Validity of hand hygiene compliance measurement by direct observation: a systematic review

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Abstract (210)

Background

Hand hygiene is monitored by direct observation to improve practice, but this approach has potential to cause information, selection and confounding bias, threatening the validity of findings.

Aims

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.

Methods

Systematic review of hospital-based intervention studies that used direct observation to monitor health workers' hand hygiene compliance.

Results

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

Conclusion

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. Standardisation of methodology would expedite comparison of hand hygiene compliance between clinical settings and organisations.

Key words: *Hand hygiene, observation, validity, bias, Hawthorne effect*

Highlights

- Results of monitoring hand hygiene compliance by direct observation are subject to bias
- 71 publications were assessed for the presence and type of methodological bias
- Sampling bias was present in all studies. Night-time measurement was absent in 46 (65%) studies
- Observers were trained in 56 (79%) of studies and 28 (39%) studies validated scores
- Inter-rater reliability was measured in 26 (37%) studies

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Introduction

Historically hand hygiene compliance (HHC) in healthcare settings has been poor[1,2] despite its ability to reduce infection risk[3]. Regular HHC monitoring is recommended to improve and sustain compliance [4]. Robust, credible data are required to measure performance, promote and sustain evidence-based practice and quality improvement[5,6,7] 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 WHO hand hygiene observation method and data collection tool [9, 10].

Monitoring technology which may improve some validity issues has been developed and introduced[11,12,13] but is not used widely. Whilst regular HHC monitoring by direct observation continues to be promoted and utilized[14,15,16] despite the recognition of the potential to produce inaccurate and unrepresentative data[17-21]. Despite these shortcomings the observation of infection control practice helps to understand what is happening in practice and to provide meaningful feedback[22] and provided 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 through human error. Information bias[25], selection bias[26,27] and confounding bias[28] have been identified as the main types of bias that 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 criticised[18,19,20,21]. Criticism of HHC data includes observer bias, observer training, limited reliability, absence of corroborative methods of data collection[32,14,15,33] and sampling bias arising because data collection has taken place primarily during the day and on critical care units[32,14,15].

Validity related to Methodology

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

Information bias includes the Hawthorne effect[29] which has been identified in several HHC studies[11,38,39,40,41,] 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 30-50%[11,41]. Observers themselves may adopt behaviour 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 has the effect of increasing inter-observer variability[53] .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[54,55] Recording rapid successive actions and prolonged periods of observation can lead to recording errors[56,57]. Bias may also occur when HHC is linked to rewards[58].

Selection bias is possible when the sample is limited to specialist units or time periods not representative of all healthcare settings or the 24-hour period[1,2,59-66]. A wider selection of clinical settings, staffing and activity and avoiding self-selection of health workers reduces sampling bias[67,68] and systematic errors in data collection[69].Ad hoc samples may be unrepresentative compared to regular planned sampling, whilst continuous sampling may be more reliable than intermittent sampling[70].

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 randomisation 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 known confounding variables.

We undertook a systematic review to document bias in HHC studies.

Aims

1. Establish biases in studies where HHC is monitored by direct observation
2. Develop a taxonomy of biases
3. Make recommendations to improve the validity of HH monitoring

Methods

We included publications that reported use of direct observation to monitor health workers' HHC in health care facilities. All study designs were included. Complex

interventions were included if hand hygiene compliance by direct observation was a component. Published peer reviewed full text studies and reports were included. Papers 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 beyond 2015 were excluded as we were seeking a sample of papers 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, grey literature primarily from NHS portals was reviewed, suggestions from other experts were sought and hand search of current relevant literature was undertaken.

Initially the systematic reviews of Haas & Larson 2007[14],Gould et al 2008[71], Gould et al 2010[72], Erasmus et al 2010[16], Huis et al 2012[73], were examined and key terms used from these publications informed terms used in the search strategy.

MeSH 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', 'behaviour', 'reliability' 'validity' 'accuracy' and 'hand wash/washing', 'clean hands'. Terms were used in combination.

Subsequently results were checked to ensure the key authors literature had been identified in the search.

Limits 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; CINAHL with Full Text.

Studies were included if they assessed healthcare workers' HHC by direct observation in acute healthcare 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.

Fisher's 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 12 for data management and statistical analysis.

