Title: Collecting the data but missing the point: validity of hand hygiene audit data.

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Summary:

Background: Monitoring of hand hygiene compliance (HHC) by observation has been used in health care for more than a decade to provide assurance of infection control practice. The validity of this information is rarely tested.

Aim: To examine the process and validity of collecting and reporting HHC data based on direct observation of compliance.

Methods: We examined 5 years of HHC data routinely collected in one large NHS hospital Trust. We reviewed the data collection process by survey and interview of the auditors. We compared HHC data collected for other research purposes undertaken during this period to the organisational data set.

Findings: There was an increase in reported compliance during this period. Examination of the data collection process revealed changes including local interpretations of the data collection system which invalidated the results. A minority of auditors had received formal training in observation and feedback of results.

Conclusions: Unless data collection definitions and methods are unambiguous, carefully supervised and regularly monitored, variations may occur which affect the validity of the data. Whilst observation of HHC is the current gold standard, in the absence of a standardised consistent methodology, by trained and supervised observers with intermittent validation it is not a robust approach to collecting accurate monitoring data. If the purpose of HHC monitoring is to improve practice then a focus on progressively improving performance rather than on achieving a target may offer greater practice improvement opportunities.

Key words: hand hygiene, direct observation, assurance, monitoring,

Background

Optimal hand hygiene practice is recognised as a key infection prevention and transmission intervention[1]. Hand hygiene compliance (HHC) in healthcare has traditionally been low[2,3]. Observation, audit and feedback of performance combined with education and the introduction of alcohol hand rub have been successfully used to increase compliance[1,4,5,6,7] although improvement was not always sustained[8].

HHC monitoring by direct observation has subsequently become regarded as 'gold standard' for measuring and reporting compliance[9,10]. Coupled with feedback, it is established practice in English hospitals[11] where participation in the 'cleanyourhands' campaign included the mandatory monitoring and feedback of hand hygiene compliance by direct observation[12]. Many healthcare organisations currently collect and report this information to provide

assurance of HHC. The expectation is that compliance is high and 100% compliance is a common aspiration.
There are recognised limitations associated with measuring observed behaviour including the Hawthorne effect[13] , observer bias[14] and observer drift[15]. Such limitations may have a significant effect on the accuracy of the data collected and reported particularly if observers are not trained and monitored[16].
This paper examines the validity of the HHC data and the data collection method in one healthcare organisation over five years. Validity is generally divided into the terms internal and external validity. Internal validity refers to the ability of the test to accurately measure what is required avoiding bias or error. Bias can be divided into three categories:

- **Selection** e.g. what group was selected for measurement
- **Information** e.g. consistency of data gathering methods
- **Confounding** e.g. the measurement of a confounding factor

External validity relates to the generalisability or extrapolation of results[17].

Introduction

In 2004 alcoholic hand decontamination was introduced to an acute hospital with >900 beds which had increased to >1000 beds by 2012. In 2005 the mean HHC of the organisation was <20%. In 2008 the organisation-wide hand hygiene compliance monitoring process commenced. In the next three years >4000 staff were trained in hand hygiene practice and hand washing facilities were improved. At the end of 2008 the mean HHC for the organisation had increased to 78% (9,328 hand washing events for 11,954 hand cleansing opportunities) with some diversity in specialities. By this time >100 staff (predominantly nurses) from 51 wards and departments were trained to undertake direct observation of HHC and provide feedback of performance to staff. The compliance tool used throughout the organization was adapted from the Lewisham tool[18] and incorporated the WHO 5 moments of hand hygiene[19]. The organisation set an improvement target of 85% rising by 5% annually until 100% was achieved. The hand hygiene policy was revised to clarify expectations and consequences of non-compliance which included disciplinary action.

By 2012 the number of wards and departments submitting monthly HHC data rose to a maximum of 98 which included all eligible areas, and the number of yearly hand cleansing opportunities had more than trebled to 42,143. The results were reported, with other organisational performance metrics, in a departmental score card and reviewed monthly by the executive board. Wards and departments were encouraged to display the latest performance data locally on infection control notice boards situated in public areas.

In 2012 the mean HHC for the organisation was 94% and reporting compliance (i.e. the percentage of departments actually submitting data) was 89% (1031 reports sent out of 1164 reports requested). Areas with scores below a lower threshold (85% in 2012) were followed up by the infection control team and managers were alerted. However the reported data were

at times at odds with observed practice, feedback from service users and random checks. This prompted an examination of the methodology and validity of the data collection process.

