Report to the Patient Safety Research Programme

on

“The National Observational Study to Evaluate the Cleanyourhands Campaign (NOSEC)”

and

“The Feedback Intervention Trial (FIT)”

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Section 1. Introduction.

1.1 Background to the evaluation of the cleanyourhands campaign (NOSEC)
The cleanyourhands campaign (CYHC) (1) was rolled out to healthcare workers (HCWs) in all 187 English and Welsh NHS acute hospital Trusts in 2004. Its aim was to combat high endemic levels of healthcare associated infection (HCAI) (2-4) and low levels of hand hygiene compliance (5). Centrally funded by the Department of Health (DoH) and planned, designed and co-ordinated by the National Patient Safety Agency, the campaign, recognised as the first such national campaign in the world (6) was introduced at a time when reduction of HCAI, and in particular, meticillin-resistant *Staphylococcus aureus* bacteraemia (MRSAB) and *Clostridium difficile* infection (CDI), had become a national priority. This followed a period (1999-2004) during which a DOH funded study (2), two National Audit Office reports (5,7) and subsequent Parliamentary Accounts Committee responses (8,9), resulted in national mandatory reporting of MRSAB, meticillin-sensitive *S.aureus* bacteraemia (MSSAB) and CDI (3,4). NHS plans were also published (10, 11) emphasising the importance of hand hygiene.

The NPSA carried out and evaluated a pilot in 2004 (12) of the campaign, whose main components were interventions reported (13-15) to be effective at the level of the single hospital (14) or individual unit (15). These were provision of alcohol hand rub (AHR) at the bedside, distribution of posters reminding Health Care workers (HCWs) to clean their hands, regular audit and feedback of compliance, provision of materials empowering patients to remind HCWs to clean their hands, and detailed guidance to help secure institutional engagement. However, such interventions had not previously been implemented or evaluated at a national level (16) and questions about their generalisability remained. The campaign was “launched” in January 2005, “refreshed” at the end of June 2006 (17), and “re-launched” with new posters in October 2007. Full details of the CYHC, its planning, piloting and
implementation can be found elsewhere (17,18) are described fully in Appendix 1 (17,18), and the timescale summarised below.

<table>
<thead>
<tr>
<th>Year</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002-3</td>
<td>NPSA and Procurement and Supplies Agency (PASA), invite soap &amp; AHR companies to tender for contracts to supply NHS with products meeting PASA standards for efficacy, safety and acceptability</td>
</tr>
<tr>
<td>September 2004</td>
<td>Release of National Patient Safety Alert mandating AHR at patients' bedside in acute hospitals. Registration for campaign by acute trusts</td>
</tr>
<tr>
<td>1st January-30th June 2005</td>
<td>Roll out of Campaign to all acute trusts in four waves (January, stMarch, April, June) (trusts randomised to starting dates)</td>
</tr>
<tr>
<td>End June 2006</td>
<td>Campaign “refreshed” with maintenance handbook reiterating main components, more emphasis on audit &amp; feedback, &amp; institutional engagement</td>
</tr>
<tr>
<td>October 2007</td>
<td>“Relaunch” of Campaign with new posters</td>
</tr>
</tbody>
</table>

Whilst the CYHC was being planned, the DoH tendered for independent research to evaluate its sustainability and effectiveness. The successful study NOSEC (National Observational Study of the Effectiveness of the clean your hands campaign) represents the outcome of a synthesis between evidence, policy, practice and research, whereby a national health system reviewed the evidence base on infection control to design an intervention, implemented it as national policy, and funded a simultaneous evaluation to inform future health policy. The policy imperative of ensuring the intervention be rolled out to all acute trusts as quickly as possible forestalled any attempt
at a randomised controlled trial or even a stepped wedge observational study. NOSEC was therefore carried out as a prospective ecological interrupted time series study.

Ecological studies recognize the influence of the environmental determinants of disease (in this case hand hygiene), can assess public health interventions and have the advantages of use of data that already exists, lower cost and use of a wider range of exposures than is possible in a trial thus providing potentially greater generalisability. Widely used in injury prevention (19), they are eminently suitable to study infection control interventions, which alter the environment affecting transmission of disease, through changing healthcare worker behaviour. The inherent disadvantages of the design are that data sources may be flawed and confounding factors hard to control for. Nonetheless, such limitations can be minimised when measurement, analysis and interpretation are at the group level, when the data is reliable and available, when inferences from group to individual level are avoided, and when confounders assessed and adjusted for.

The aim of the NOSEC study was to assess the campaign’s implementation, effects on hand hygiene and rates of MRSAB, MSSAB and CDI, and sustainability from 1st July 2004 to 30th June 2008. The null hypothesis was that initial uptake of the intervention would not be sustained and that there would be little effect on levels of hand hygiene, MRSAB, MSSAB and CDI.

1.2 Background to the Feedback Intervention Trial (FIT)

The same research call also asked applicants to design a randomised controlled trial of an intervention to produce sustained long term increases in hand hygiene compliance. The successful application resulted in a three year stepped wedge randomised controlled trial (20) in 60 wards in 16 hospitals (FIT, the Feedback Intervention Trial). The study used a theoretically based feedback intervention to improve hand hygiene compliance in healthcare workers in intensive care units (ITU) and acute care of the elderly or general medical wards (ACE/GM). The null hypothesis was that the intervention would not improve compliance.
Feedback was chosen because the only systematic review of hand hygiene interventions then available (13) had identified this as the intervention most likely to be successful, although the authors commented that its effect was short-lived, and that it probably needed to be repeated regularly and to be part of a multi-faceted intervention. The review called for well-designed long-term controlled trials of behavioural interventions as previous studies were short-term and poorly designed.