Results

5,206 abstracts were identified. Of these 118 full text publications potentially met the inclusion criteria and 71 were described in enough detail to be included (Diagram). No significant trends were detected according to country of origin (p = 0.259) or year of publication (p = 0.188). Most studies were from Europe or North America Table II. Table III summarises bias in publications. Table IV is a summary of results with references.

Information bias

The Hawthorne effect[29] was identified in 12 (17%) studies. Attempts were made to control it in 31 (44%) studies through covert or inconspicuous observation. One study was halted when staff became suspicious of observers[139]. The purpose of data collection is likely to have become clear in studies where HCWs were shadowed[97,101,105] received feedback[136], were sited in patient's rooms[89,91], exposed to prolonged observation periods[122] or subjected to intense observation. In one study each individual was observed for 2 hours per shift on three occasions[81] while in another simultaneous observation of the same individual by two observers took place[82]. Obtaining ethical approval is likely to have resulted in awareness of the purpose of the study. Informed consent was required in 11 (15%) and in 41 (58%) ethical approval was necessary. In one study compliance increased the longer auditors remained in the clinical area[20].

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, familiarisation and concurrent pilot or trial observations. In 9 (13%) studies, observers had previously received training. Method of training was only specified clearly in 23 (32%) studies. Validation of scoring within training was undertaken in 28 (39%) studies. In 15 (21%) studies observers were internal to the organisation and could have been known to staff. In 11 (16%) observers were external, in 45 (63%) studies the origin of observers was not stated or unclear, and in 12 studies (17%) the authors were observers.

In 47 (66%) study duration was <twelve months and 18 (25%) were > twelve months. In 18 (25%) observation was < one hour, in 16 (23%) it was ≥ one hour while in others observation took place continuously with 20-minute audits every 24 hours[123,122]. Audit frequency, study length, or both were not stated or unclear in 58 (82%) of 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. There were on-going tests for inter-rater reliability with use of the *kappa* statistic in 6 (8%) studies. Assessment of information bias was hampered by lack of details of the methods used in many studies.

Selection Bias

Sampling bias as a result of timing of observation, the setting where observation was conducted, or both was evident in all studies. Observations were restricted to single-specialty wards such as adult, neonatal critical care or paediatrics in 35 (49%) studies. Monitoring took place in more than one hospital in 11 (16%) studies. 54 studies (76%) reported time of the day when observations were conducted. 50 (70%) reported observation partly or entirely during the day. Observation at night was undertaken in 25 (35%) studies. Weekend observation was undertaken in 10 (14%) studies. Those observed were primarily doctors and nurses. In 16 (23%) studies occupational group was not specified. Occupational group of the observers was unspecified in 33 (46%) papers. In the others observation was conducted by students, infection control staff, nurses, researchers and doctors.

Confounding

27 studies (38.0%) attempted to control for confounding by measuring confounding variables and used this data to undertake a multivariate analysis.

Comparability of studies

Data from the different studies were not comparable as the definitions of hand hygiene and hand hygiene compliance; measurement criteria, including hand of 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 seven different terms.

Most studies did not specify how they undertook the observations in detail. The number of observations undertaken, or other outcome measures was not reported or was unclear in 12 studies. The periods of time observed, 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 reported to have been 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 the four of the recommended Five Moments for hand hygiene[81,82,116.] In 7 studies the nature of the data collection tool was not apparent.

These variations and adjustment in the tools used in studies made summarising and comparing the criteria used for measurement difficult. For example Boscart et al[81] used the 'Ontario tool' in 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. According to the criteria adopted in some data collection tools, failure to perform hand hygiene after removing gloves was considered non-compliant[83,84,141] whilst in others glove use was not included as part of HHC monitoring.

Other differences included only stipulating hand hygiene following contact with a contaminated environment or objects, rather than all patient environments[85,100] . This extended to applying a risk assessment to criteria in some studies[112,114] .

Three studies adopted very specific actions and expectations[109,125,138] for hand hygiene opportunities whilst others referred to standard criteria such as 'WHO Five Moments'. Others were specific but omitted to explain if the expectation was before and after contact[132]. Other adjustments included excluding the first patient contact because observers were waiting outside the patient room and could not see if the health worker had cleaned their hands in the previous room[113], whist others focused only on hand hygiene before contact with the patient as it was perceived to be important and to simplify the observers' task[126].