Methods

A number of methods were used to obtain a more comprehensive picture of the data collection process.

Standard routine organization-wide HHC data collection process - Most wards submit their monthly report and reminders are sent towards the end of each month. We manually check for anomalies, process the results and store them in a secure database by means of a computer programme; these data are subsequently used to calculate ward, divisional and board level hand hygiene compliance statistics. The monthly reports compliance is calculated as HHC = HHE / HHO x 100 where HHE are the number of hand hygiene events observed and HHO are the number of hand hygiene opportunities during three 20-minutes sequential periods in one ward or department.

Additional hand hygiene compliance data – these data were collected for research purposes in the organisation during the same time period and were compared to the routine data set[20] and another unpublished study by the same group..

Staff survey and interviews - We used an online structured questionnaire tool ('Survey monkey') to assess the level of training, knowledge and the learning needs of the staff monitoring hand hygiene compliance; six months later we used a questionnaire based interview to improve the response rate and obtain a more comprehensive picture. This included additional questions about actions taken if scores were high or low and perception of value and satisfaction with the process.

Product usage –On examination of the purchasing data for the preceding 5 years we found that this related to where the product was delivered to rather than where it was used. It was concluded that this was of little value in determining ward based usage and was not examined further.

Data analysis – All statistical analyses were carried out in STATA 12.0. We used hand-hygiene compliance data collected between 2008 and 2012. As % compliance and the number of hand hygiene opportunities are not necessarily normally distributed statistics we used medians and interquartile ranges for descriptions of the distribution of % compliance. To test the significance in the difference between samples of hand hygiene compliance estimates we used non-parametric statistics and tests because of the non-normal nature of HHCs and the relatively low sample sizes, such as medians and the two-sample Wilcoxon rank-sum (Mann-Whitney) test. P-values less than 0.05 were considered statistically significant.

Results

The number of hand hygiene opportunities - The reported number of hand hygiene opportunities peaked in 2009 and remained high over the remaining period (Table I), although this number varied widely between reporting locations, some of which reported zero opportunities (making it impossible to assess hand hygiene compliance), others reported as many as 615 opportunities (equivalent to one opportunity observed every three seconds). Some locations showed significant declines in the average number of observed hand hygiene opportunities (Table II). The Neonatal Unit observed the opposite trend, rising from an average of 32 opportunities in 2008 to 241 in 2011. This directly related to the employment of an embedded infection control nurse who undertook regular comprehensive monitoring.

Hand hygiene compliance - Between 2008 and 2012 hand hygiene compliance increased from 78% to 95% (Figure 1). Table III shows the degree of heterogeneity between wards and departments. 63% of all submitted reports declared hand hygiene compliance below 85% in 2008 and by 2012 this percentage had fallen to 11%.

Frequent changes in configuration and location of services, made the interpretation of differences in compliance scores in wards and departments difficult. Many data sets were incomplete or not directly comparable as wards had moved, closed, opened and split.

A small number of departments had modified the data collection methodology with the Infection Control team, e.g. theatres and emergency department; as the observation monitoring tool of the organisation did not reflect the context or activity in the area. Some areas had independently changed the methodology and format of data collection. Other wards with low scores were not reporting the data. Administrators reported that some areas repeatedly submitted the previous month's data.

Additional compliance results. One research project[20] that took place between October 2011 and April 2012 carried out 157 independent estimates of hand-hygiene compliance from three separate wards (Table IV). The median% compliance is always much lower than that from routine monitoring: 50% vs 91% (ward 1; p=0.0135), 43% vs 97.5 (ward 2; p=0.0045) and 40% vs 100% (ward 3; p=0.0053). The extent of the bias is evident when considering that the 3rd inter-quartiles from the research project were always much smaller than any reported by routine surveillance over the same time period. Another unpublished independent study carried out in 2009 on a single ward showed 30.7% compliance (HHE = 113, HHO = 368) on ward bays and 48.1.% compliance in isolation rooms (HHE = 25, HHO = 52), both much smaller than the median of 82.7 from the 8 routine monitoring reports received in the same year (Interquartile range: 80.5, 84.8).