Systematic review of controlled trials of feedback in multiple fields of healthcare generally (21, 22) reported that it had significant, but modest effects. Its effect in these trials may have been limited by failure to use psychological theory in designing feedback interventions (23). The FIT study therefore chose the evidence-based theories of “goal-setting theory” (24) and “control theory” (25) to design the intervention. They conceptualise behaviour as goal driven and feedback controlled, with goal setting and action planning augmenting the effect of feedback. Operant learning theory was a further theory that was used, providing a reward component to the intervention.

The intervention was designed by Health Psychologists with relevant expertise, with the aim of developing an intervention that would be sustainable in the long-term without requiring resources in addition to those available within the NHS at that time. Key components of the intervention were goal setting, feedback, action planning and rewards at both individual and group levels. Focus groups with HCWs who had knowledge and experience of the healthcare context were conducted to assess any concerns about the implementation of the proposed intervention. A number of modifications to the ward co-ordinator role, individual goals and planning, and observation and feedback components of the intervention were made in response to these concerns.

A small-scale stepped wedge study designed to mirror and pilot the intended main trial was carried out between October 2006 and May 2007. Seven wards
in three hospitals were sequentially introduced to the intervention between October '06 and March '07.

The intervention involved a four-week cycle of hand-hygiene observation and feedback carried out by a member of the ward staff. In week 1 an individual HCW was observed for 20 minutes, their performance was feedback to them and an individual action plan formulated to maintain or improve compliance. In week 2, another HCW was assessed with feedback and goal planning. In week 3 a group of HCWs were observed for 30 minutes without feedback. In week 4, group feedback was given in a ward meeting and action plans were formulated. Observations, feedback and goals were all recorded on a separate form each week and kept for analysis. The plan was that every member of staff would be observed at least once a year. If compliance was 100%, the staff member was praised and given a certificate that was filed for use in future appraisal. If less than 100%, the staff member was observed at some point within the subsequent month. Observation was discrete and carried out by staff that were routinely in the ward, minimising the chance of awareness of observation and therefore untypically compliant behaviour.

During the pilot, implementation of the individual level components of the intervention occurred consistently (86% of the time) whilst the group level components were poorly implemented (21% of the time). Overall, problems with implementation pointed to the need for more training for ward co-ordinators around identifying hand-hygiene opportunities, developing an appropriate action plan, and delivering feedback during the ward meeting. Detailed training materials were developed prior to the main trial.

1.3  Scope of report

This report shows that the NOSEC and FIT studies have fulfilled the objectives of the grant call by completing the evaluation of the cleanyourhands campaign (CYHC) over the four years of its implementation and by running a three year controlled trial of an intervention intended to achieve sustained improvement in hand hygiene compliance. It briefly describes the timescale
of the study, summarises the results of both the NOSEC and FIT studies, and reviews the additional outputs from the study, which were not originally envisaged, but which accrued during its lifetime. These comprised methodological tools, national and international partnerships, and workshops. It lists the conference platform and abstract presentations, published, submitted and draft papers, and concludes with clinical, service and research implications. The report is an overview and has accompanying appendices which give full details of the outputs, methods of data collection and statistical analysis. The report itself includes only brief summaries of the data collection and statistical approaches and most important results in order to avoid the main messages being lost in technical details and detailed results fully explained in the accompanying papers.

1.4 Timetable of study

<table>
<thead>
<tr>
<th>NOSEC</th>
<th>FIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>First NOSEC questionnaire</td>
<td>Development of observation tool.</td>
</tr>
<tr>
<td>December 05</td>
<td>Mar 05 - June 06</td>
</tr>
<tr>
<td>Second NOSEC questionnaire</td>
<td>Development and piloting of feedback intervention.</td>
</tr>
<tr>
<td>June 06</td>
<td>Jan 06 - Jun 07</td>
</tr>
<tr>
<td>Third NOSEC questionnaire</td>
<td>Recruitment, Ethics and R&amp;D approval</td>
</tr>
<tr>
<td>December 06</td>
<td>Aug 05 - Oct 06</td>
</tr>
<tr>
<td>Fourth NOSEC questionnaire</td>
<td>Study start (baseline)</td>
</tr>
<tr>
<td>June 07</td>
<td>Oct 06</td>
</tr>
<tr>
<td>Fifth NOSEC questionnaire</td>
<td>First wards randomised</td>
</tr>
<tr>
<td>December 07</td>
<td>June 07</td>
</tr>
<tr>
<td>Sixth NOSEC questionnaire</td>
<td>Final wards randomised</td>
</tr>
<tr>
<td>June 08</td>
<td>May 08</td>
</tr>
<tr>
<td>Submission of first draft for publication</td>
<td>Study end date</td>
</tr>
<tr>
<td>July 09</td>
<td>Dec 09</td>
</tr>
</tbody>
</table>
The CYHC began rolling out the campaign in December 2004 to 6 trusts with the main roll out beginning in January 2005. A research fellow was appointed in December 2004 and was able to start at the beginning of February 2005, piloting the tools to be used for the NOSEC and FIT studies including recruiting pilot sites to develop the FIT intervention. CYHC finished in March 2008 and the final results of NOSEC were available in June 2009. FIT began in October 2006 and the trial was finished at the end of December 2009.