Other measurements

Hand hygiene product usage was measured in 14 (20%) studies though the method varied and was mostly limited to staff assessing how much was left in individual dispensers[83]. Only 15 (20%) studies assessed 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 summarised in Table I and the potential bias for each paper is identified in Table II. The extent of bias identified in this review are summarised in Table III. Types of bias identified reflect those reported in earlier, narrative reviews[32,14,15,33,16].The most frequent forms of selection bias found were associated with limiting the number of hospitals studied, and not monitoring week-ends. Whilst internal rather than external observers and the frequently of observation were the most frequent forms of information bias identified.

Though 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 is a sample of behaviour which will be affected by several variables. Though potentially inaccurate, if the methods, conditions and degree of error are relatively constant, then the results of observation may be a pragmatic indicator of performance for inspection of trends, although this could also apply to other forms of bias.

Limitations of the review

The main limitation of the 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 published accounts. Hand hygiene is assessed as part of a complex intervention in many infection prevention studies and the search strategy, although comprehensive, may not have identified all potentially eligible reports. In studies where hand hygiene would not be the main outcome measure, it is unlikely that hand hygiene methodology would have been described in enough detail to permit extraction information required for the review.

Conclusions

Multiple sources of bias were detected in all studies where HHC is 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[142]. Observation is used to assess clinical competence[143] and to gain insights into what happens in practice. Developing insight may lead to the rejection or modification of established assumptions to develop a new approach to issues[144]. This may also lead to the challenge 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 as attention may be highly selective[145]. Even experienced observers may be subject to in-attentional blindness when focused on a single process which is familiar and predictable[146].

However, experienced observers may be more successful than a novice at detecting patterns and anomalies[147]. Expertise and preparedness create a 'search image' which combined with situational awareness filters out irrelevant information which may overwhelm the analytical skills of a novice[148]. 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 utilisation of improvement opportunities, could add value to the observation monitoring process. Other significant factors which influence compliance may include ambiguity[149] and lack of self-efficacy[150] 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 hand hygiene compliance would not be valid and is unlikely to be affordable[13]. Automated options are available but 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 are required which reduces data collection errors and variability and assists in improving compliance.

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151	Ward MA, Schweizer ML, Polgreen PM, Gupta K, Reisinger HS, Perencevich EN. Automated and electronically assisted hand hygiene monitoring systems: a systematic review. Am J Infect Control 2014;42(5):472-8.

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Table I Data collection of bias and rational for inclusion

Information extracted	Rationale
When was the study published?	Provides context particularly as in earlier studies HHC monitoring was not well established
Where was it undertaken	Generalizability- external validity [25] and to identify sample selection bias[70]
Ethical or equivalent approval and or consent for participation (HCW)	Requirement for consent for participation may lead to self-selection[14] e.g. for poorly performing staff to opt out or high performing staff to opt in. This would create selection bias[70] 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[76], inter observer variability[55] and reactive effect of observation[44]
Internal or external observers	Observer bias due to allegiance[45,11] or knowledge of people and or area, reactive effect of observation[44].
Preparation and training of observers	Inter observer variability[55], observer drift[56], observer bias[76], measurement bias (errors)[56] may occur if observers are not prepared[57]
Overall time period in the duration of the study that observation was undertaken	Observer drift[56] may occur over a long period. Measurement bias may occur with variations in observers or clinical practices over a long period. Inter observer variability[55] related to numerous observers
How long were observers observing for on each occasion	The novelty effect of being observed may diminish with time[46]. Observer drift or fatigue[56] & measurement bias may occur in long sessions.
How frequently did they	Reactive effect of observation may reduce if it is a routine[46]; measurement bias may occur if observers

undertake observations	are rarely undertaking measurement. Very limited measurements may not be generalizable[25]
Who was being observed	To identify sample selection bias[70]
Monitoring tool utilized (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[78]
Covert or overt observation (obtrusive unobtrusive)	Reactive effect of observation[44]
Reason for monitoring /measuring	Confirmation and other bias related to influence[42,77,53], selection bias
Definitions of HHO & HH	Comparability of results
Quality of HHC recorded, was it measured?	Complexity of measurement,
Number of observations or other criteria such as HH opportunities	Comparability of results
Reliability tests used	Reliability
Product measured	Confirmatory
Was author of the paper an observer	Confirmation bias[42,77,53]
Time of day, nights and weekend	Sample selection bias & comparability
What did they actually do?	Validity related to replication