Staff survey - A short online survey of the learning needs of hand hygiene auditors was undertaken. Seventy -one members of staff who had reported hand hygiene compliance data were invited to participate and 18 (25%) responded: 13 (72%) had collected data for more than 2 years, 7 (39%) had not received any training and one person was not sure. The period

of observation varied widely between 10 to > 60 minutes. Several auditors collected data for more than one area. Additional feedback included a number of criticisms and comments including:

- '*cumbersome and time consuming'* process
- the tool was '*useless in identifying what is needed to improve practice'*
- '*no more than a tick box exercise as obtaining a low score is unacceptable'*

Interviews-– We interviewed 52 hand hygiene observers from 61 of 104 clinical areas where reporting was routinely undertaken. One person undertook all interviews. Interviewees were predominantly nurses but included nursing assistants, dental nurses, physiotherapists and housekeepers.

Training: - only 22 (42%) had received the formal training in observation and feedback of results provided by the infection control team and 3 (6%) had received an update on their training; other responses included '*I can't remember'*, '*I learnt from the form'*, '*self taught'* and '*Someone on the ward showed me for 20 minutes'*.

Time taken to undertake monitoring*:* - 35 (67%) were allocated no time to collect the data and did it in their breaks or when there was a quiet period; the time spent by staff doing the monitoring ranged from 20 minutes to 7.5 hours a month; some undertook individual approaches such as '*I do it all the time rather than for periods of time*' and '*3-5 minutes per patient - longer if in a quiet period*'; the frequency of observation also varied ranging from daily to monthly.

Changes to the data collection methodology:- the organisation had removed low risk scores from the target within the first year of auditing; this led to staff not collecting or reporting this data in some areas whilst in other areas they continued to collect but not report it: only 13 (25%) were aware of any changes in the audit and 21 (41%) routinely varied the period of observation; comments included: '*it changes from week to week'* and *'it depends how busy the ward is'*.

What happens if score is very low or very high: - 13 (25%) redid the audit until a high score was obtained; comments included *'if it's >85% report it as it is, if it's <80% I redo it and remind staff'* and '*Low score - disregard and redo another time'*.

Additional findings: - the majority of auditors were nurses including ward sisters; on the basis of 60 minutes observation per month, 30 minutes data input and feedback this was calculated to cost more than £28,800.00 per annum for the organisation

Discussion

Despite widespread use of hand hygiene monitoring by observations this is one of the first studies to explore how well it is undertaken although this is only in one organisation. The data collection process had changed with time. The data collected and reported varied amongst auditors. This is not a unique finding; in a study of several centres collecting central intravenous line infection data Dixon-Wood[21] found 'localized interpretations rather than a standardized dataset' (page 548). 'Observer drift' where definitions used by observers change

is a recognised phenomenon[15]. In this instance it was probably due to insufficient training, supervision and inadequate validation of the data collection process.

Staff spent less time collecting data than was initially envisaged and conducted it at times when the ward or department was not busy. This was influenced by the lack of time allotted and a lack of recognition of the requirement to collect a representative, comparable and consistent data set.

The tool and method was more than six years old and had not been revised. It did not reflect changes and constraints such as dependency, case mix, workflow and workload. Some areas had already opted out of the system and either used a tailored tool focused on continuous quality improvement or something they had developed themselves. Whilst standardisation of the data collection system makes analysis and comparison easier, variations will emerge and this may be useful in reflecting local risks and requirements.

There was evidence of not reporting and repeating low score audits although this was not widespread. It was easier to report a high score than a low score as a low score required action to improve. 'Observer bias' has been described previously in which researchers were influenced to produce positive results[14].

Some of the staff interviewed collected the data but anticipated no change in practice. The purpose of data collection became a process of providing assurance that targets were achieved rather than one of continuously identifying where practice improvements could be made. The assumption that data collection provides a 'dial' rather than a 'tin opener' which could reveal a can of worms, is a recognised phenomenon in measures of organisation performance[22].

The omission in compliance reports of hand hygiene opportunities which were perceived to be low risk, recording observations at quiet times and repeating audits which gave a low score, produced an incomplete and inaccurate picture of practice. Although considerable reliance was placed on these data within the organisation, it engendered overestimates of compliance. This is therefore false assurance and it is not a useful comparator.

The organisation was successful at collecting these data and reported a high level of compliance related to the target. Initially there was a momentum of improvement but this flattened out in time as the target was near achievement. This may have led to an assumption that hand hygiene compliance was generally adequate. The measurement of hand hygiene practice is a process; the desired outcome and the value of the undertaking is a reduction in transmission and acquisition of infection. Collecting poor quality data does not contribute to value or positive outcomes[23].