1.5 Staffing
The research fellow was joined by a research assistant to help plan the FIT study, co-ordinate the NOSEC study and its data collection and analysis. Two years later another research assistant was employed to collect hand hygiene compliance data through direct observation. The initial intention of the FIT study was to recruit and train 12 observers, who were to be paid piecemeal. They were recruited from HCWs and medical (and nursing) students, and either worked shift systems or during ad hoc times that were free of formal commitments. Training followed the workshop format and was followed by 4-6 hours of supervision and learning on the ward. However, the logistic difficulties of ensuring that individual observers were available when required to carry out observation sessions, necessitated abandoning this workforce and using the funds set aside for their payment to employ a 0.8 whole time equivalent research assistant who combined this work with pursuing her MSc in Health Psychology.

The workforce was augmented early on by a Hospital Infection Society funded psychology PhD student from UCL who, in addition to other work for his PhD under the supervision of Professor Susan Michie (Health Psychology, UCL), used a behavioural framework (22) to design the intervention, piloted it, helped develop training materials, and assessed the barriers and facilitators to the implementation of the intervention. His PhD (26) concerned the development of the intervention and its use in the pilot study that preceded the full trial. For the full trial, the research fellow was responsible for training and supporting implementers across the 60 wards of the study. Research
recommendations 9 and 10 relate to future staffing considerations for such trials.

**Job roles of staff employed on the project**

<table>
<thead>
<tr>
<th>Job title</th>
<th>Timescale</th>
<th>Main duties</th>
</tr>
</thead>
</table>
| Research Fellow                   | Jan 2005 to Nov 2010    | 1. Ensuring project goals met  
2. Recruiting study sites  
3. Ethics/ research governance  
4. Designing protocols and training materials  
5. Preparing reports, presentations & publications. |
| Research Assistant                | Jan 2006 to March 2010  | 1. Development of data collection systems  
2. Data collection.  
3. Data entry /data management.  
4. Production of reports and basic data analysis.  
5. Hand hygiene observation. (20% of workload)  
6. Assisting with training. |
| Hand-hygiene observer (0.8 WTE)   | June 2007- Oct 2009     | 1. Hand Hygiene observation (60% )  
2. Data entry and cleaning (40%) |
Section 2. Summary of Main NOSEC and FIT results

2.1 NOSEC (Appendix 1)
The NOSEC study evaluated the implementation of the components of the CYHC campaign through a voluntary questionnaire (the NOSEC questionnaire, Appendix 2) distributed at 6 monthly intervals to all 187 acute NHS trusts from 6-36 months after completion of national roll out (November 2005-June 2008). The first five questionnaires were voluntary but the final and sixth questionnaire was included in National Audit Office’s mandatory questionnaire on HCAI which enabled the NOSEC study to get a snapshot of practice across the NHS three years after completion of national roll out.

Working with PASA (later NHS Supply Chain), monthly data on trust level procurement of AHR and soap was collected from 6 months before the start of national roll out of CYHC until 3 years post completion of roll out (1st July 2004- 30th June 2008). Quarterly numbers of MRSA bacteraemias (MRSAB), MSSA bacteraemias (MSSAB) and clostridium difficile infections (CDI) for each trust were collected from the Health Protection Agency mandatory reporting scheme database over the same time period. The denominator for consumables and infections was trust level occupied bed days. Data on potential confounders such as length of stay, hospital type (i.e. whether it was a teaching acute or specialist hospital) were collected for each hospital together with data on other national interventions targeting these infections, such as Saving Lives (July 2005), the announcement of a national target for MRSAB reduction (November 2005), visits by Department of Health (DoH) Improvement Teams (from April 2006) and the publication of the Health Act (October 2006).

The results of the NOSEC study showed that the CYHC was effectively implemented and sustained long-term across acute NHS trusts in England and Wales, with widespread early implementation of bedside AHR and posters and a gradual rise in audit and feedback (Table 1).
Table 1: Percentage of respondents to questionnaires 1-6 (N1-6) agreeing or strongly agreeing with statements:

<table>
<thead>
<tr>
<th></th>
<th>N1 6 months post roll out</th>
<th>N2 12 months post roll out</th>
<th>N3 18 months post roll out</th>
<th>N4 24 months post roll out</th>
<th>N5 30 months post roll out</th>
<th>N6 36 months post roll out</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management’s actions show the campaign is a top priority in Trust</td>
<td>78</td>
<td>71</td>
<td>75</td>
<td>78</td>
<td>74</td>
<td>90</td>
</tr>
<tr>
<td>AHR near-patient in &gt;75% wards</td>
<td>94</td>
<td>88</td>
<td>85</td>
<td>83</td>
<td>86</td>
<td>96</td>
</tr>
<tr>
<td>Posters on &gt;75% wards</td>
<td>88</td>
<td>79</td>
<td>79</td>
<td>74</td>
<td>79</td>
<td>97</td>
</tr>
<tr>
<td>Patient empowerment materials reaching patients on wards</td>
<td>68</td>
<td>48</td>
<td>41</td>
<td>38</td>
<td>65</td>
<td>65</td>
</tr>
<tr>
<td>Materials are changing patient’s behaviour</td>
<td>46</td>
<td>49</td>
<td>46</td>
<td>34</td>
<td>41</td>
<td>35</td>
</tr>
<tr>
<td>Audit &amp; feedback in last 6 months on &gt;75% wards</td>
<td>47</td>
<td>51</td>
<td>53</td>
<td>64</td>
<td>75</td>
<td>91</td>
</tr>
<tr>
<td>Total number (%) of responses</td>
<td>134 (71%)</td>
<td>126 (67%)</td>
<td>108 (58%)</td>
<td>99 (53%)</td>
<td>82 (44%)</td>
<td>167 (90%)</td>
</tr>
</tbody>
</table>

Although questionnaire response rates gradually fell from 71% at 6 months to 44% at 30 months, rising to 90% for the final mandatory one there was no evidence of attritional or selection bias from falling response rates. At 36 months after completion of roll out (June 2008), 90% of trusts reported CYHC to be a top hospital priority, with implementation of AHR, posters and audit reported by 96%, 97% and 91% respectively. Patient empowerment was implemented less successfully.