Diagram I Search Flow Diagram (based on Moher et al 2009[152])

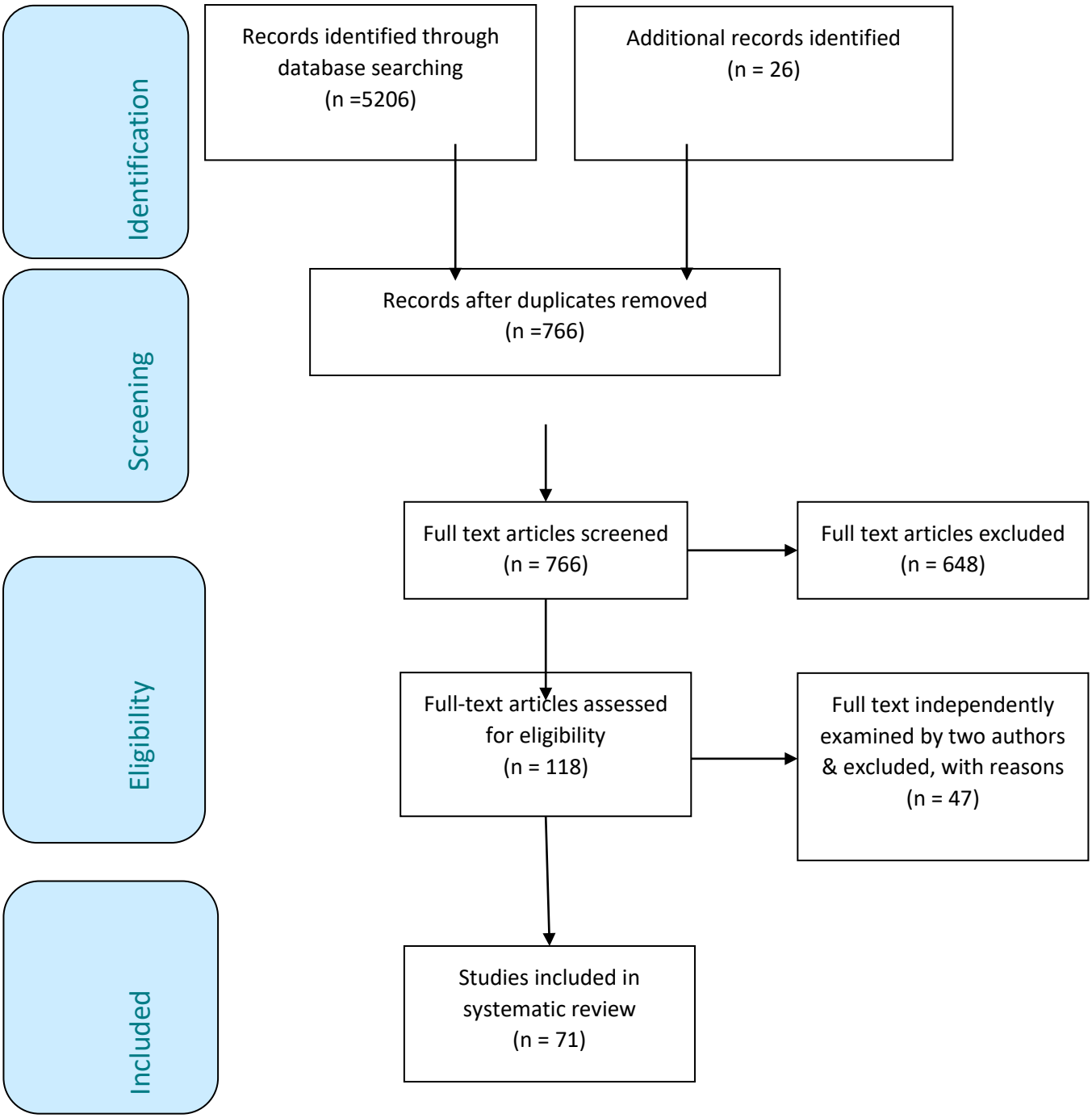

Table II Papers selected for systematic review detail of origin and type of potential bias identified

