 137
Length of observation period was under 1 hour	18 (25.4)	71, 72, 77,78, 80, 90, 94, 103, 107, 109, 111, 114, 115, 118, 119, 128, 130, 135
Length of observation was at least 1 hour	16 (22.5)	39, 76, 79, 81, 88, 89, 92,97, 98, 102, 105, 106, 108, 124, 126, 137
Audit frequency, study length, or both were not stated or were unclear	58 (81.7)	2, 20, 39, 72–82, 84–90, 83–89, 92–97, 100, 101, 103–108, 110–117, 119–128, 130–134, 136
Frequency of observation measurement was clearly stated	16 (22.5)	74, 88, 91, 98, 100, 102, 104, 109, 110, 118, 120, 127, 129, 135–137
Inter-rater reliability checking was undertaken	26 (36.6)	2, 39, 71, 70, 73, 74, 77, 78, 80, 90–92, 98, 99, 101, 104, 106, 109–112, 115, 116, 127, 130, 132
Inter-rater reliability was undertaken only in training	16 (22.5)	6, 39, 69, 71, 73, 74, 78, 80, 90, 98, 104, 112, 115, 127, 132
Practiced ongoing tests for inter-rater reliability (eg, kappa statistic)	6 (8.45)	77, 99, 101, 106, 110, 111
Attempted to control for Hawthorne effect bias by covert or inconspicuous observation	31 (43.7)	69, 71, 73–76, 79, 81, 82, 84, 88–90, 92, 93, 94, 97, 100, 102, 104, 105, 108, 113, 116, 117, 121, 128, 131, 134, 135, 137
Required informed consent from staff	11 (15.5)	77, 80, 93, 95, 101, 108, 111, 115, 118, 119, 127
Required ethics or a similar approval process	40 (56.3)	2, 70, 72, 74, 75, 77, 78, 80, 81, 83, 87–93, 95, 98–100, 102, 106, 108–111, 115–119, 121–123, 128, 130, 131, 133, 135
Selection		
Observations were undertaken in single-specialty ward locations, such as adult and neonatal intensive care or pediatrics	35 (49.3)	39, 69, 70, 74, 76–78, 81–83, 89, 90, 92, 95, 96, 100–103, 105, 108, 112, 115, 117, 120, 121, 124–128, 132, 133, 136, 137
Reported monitoring locations in more than 1 hospital	11 (15.5)	71, 72, 80, 86, 88, 93, 107, 109, 123, 123, 130
Detailed the time of day when observations were carried out	54 (76.1)	2, 10, 20, 39, 71, 73, 76–82, 84, 90, 108–111, 113, 115–121, 124–126, 128–135, 137
Conducted observations at night	25 (35.2)	2, 71, 80, 95, 98, 99, 100, 102, 104, 111, 113, 115, 116, 118, 119, 121, 124–126, 129, 130, 132–34,136
Observations were carried out also on the weekends	10 (14.1)	20, 84, 102, 104, 108, 116, 130, 133, 134, 137
Role of the observed health care worker was not specified	16 (22.5)	73, 85, 87, 88, 94, 95, 98, 109, 112, 120, 124, 125, 129, 130, 135
Professional role of the observers was not specified	33 (46.5)	2, 20, 72–74, 77, 78, 82–84, 86, 90, 91, 99, 101, 102, 104–108, 110, 114, 115, 116–119, 121, 125–127, 129, 132, 133
Confounding		
Attempted to control for confounding bias by measuring confounding variables and used these data to undertake a multivariate analysis	27 (38.0)	2, 39, 71, 72, 79, 82, 84, 88–90, 93, 95, 97, 99, 104, 106, 113, 115–119, 122, 128, 131, 133
Comparability		
Number of observations undertaken was not reported	12 (16.9)	20, 73, 92, 94, 100, 101, 105, 108, 120, 129, 136, 137
Definitions of hand hygiene and hand hygiene opportunity were unclear	4 (5.63)	71, 79, 80, 95
Reported use of standard tools such as the World Health Organization compliance tool	32 (45.1)	70, 72, 73, 77, 78, 84, 85, 87, 90, 94, 97, 102, 108, 110–112, 114, 115, 118, 119, 121, 126, 127, 127,130, 131, 133–137
Created their own reporting tool	17 (23.9)	2, 74, 76, 79, 88, 91, 95, 96, 104, 106, 113, 116, 117, 120, 125, 128, 132
Modified or adapted a standard tool	15 (21.1)	20, 39, 75, 80, 81, 83, 86, 89, 94, 101, 107, 109, 122, 123, 129
Unclear what reporting tool was used	7 (9.86)	71, 82, 83, 98, 103, 105, 126
Measured hand hygiene product usage	14 (19.7)	74, 76, 79, 88, 92, 94, 98, 102, 110, 111, 115, 124–126
Assessed hand hygiene method, which variously included time taken, coverage of hands, drying, and turning off taps	15 (21.1)	80, 85, 87, 92, 96, 99, 101, 103, 108, 109, 120, 121, 125, 132, 136

collection errors and variability and assist in improving compliance, are required.

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