Combined soap & AHR procurement tripled from 22mls during the baseline period to just under 60 mls per patient-bed-day (figure 1).
**Figure 1:** Estimated quarterly hand hygiene consumable usage by quarter. Roll out phase in yellow. Perpendicular lines represent refreshment (end of June 2006) and relaunch phases (October 2007) of campaign.

AHR procurement in particular increased significantly during the roll out (average increase 1.83 [1.60, 2.07] ml/bed day/quarter), and following refreshment (1.40[1.1, 1.7] and relaunch (1.28[1.16, 1.41]) phases of the campaign.

MRSAB rates halved (falling from 1.88 to 0.91 cases per 10,000 bed days) and those of CDI fell by 40% (from 16.75 to 9.5 cases per 10,000 bed days). MSSAB rates did not fall. A mixed-effects Poisson regression model assessed associations between procurement and HCAI rates, testing for the effects of hospital heterogeneity. Each extra ml/patient-bed-day of soap was strongly associated with a 0.7% reduction in CDI throughout the study (IRR 0.993 [0.99, 0.996] p<0.0001). Each extra ml/patient-bed-day of AHR was strongly
associated with a 1% reduction in MRSAB (Incidence Rate Ratio (IRR) 0.990 [0.985, 0.995]; p<0.0001) but only in the last four quarters of the study (Figure 2).

**Figure 2:** Estimated IRR for MRSA bacteramia for a 1 ml per bed day increase in AHR by quarter

These associations remained even after adjusting for the other variables significantly associated with reduction of MRSAB and CDI: publication of the Health Act (IRR 0.86 [0.75, 0.91]; p=0.02 for MRSAB, and 0.75 [0.67, 0.84]; p<0.0001) for CDI) and Department of Health Improvement Teams visits (IRR 0.91 [0.83, 0.99]; p=0.03 for MRSAB and 0.80 [0.71, 0.90]; p=0.01 for CDI) two or more quarters post-visit. There was no relationship between improvement team visits and increases in alcohol and soap procurement by trusts.

The limitations of the NOSEC study arose from three particular difficulties encountered in carrying out its ecological design (see above). Firstly, participation by acute hospitals in the evaluation, as distinct from the
intervention, was not mandatory. This limited the questionnaire response rates and the ability to collect a wider range of non mandatory infection data as originally intended (such as ESBL, norovirus, carbapenem resistant & non resistant acinetobacter, and MRSA acquisition) which would have extended the generalisability of the findings to other forms of HCAI. Secondly, the intervention was rolled out both earlier and more quickly than originally anticipated, which limited the collection of baseline data, in particular of hand hygiene consumables, which was not available from before July 2004. Thirdly, data sources were unavailable for broad spectrum antibiotic use, changes which might have contributed to the falls in MRSAB and CDI and therefore be an important confounder for the strong associations between reduction of these and increases in consumables.

Although the problem with questionnaire response rates could be addressed and the of lack of baseline data for hand hygiene consumables could be partially addressed, there were no robust systems to collect antibiotic data in almost all hospitals during the study, and no alternative sources for this data. However, there would have to be a strong correlation between rises in consumables and decreases in selected antibiotics to abolish the strong independent associations between consumables and infections.

The full description of both the CYHC and the NOSEC study, together with the data collection, results, analysis, consideration of its strengths and weaknesses, and conclusions is presented in Appendix 1 as a paper that was initially presented to the Lancet. The Editor suggested revisions (all of which have been incorporated into the current version) and resubmission to Lancet Infect Diseases where it awaited review from July 2010 til January 2011. The paper was submitted to BMJ in February 2011 and is now being revised for a resubmission there. The conclusions and limitations of the NOSEC study are reflected in clinical/service recommendations 1-4, 5, 7 &17, at the end of this report.
2.2 Summary of the FiT results (Appendix 2)

Sixty wards (16 ITUs and 46 acute care-of-the elderly/general medical [ACE/GM] wards were recruited in 16 NHS acute hospital trusts across England and Wales (see acknowledgments below). These wards were chosen as these patient groups have high levels of HCAI, MRSA and CDI. Hospitals were randomly allocated using the Research Randomizer website (www.randomizer.org) to the intervention in a step-wise manner with the null hypothesis that the intervention would be ineffective. The primary outcome measure was directly observed hand hygiene compliance, expressed as a percentage, measured using a robustly standardised tool (the Hand Hygiene Observation Tool) with clear standard operating procedures developed for the trial (see below, section). The tool was administered by a trained observer blinded to the allocation of the ward to the intervention, for an hour every six weeks. The secondary outcome was ward level procurement of AHR and soap (expressed as mls per patient bed day), a proxy measure of hand hygiene more likely to reflect 24/7 use and less subject to possible reactive effects of direct observation. The tertiary outcomes were rates of MRSAB, MSSAB and CDI and MRSA acquisition, and prescribing rates (as defined daily doses per 1000 bed days) of antibiotics used to treat MRSA infection, vancomycin, doxycycline and teicoplanin. The antibiotic data were used as a surrogate marker for all MRSA infections.