Reference in text	Paper	Year of publication	Country	Type of potential bias identified Selection bias - S Information bias =I Confounding bias =C
74	Abela N, Borg MA	2012	Malta	S, I, C.
75	Aboumatar H, Ristaino P, Davis RO, et al	2012	USA	S, I, C.
76	Allegranzi B, Sax H, Bengaly L et al	2010	Mali	S, I, C.
77	Allegranzi B, Gayet-Ageron A, Damani N et al	2013	Costa Rica, Italy, Mali, Pakistan, Saudi Arabia	S, I.
78	Al-Wazzan B, Salmeen Y, Al-Amiri E et al	2011	Kuwait	S, I, C.
79	Biddle C, Shah J.	2012	USA	S, I, C.
80	Bischoff WE, Reynolds TM, Sessler CN et al	2000	USA	S, I, C.
81	Boscart VM, Levchenko AI, Fernie GR.	2010	Canada	S, I, C.
82	Boscart VM, Lee JH, Márquez-Chin C et al	2011	Canada	S, I, C.
83	Brown SM, Lubimova AV, Khrustalyeva NM et al	2003	Russia	S, I, C.
84	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.
85	Creedon SA.	2006	Ireland	S, I, C.

86	Dedrick RE, Sinkowitz-Cochran RL, Cunningham C,	2007	USA	S, I, C.
87	di Martino P, Ban KM, Bartoloni A, 2011	2011	Italy	S, I, C.
88	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.
89	Eveillard M, Hitoto H, Raymond Fet al	2009	France	S, I, C.
90	Eveillard M, Pradelle MT, Lefrancq B, et al	2011	France	S, I, C.
91	Eveillard M, Raymond F, Guilloteau V et al	2011	France	S, I, C.
92	Fuller C, Savage J, Besser S et al	2011	UK	S, I, C.
93	Golan Y, Doron S, Griffith J et al	2006	USA	S, I, C.
94	Harbarth S, Pittet D, Grady L et al	2001	USA	S, I, C.
95	Harne-Britner S, Allen M, Fowler KA et al	2011	USA	S, I, C.
96	Helder OK, Brug J, Looman CW et al	2010	The Netherlands	S, I, C.
97	Huis A, Schoonhoven L, Grol R et al 2013	2013	The Netherlands	S,I.
98	Johnson PD, Martin R, Burrell LJ et al	2005	Australia	S, I, C.
99	Korniewicz DM, El-Masri M	2010	USA	S, I, C.
100	Lam BC, Lee J, Lau YL. 2004	2004	Hong Kong	S, I, C.

101	Lankford MG, Zembower TR, Trick WE et al	2003	USA	S, I, C.
102	Larson EL, Albrecht S, O'Keefe M. 2005	2005	USA	S, I, C.
103	Laustsen S, Lund E, Bibby BM et al	2009	Denmark	S, I, C.
104	Linam WM, Margolis PA, Atherton H et al	2011	USA	S, I, C.
105	Luke, Molli M, Alavosius M.	2011	USA	S, I, C.
106	Marra AR, Moura DF Jr, Paes AT et al	2010	Brazil	S, I, C.
107	Mathai AS, George SE, Abraham J.	2011	India	S, I, C.
108	Mayer J, Mooney B, Gundlapalli A et al	2011	USA	S,I.
109	McArdle FI, Lee RJ, Gibb AP et al	2006	UK	S, I, C.
110	McAteer J, Stone S, Fuller C et	2008	UK	S, I, C.
111	McLaws ML, Pantle AC, Fitzpatrick KR et al	2009	Australia	S, I, C.
112	Meengs MR, Giles BK, Chisholm CD et al	1994	USA	S, I, C.
113	Mertz D, Dafoe N, Walter SD et al	2010	Canada	S, I, C.
114	Mestre G, Berbel C, Tortajada P et al ,.	2012	Spain	S, I, C.