Hand hygiene compliance data can be collected in other ways including product usage and automation although this can be expensive and has limitations[16]. A benefit of direct observation is that it produces a change in behaviour[24] and an opportunity to observe other practice or standards. The effect on behaviour is also problematic as the behaviour observed may not be representative. Much of this reporting was also in effect self reporting by staff with an alliance to the area. Both self reporting and an alliance affect the objectivity and may effect results[25, 26].

The role of training and supervision in managing ambiguity and achieving a consistent standard of monitoring and data collection is important but time to undertake the work and training is also required.

The internal validity of the data collected and examined in this study was poor. The effect of observation on hand hygiene compliance is already known to affect the results obtained. The lack of consistency in the methodology used and lack of training or standardisation of auditors are threats to the validity of the data collected. There was also considerable risk of bias in the selection of what and who is observed, particularly as it is self reporting by an interested party. The data is not representative of all activity as it is undertaken in the day time and often at quiet periods. In addition there was some instrumental bias as with time observational methods and practice changed.

Whilst observation of HHC is the current gold standard, in the absence of a standardised consistent methodology, by trained, supervised observers and intermittent validation, it is not a robust approach to collecting accurate monitoring data. However if the purpose of HHC is to improve practice rather than to meet a target, a focus on improvement offers opportunities to examine in detail the barriers and opportunities to increase hand hygiene compliance rather than focus on non compliance. This would also facilitate an adaptable system which reflects local risks and requirements. As a result of this work this approach was subsequently developed.

This work was based on a small sample confined to one organisation. This may not be representative or generalizable. It would be useful to repeat this exercise in other organisations to compare results.

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TABLE I. Average number of hand hygiene opportunities reported in the monthly reports. IQ = interquartile.

Year	Number of locations	Number of reports	Number of hand hygiene opportunities:					
			Min	1st IQ	Median	Mean	3rd IQ	Max
2008	75	390	0	9	19	30.4	40	244
2009	87	536	2	18	32	46.1	60	370
2010	96	975	1	15	29	42.3	54	384
2011	95	995	0	13	26	38.3	49.5	615
2012	104	1041	0	17	29	40.3	52	543

TABLE II. Wards and departments with a declining trend in the average number of hand hygiene opportunities (the peak figure is marked in bold).

Ward	2008	2009	2010	2011	2012
Ward 1	27	44	**49**	36	32
Ward 2	32	**75**	64	54	48
Department 1	51	**92**	46	38	32
Ward 3	60	**103**	74	68	60
Ward 4	8	47	**94**	47	36
Ward 5	14	**72**	52	22	24
Ward 6	14	**69**	46	19	23
Department 2	0	**28**	24	17	10
Department 3	53	**87**	63	52	49
Department 4	-	22	**30**	17	10
Department 5	-	**199**	149	27	36
Department 6	2	**34**	31	29	21
Ward 7	10	82	**158**	72	41
Department 7	16	38	**52**	43	25
Ward 8	85	**131**	127	68	65

Table III. Hand hygiene compliance (%) reported in the monthly reports. IQ = interquartile. See text for more detail. *2013 relies on data collected in the first 6 months of the year only. The last three columns show the percentage of reports declaring <85%, 90% and 95% hand hygiene compliance respectively.

Year	Min	1st IQ	Median	Mean	3rd IQ	Max	% <85	% <90	% <95
2008	0	63	79	74	90	100	63	75	87
2009	20	80	89	86	94	100	35	53	77
2010	0	87	93	90	97	100	21	35	65
2011	23	91	96	94	100	100	10	19	45
2012	30	92	96	94	100	100	11	19	41
2013*	42	92	97	95	100	100	10	15	37

Table IV. Median hand hygiene compliance measured independently of the routine surveillance, from three ward locations. Numbers in round brackets are sample sizes.

Ward: Month:	Ward 1	Ward 2	Ward 3
October 2011	50 (13)	33 (11)	34.5 (12)
November 2011	50 (5)	53.5 (8)	40 (9)
December 2011	46 (6)	42 (3)	43 (3)
January 2012	55 (11)	50 (7)	35.5 (12)
February 2012	-	-	-
March 2012	40.5 (20)	-	47 (28)
April 2012	-	43 (9)	-
Overall median	50 (55)	43 (38)	40 (64)
1st Interquartile	38	35.3	33
3rd Interquartile	60	55.8	50.5
Maximum	100	75	86
Routine surveillance	91 (7)	97.5 (5)	100 (5)

FIGURE 1 LEGEND

Figure: Organization-wide hand hygiene compliance (HHC) for Board A (thick black line), .Board B (thick grey line) and Board C (broken thin black line).

FIGURE 1