It had been intended that MRSA prevalence be measured every quarter, as this would provide a more common infection outcome, thus more likely to see a reduction as a result of the intervention, with approximately 20% of ACE/ITU patients carrying MRSA. Ethical approval was obtained for anonymised and confidential sampling. However, in the baseline period of the trial only five hospitals were willing to do this. Chief amongst objections were that the staff wanted to know the results of the MRSA screens. This would have resulted in clinical action such as isolation and eradication, which might have confounded any effect of the feedback intervention. This part of the study was, therefore, abandoned.
The null hypothesis was that the intervention would not increase hand hygiene compliance. A simulation approach was used to provide an estimate of power for a stepped wedge design of total duration 36 months, with six-weekly hand hygiene observations in each ward, and one ITU and two ACE wards at each hospital, based on observations in the pilot study. A linear “mixed” model was fitted to the simulated compliance data and 1000 simulations were performed for combinations of intervention effect from 0% to 12% increase in compliance and 10-20 participating trusts. This gave a trial of 16 trusts 80%, 88%, 93% and 96% power to detect a 7%, 8%, 9% and 10% difference in compliance respectively. In practice, the 16 trusts often had more than two ACE wards and wanted all of them to participate. Thus, the final trial had 60 wards.

A mixed effect regression analysis was performed (43) with the number of compliant hand hygiene opportunities as the outcome variable, and the total number of hand hygiene opportunities as the binomial denominator. Hospital and ward within hospital were fitted as random effects and temporal trends in compliance were adjusted for by fitting the consecutive month as a 39 level ordered categorical factor. In order to take into account the fact that several wards were randomised to the intervention but never implemented it, and that there was often a delay between the expected start date and the actual start date, an “intention-to-treat” analysis was carried out for all wards and a “per-protocol analysis” for implementing wards. The per protocol analysis examined the effect of fidelity to intervention (the degree to which the implementing wards complied with the four week cycle of observations, feedback and goal setting), measuring fidelity by the number of forms (see above 1.2) filled in each month on each ward.

For the “intention to treat” analysis post randomisation outcomes were compared to pre randomisation (baseline) outcomes. For the “per protocol” analysis post-implementation outcomes were compared to baseline. Type of ward (ITU or ACE) was entered as an effect modifier, with confounders (such as staffing levels, and skill mix) and fidelity to intervention fitted as covariates.
Results were presented as estimated odds ratios (95% CI) for hand hygiene compliance, as the relative change in monthly volume of soap or AHR (for consumables) and as the estimated incidence rate ratio for the tertiary infectious outcomes, on each ward type, comparing post-randomisation and post-implementation with pre-randomisation levels. The monthly procurement of consumables was smoothed to allow for procurement spikes caused by less frequent bulk orders.

Although all wards were randomised to start the intervention only 33 wards implemented it (11 ITUs, 22 ACE/GM wards). Eight wards (seven non-implementing wards) closed during the trial.

ITT analysis showed that the estimated odds ratio (OR) for hand hygiene compliance in ITUs, but not ACE/GM wards, was significantly higher post-randomisation than pre-randomisation (1.44; 95% CI 1.18, 1.76) (Table 2).

**Table 2:** Estimated odds ratios (95% CI) of hand hygiene compliance for the intervention allowing for effect modification by type of ward

<table>
<thead>
<tr>
<th>Factor</th>
<th>Estimated odds ratio</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACE</td>
<td>Before randomisation</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>After randomisation</td>
<td>1.06</td>
<td>0.87 to 1.27</td>
</tr>
<tr>
<td>ITU</td>
<td>Before randomisation</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>After randomisation</td>
<td>1.44</td>
<td>1.18 to 1.76</td>
</tr>
</tbody>
</table>

PP analysis for implementing wards showed a significant rise in compliance after implementation, compared to the baseline phase (pre-randomisation), for both ACE/GM wards, OR 1.67 (1.28; 2.22; p<0.001) and ITUs, OR 2.09 (1.55; 2.81); p<0.001.
For ITUs, but not ACE/GM wards, the greater the fidelity to intervention (ie the number of forms filled and returned each month) the higher the compliance, with an OR for each returned form of 1.12 (1.04, 1.20, p=0.003 (Table 3).

**Table 3:** Estimated odds ratios (95% CI) for hand hygiene compliance on ITUs for 0, 1, 2, 3, or 4 forms returned in any one month compared to the compliance prior to randomisation

<table>
<thead>
<tr>
<th>Factor</th>
<th>Estimated odds ratio</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITU</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>After implementation no forms returned</td>
<td>1.83</td>
<td>1.33 to 2.50</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>After implementation one form returned</td>
<td>2.02</td>
<td>1.50 to 2.72</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>After implementation two forms returned</td>
<td>2.23</td>
<td>1.65 to 3.02</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>After implementation three forms returned</td>
<td>2.46</td>
<td>1.78 to 3.40</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>After implementation&gt;=four forms returned</td>
<td>2.71</td>
<td>1.90 to 3.88</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

The odds of compliance for non implementing ACE/GM wards fell post randomisation (0.64 [0.48, 0.84] p<0.001) and but did not change on ITUs (OR 1.14 [0.82, 1.58] p=0.45).