115	Monistrol O, Calbo E, Riera M et al	2011	Spain	S, I, C.
116	Mukerji, A., Narciso, J., Moore et al	2013	Canada	S, I, C.
117	Novoa AM, Pi-Sunyer T, Sala M,	2007	Spain	S, I, C.
118	Pan A, Mondello P, Posfay-Barbe K et al	2007	Italy	S, I, C.
119	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.
120	Pittet D, Mourouga P, Perneger TV	1999	Switzerland	S, I, C.
121	Pittet D, Stéphan F, Hugonnet S, et al	2003	Switzerland	S, I, C.
122	Randle J, Arthur A, Vaughan N et al .	2014	UK	S, I, C.
123	Randle J, Arthur A, Vaughan N.	2010	UK	S, I, C.
124	Rosenthal T, Erbeznik M, Padilla T et al	2009	USA	S, I, C.
125	Sahay S, Panja S, Ray S et al	2010	India	S, I, C.
126	Saint S, Bartoloni A, Virgili G et al	2009	Italy	S, I, C.
127	Saint S, Conti A, Bartoloni A et al	2009	Italy	S, I, C.

128	Scheithauer S, Haefner H, Schwanz T et al.	2009	Germany	S, I, C.
129	Scheithauer S, Oberröhrmann A, Haefner H et al.	2010	Germany	S, I, C.
130	Scheithauer S, Oude-Aost J, Heimann K et al	2011	Germany	S, I, C.
131	Scheithauer S, Kamerseder V, Petersen P et al	2013	Germany	S, I, C.
132	Smith SJ, Young V, Robertson C et al	2012	UK	S, I, C.
133	Son C, Chuck T, Childers T et al	2011	USA	S, I, C.
134	Steed C, Kelly JW, Blackhurst D et al.	2011	USA	I,C
135	Tromp M, Huis A, de Guchteneire I et al	2012	The Netherlands	S, I, C.
136	van den Hoogen A, Brouwer AJ, Verboon-Maciolek MA et al	2011	The Netherlands	S, I, C.
137	Venkatesh AK, Pallin DJ, Kayden S et al	2011	USA	S, I, C.
138	Wendt C, Knautz D, von Baum H.	2004	Germany	S, I, C.
139	Whitby M, McLaws ML.	2004	Australia	S, I, C.
140	White CM, Statile AM, Conway PH et al	2012	USA	S, I, C.

141	Won SP, Chou HC, Hsieh WS et al	2004	Taiwan	S, I, C.

Table III 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 week-ends?	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
Inter-observer variation measured?	Information	45	63.4
External vs internal observers	Information	60	84.5
Multivariate analysis	Confounding	44	62

Table IV Summary of results with references

Information bias	**N papers** (%)	**References**
The number of observers in each audit not stated	31 (43.7)	2,75,77,79,84,86,88,89,91,92,93,95,96,98,99,101,106 ,108, 111,112,115,116,118,122,124,133,135,136-8,140
1-2 people were involved in each audit	33 (46.5)	39,74,76,78,80-3,85,90,94,97,100,102,103,105,107, 109,110,114,117,119,120,123,125,128,129,130-2,134, 139,141,
Observers were trained	56 (78.9)	20,39,75,76,78,79,81-4,86-8,90-5,97,99-104,106, 108,110,111,113-28,131-6,138-41
Observers had received training previously	9 (12.7)	92,115,119,121-3,127,128,131
The method of training was specified clearly	23 (32.4)	75,78,79,82,84,88,92,95,97,101,104,106,108,111,114 , 116,124,126,127,134-6,141,
Validation of scoring within training was undertaken	28 (39.4)	2,39,75,79,82,84,92-4,96,102,108,114,116,119,120, 131,134,136,
Observers were internal to the organisation	15 (21.1)	39,80,93,98,104,108,109,111,114,132,133,136,138,140,141,
Observers were external to the organisation	11 (15.5)	79,83,87,89,90,91,103,124,126,127,139,
The origin of the observers was not stated or unclear	45 (63.4)	2,20,74-8,81,82,84-6,88,92,94,95-7,99-102,105-7,110,112,113,115-23,125,128-31,134,135,137
The authors are observers	12 (16.9)	2,78,80,81,85,98,103,109,110,119,126,127
The duration of the study was under 12 months	47 (65.3)	2, 39, 76,78-80,82,83,86-8,90-2,94,95, 98-102,105-7, 110-12,115-7, 119-23,125-28 130-32,134-36,138,139,
The duration of the study was more than 12 months	18 (25.4)	20,74,75,77,81,93,96,97,103,104,108,113,114,124,133, 137,140,141,
Length of observation period was under	18 (25.4)	77, 78, 81,82, 84, 94, 98,107,111,113,115,118, 119,122,123,132,134,139,