To put this in terms of compliance, the ITT analysis equated to an increase of 9% in ITUs, when the compliance without the intervention was 50%, and to an increase of 7% when compliance without the intervention was 70% (Figure 3).
Figure 3: Hand hygiene compliance in ITUs (ITT analysis) (lower panel)- Intention to treat analysis (black = pre- and blue = post- randomisation)

Despite a downward secular trend in hand hygiene compliance during the study, the difference was relatively constant over time, consistent with a sustained effect of the intervention.

The per-protocol analysis equated to an increase in hand hygiene compliance of 13% in ACE wards when the compliance without the intervention was 50%, to just under 10% when the compliance without the intervention was 70%. For ITUs this equated to an increase of 18% when the compliance without the intervention was 50%, to 13% compliance without the intervention was 70% (figure 4). Despite a downward secular trend in hand hygiene compliance during the study, the difference was relatively constant over time, consistent with a sustained effect of the intervention.
Figure 4 – Hand hygiene compliance in ITUs (upper panel) and ACE wards (lower panel)-Per protocol analysis (black = pre- and green = post-implementation)

For the secondary outcome of consumables procurement, analysis was restricted to the 37 wards that could provide consistent monthly AHR procurement data (23 implementing and 14 non implementing) and to the 28
wards that could provide the same for soap (16 implementing, 12 non-implementing). Neither ITT nor PP analyses found any effect on AHR procurement. However, ITT analysis found a significant 30% increase in soap procurement on ITUs (relative increase 1.314 (1.114, 1.548) but a non-significant 13% increase in ACE/GM wards. The per protocol analysis showed a similar result with a strong effect of fidelity to intervention on ITUs, where each form returned per month was associated with an estimated 12% significant increase in soap procurement.

For the tertiary infection outcomes of MRSAB, MSSAB and CDI analysis was restricted to the 55 wards with MRSAB data, the 50 with MSSAB data, the 55 with CDI data, and showed no effect of the intervention. ITT analysis of the 50 wards with new MRSA acquisition data showed an increase on both types of ward, which was also seen on the per protocol analysis for ACE/GM wards. This should be interpreted with caution as definitions of acquisition were defined locally and screening practice are very likely to have changed and increased over this time in line with national trends. However, ITT analysis of the surrogate marker of total MRSA infection, based on the 48 wards with available data, showed a significant reduction (17%) in ACE/GM wards. No effect was found on ITU wards. PP analyses showed significant reductions of 51% and 41% in ACE/GM wards and ITUs respectively, with a strong effect of fidelity to intervention in both settings. Again this should be interpreted with caution as this outcome measure has not been validated, is a tertiary measure for which the study was not powered, and may have been influenced by other interventions such as screening which was not assessed in this trial.

A cross-sectional interview study to investigate implementation was conducted by the psychology PhD student (Appendix 3). Seventeen ward co-ordinators (10 from ACE / GM wards, and 7 from ITUs) and 11 infection control nurses from 11 hospitals were interviewed to analyse perceived barriers and facilitators to implementation of the intervention. A set of interview questions was developed, based on a core set of 12 theoretical domains, identified by a behavioural framework for understanding
implementation in health care and reflecting those psychological theories and constructs most relevant to implementation (23). The findings suggested that ensuring the following would facilitate implementation of the intervention:

1. designated time for the intervention
2. that there be more than one person responsible for implementing the intervention per ward
3. that usual ward practice included feedback to staff about their hand hygiene compliance
4. that the intervention was seen as an integral part of the ward’s audit quality assurance programme.

The limitations of the study were that the intervention proved more difficult for wards to adopt than appeared from the pilot phase. This in part may have reflected changes in the NHS and context within which the study was conducted, such as competing for staff time with other quality improvement initiatives, and may have been avoided had there been a larger number of research staff to train, liaise with and encourage the ward staff. In addition, ward co-ordinators neither had their training repeated nor their performance monitored. This may have reduced the effect of the intervention, and contributed towards the gradual decline in compliance although this was taken account of in the analysis. The absence of consistent monthly consumables data for all wards limited the analysis of this outcome. These limitations are addressed in the research and clinical recommendations.

Nonetheless, the trial showed that the Feedback Intervention was modestly effective in ITUs on an ITT analysis. This effect was stronger on implementing wards, ITUs especially, with better fidelity to intervention resulting in greater compliance. In implementing wards the intervention was associated with 13-18% higher compliance on ITUs and 10-13% higher compliance on ACE wards. Soap procurement was increased by 30% on ITUs with a strong effect of fidelity to intervention. Infection outcomes were largely unaffected by the intervention. However, the surrogate marker for antibiotic treatment of MRSA
infections suggested a 40-50% reduction in these infections in both settings implementing the intervention, with a strong effect of fidelity to intervention.

In conclusion, both intention to treat and per protocol analyses suggest that a theoretically-based feedback intervention, informed by behavioural science, modestly increases hand hygiene compliance and soap procurement on both ITUs and ACE/GM wards. The effect also appears to increase as fidelity to intervention increases. The intervention proved harder to implement than anticipated, and study of the predictors of implementation and fidelity to intervention is required in order to improve implementation. Consideration should be given to designing a further trial to determine whether a modified intervention is easier to implement and has a greater effect. However, before doing this the staffing implications for the NHS, should the intervention be proven, should first be considered.

The trial and its analysis is described more fully in Appendix 2, which is a paper PLoS Medicine have suggested be presented to PLoS. The conclusions and experience of the FIT study are reflected in clinical/service recommendation 9 and research recommendations 5-11 & 21 (see below).
Section 3. Additional outputs - methodological tools

3.1 The hand hygiene observation tool (Appendix 4)

When planning the FIT trial, it was necessary to have a method of measuring hand hygiene compliance that was not only valid, but with proven inter-rater reliability (both for individual hand hygiene opportunities and behaviours and for overall compliance) and with clearly described standard operating procedures (SOP). There appeared to be no such measure in the published literature, as now reported by recent systematic reviews (27, 28). We therefore developed such a measure, the HHOT (hand hygiene observation tool), based on the Geneva tool (14). It is currently the only observational measure of hand hygiene with rigorously tested inter-rater reliability, clearly described and easily accessible SOPs and demonstrated sensitivity to change.

In brief, inter-observer agreement for each category was assessed by observation of 298 hand hygiene observations and hand hygiene behaviours by two independent observers. Raw agreement (%), estimated Kappa and 95% confidence intervals (CI) were 76% and 0.68 (95% CI: 0.61-0.74) for the behaviours, and 83% and 0.77 (95% CI: 0.71-0.83) for opportunities. Inter-observer agreement for overall compliance of a group of HCWs was assessed by observation of 1191 hand hygiene observations and behaviours by two pairs of independent observers. Overall agreement was good (intraclass correlation coefficient 0.79 (95% CI: 0.62-0.96). Differences of more than 10% were most likely to be seen if there were <15 hand hygiene behaviours observed per hour. Sensitivity to change was examined by autoregressive time-series modelling of longitudinal observations for 8 months on an intensive therapy unit during an Acinetobacter baumannii outbreak and subsequent strengthening of infection control measures. Sensitivity to change was demonstrated by a rise in compliance from 80 to 98% with an odds ratio of increased compliance of 7.00 (95% confidence interval: 4.02-12.2) P < 0.001.

Its development and assessment is described fully in the published paper in the Journal of Hospital Infection (JHI) in Appendix 4. The paper shows how to
assess inter-rater reliability of individual hand hygiene opportunities and behaviours through simultaneous observation by two observers. The careful pairing of independent observations to assess reliability for each unique hand hygiene opportunity had not been described previously in the hand hygiene literature, where only assessment of inter-observer reliability of overall compliance has been addressed. This study therefore made a contribution to the development of hand hygiene observation methodology.

The standard operating procedures were described in a very abbreviated form in the paper, but a longer version was published on the National Patient Safety Agency cleanyourhands website, where it was recommended for use by NHS Trusts’ infection control teams, with a link to the NOSEC/FIT study’s website (www.idrn.org/nosec) where the full SOPs were available. To our knowledge this is the only hand hygiene tool which has easily accessible fully explained SOPs available for other HCWs or researchers to replicate the hand hygiene observation method. Appendix 5 contains the short version of the SOPs that was available on the cleanyourhands website and Appendix 6 consists of the full SOPs available through the link on the CYHC site and the NOSEC/FIT site.

The HHOT was used in the trial to observe hand hygiene compliance directly on wards for one hour every six weeks, although it can be used for longer and shorter periods. Training materials were developed to teach observers how to use it, and after presentation of the study at scientific meetings and the publication of the paper, there were requests for workshops to teach the method to infection control teams (see below). Appendix 7 contains the training materials. The publication and dissemination of the HHOT lead to a collaboration with the Infection Control Prevention Society, who had been tasked by the DoH with producing national audit tools for infection control for the four home nations. It was decided that these would include the HHOT, as the hand hygiene audit tool (see below). For this purpose, the HHOT was revised to bring its terminology into line with the World health Organisation’s “Five Moments for Hand Hygiene”, which had been published since the HHOT’s development. Appendix 8 contains the agreement between the IPS
and University College London to use the HHOT for this purpose. Appendix 9 contains the updated version of the HHOT which uses the WHO’s terminology. Our experience of developing and using the HHOT are reflected in clinical recommendation 6 and research recommendation 12 (see below).

### 3.2 Training material for the Feedback Intervention (Appendix 10)

The FIT study required ward implementers to be trained not only in hand hygiene observation, but in how to deliver the intervention, both to individuals receiving feedback, and to groups of HCWs receiving feedback. They had to be able to decide what and how to feed back, how to help HCWs decide on their own hand hygiene goals, and how to provide contingent rewards. Although it was originally conceived that infection control nurses would train ward staff, it soon became clear that this was not feasible. The training was, therefore, delivered by the study Research Fellow or Research Assistant to the ward coordinators. Since ward staff generally had little time to attend the training, it was normally completed in 1 to 1 ½ hours. Training comprised talking through the training materials and going through a series of structured exercises. The training materials are given in Appendix 10 and referred to in clinical recommendation 9.

### 3.3 Assessment of Blinding of Hand Hygiene Observers in hand hygiene trials- Appendix 11

Since FIT was a stepped wedge CRCT, the observer of hand hygiene compliance had to be blinded as to whether the ward had been allocated to the intervention or not. The degree of blinding had to be tested to assess the possibility that the observer might systematically over-estimate compliance in wards allocated to the intervention, and under-estimate it in those not allocated to the intervention, thus biasing the results of the trial. Blinding and assessment of its efficacy is the only way to prevent such bias, and is therefore a standard part of trial methodology (29, 30). We were able to blind the hand hygiene observer to the allocation of wards by not informing them of the allocation and being careful not to speak about this in her presence. However, the possibility of unanticipated cues from working in the research office and on the trial wards (e.g., overhearing the allocation of
individual wards, or observing interactions between staff) necessitated demonstrating that blinding had been preserved and that these cues had not resulted in systematic bias. This issue had not previously been considered in the hand hygiene intervention literature, and there was therefore no precedent in this literature to guide us.