an hour		
Length of observation was at least one hour	16 (22.5)	39, 80, 83, 85, 92, 93, 96,101, 102, 106, 109, 110, 112, 128, 130,141,
Audit frequency or study length, or both were not stated or unclear	58 (81.7)	2,20,39,74-7,79,80-6,88-94,96-101,104,105,107-12, 114-21,123-32,134-8,140,
The frequency of observation measurement was clearly stated	16 (22.5)	75, 92, 95,102-3,106,108,113-4,122,124,131,133, 139-41,
Inter-rater reliability checking was undertaken	26 (36.6)	2,39,74,75,78,79,81,82,84,94,95,96,102,103,105, 108,110, 113,114,115, 116,119,120,131,134,136
Inter-rater reliability was undertaken only in training	16 (22.5)	39,74-5,78-9,82,84,94-6,102,108,116,119,131,136
Practiced on-going tests for inter-rater reliability (e.g. kappa statistic)	6 (8.45)	81,103,105,110,114-5
Attempted to control for Hawthorne effect bias by covert or inconspicuous observation	31 (43.7)	74-5,78-80,83,85,86,88,92-94,96,97,100-1,104,106, 108-9,112,117,120-1,125,132,135,138-9,141,
Required informed consent from staff	11 (15.5)	81, 84, 119, 97, 99, 105, 112, 115, 122, 123, 131
Required ethics or a similar approval process	40 (56.3)	2, 74, 76, 78-9, 81-2, 84-5,87,91-2,93-7,99,102-104,106, 110, 112-5,119-23,125-7,132,134-5,137,139
Selection Bias	**N papers** (%)	**References**

The observations were undertaken in single-specialty ward locations such as adult and neonatal intensive care or paediatrics	35 (49.3)	39,74-5,79,81-3,85-7,93-4,96,99,100,104-7,109,112,116,119,121,124-5, 128-32,136-7,140-1
Reported monitoring locations in more than one hospital	11 (15.5)	77, 78, 84, 90, 92, 97, 111, 113, 127, 126,134
Studies that detailed the time of day when observations were carried out	54 (76.1)	2,20,39,74,78,80-6,88,94-10,112-5,117,119,120-5,128-30, 132-9, 141,
Studies that did observations the night-time	25 (35.2)	2,78,84,99,102-4,106,108,115,117,119,120,122-3, 125, 128-30, 133-4,136-8,141
Observations were carried out also in the week-end	10 (14.1)	20,88,106,108,112,120,134,137,138,141
The role of the observed HCW was not specified	16 (22.5)	74, 89, 91, 92, 98, 99, 102, 113, 116, 124, 128, 129, 133, 134,139,
The professional role of the observers was unspecified	33 (46.5)	2, 20,74-5,77, 81-2, 86-8,90,94-5, 103,105, 108-12, 114, 118-9,121-3, 125,129-31,133, 136-7,
Confounding bias		
Attempted to control for confounding bias by measuring confounding variables and used these data to undertake a multivariate analysis	27 (38.0)	2, 39, 76-7, 83, 86, 88, 92-4, 97, 99, 101, 103,108,110, 117,119-23,126,132,135,137,
Comparability		
The number of observations undertaken was	12 (16.9)	20,74,96,98,104,105,109,112,124,133,140,141,

not reported		
Definitions of HH and HHO were unclear	4 (5.63)	78,83,84,99
Reported that they used standard tools such as the WHO compliance tool	32 (45.1)	74, 76-7, 81-2, 88-9, 91, 94, 98, 101, 106, 112, 114-6, 118-9, 122-3, 125, 128, 130-1,134-5, 137-41
Created their own reporting tool	17 (23.9)	2,75,80,83,92,95,99,100,108,110,117,120,121,124,129, 132,136,
Modified or adapted the/ a standard tool	15 (21.1)	20,39,79,84-5,87,90,93,98,105,111,113,126-7,133
Unclear what reporting tool they used	7 (9.86)	78, 86, 87,102, 107,109,130
Measured hand hygiene product usage	14 (19.7)	75,80,83,92,96,98,102,106,114,115,119,128,129,130,
Assessed hand hygiene method which variously included time taken, coverage of hands, drying and turning off taps	15 (21.1)	84,89,91,96,100, 103, 105,107,112,113,124,125,129, 136,140,