Assessment of blinding was done by recruiting and training another observer, who was trained to use the HHOT tool and told she had been employed to test its reliability. She was completely blinded to allocation of the wards, did not share the same office space as the rest of the research team, and was not even told that there was a trial going on. Once trained to use the HHOT, her performance using the tool was compared with that of the main trial observer in a series of simultaneous observations over 20 hours (1030 hand hygiene opportunities) on 7 wards implementing and 6 wards not implementing the intervention. Differences between observers for overall group compliance was not significantly different between types of ward (U 5 10, n1 5 7, n2 5 6, P < 0.07). Interrater reliability was excellent for individual hand hygiene behaviours on intervention wards (raw agreement 91.53%, $k = 0.886, P< 0.001$) and non-intervention wards (94.94%, $k = 0.908, P < 0.001$).

This showed not only that there was no bias and that the main trial observer had been effectively blinded but that the reliability of the HHOT was even higher than described in the original paper. Appendix 11 gives full details on the study and its findings, taking the form of a paper published in the American Journal of Infection Control as a “technical note” on the assessment of blinding in trials of hand hygiene interventions, and thus contributing to the further development of the methodology of hand hygiene observation. This output of the research programme is reflected in clinical recommendation 13 and research recommendation 13.
3.4 The length of periods of direct observation of hand hygiene compliance (Appendix 11)

Although direct observation of hand hygiene compliance is considered the gold standard, there are concerns, well summarised in the most recent comprehensive review of hand hygiene observation methodology recent literature (16), that it may be affected by awareness of being observed and does not reflect 24 hour seven days a week use. Many hand hygiene assessments use 20-30 minute periods of observation, but it is unclear what the optimal period of observation is to provide a representative sample of behaviour. Short periods of observation may occur during periods of relatively low clinical activity, with fewer hand hygiene opportunities or hand hygiene moments, and a small number of healthcare workers. The HHOT study reported that differences between observers observing the same hand hygiene opportunities were greater if there were less than 15 opportunities observed. It is also unclear how possible reactive effects may operate, even when observers make every effort to be covert, as in this study. Is it greater at the start of observation or the longer observation goes on?

We therefore carried out a study during the baseline phase of the trial in 13 ITUs and 36 ACE wards in 13 hospitals not yet randomised to the intervention, where covert observations were performed for four hours at a time on each ward. There were 53 such “four hour” observation periods, with observations recorded in 20 minute sequential segments, to determine whether there was substantial differences in overall compliance between 20 minute and one hour observations and between one, two, three and four hours of observation. Observation began in the morning when the wards were likely to be busier and the number of hand hygiene opportunities therefore higher. Preliminary analysis suggested that compliance recorded during the first hour of observation was not substantially different from the full four hours of observation. We therefore adopted this period of observation for the rest of the trial, partly on the basis of the analysis and partly for pragmatic reasons, in that it was not feasible to observe for four hours at a time when visiting three or four wards on 16 sites around the country.
Full analysis examined the hour to hour variation in hand hygiene compliance was by a mixed effects logistic regression model with a binary outcome of being hand hygiene compliant or not. Hospital and ward within hospital were included as random effects. Ward type (ITU or ACE) and sequential hourly observation period (<= 60 mins, 61-120 mins, 121-180 mins, and 181-240 mins) were included as fixed effects. A similar analysis was carried out to examine the variation in compliance over sequential 20 minute periods of observation but with sequential 20 minute periods replacing the hourly sequential periods as a fixed effect. After tests of interaction between fixed effects and a main effects model found that ward type had no effect, this was excluded from further analysis.

Overall compliance was 75%. It was lowest in the 1st hour (71.4%) and increased by 5.6% in the 2nd hour of observation, remaining stable thereafter. The estimated odds ratio (95% Confidence Intervals) for compliance at individual hand hygiene moments in the 2nd hour, compared to the 1st, were significantly higher at 1.32 (1.08-1.61); p=0.007, remaining stable thereafter (Table 4).

Table 4: Estimated odds ratio for hand hygiene compliance in each hour of observation

<table>
<thead>
<tr>
<th>Hour</th>
<th>No of observations</th>
<th>Compliance (%)</th>
<th>Odds Ratio.</th>
<th>95% CI</th>
<th>p. value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st</td>
<td>1212</td>
<td>71.4</td>
<td>reference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd</td>
<td>1088</td>
<td>77.0</td>
<td>1.32</td>
<td>1.08 to 1.61</td>
<td>0.007</td>
</tr>
<tr>
<td>3rd</td>
<td>997</td>
<td>76.2</td>
<td>1.32</td>
<td>1.07 to 1.62</td>
<td>0.008</td>
</tr>
<tr>
<td>4th</td>
<td>692</td>
<td>76.4</td>
<td>1.40</td>
<td>1.11 to 1.76</td>
<td>0.004</td>
</tr>
</tbody>
</table>

Analysis of the 20 minute segments showed that compliance was lowest in the 1st 20 minutes (69%), increased by 5.3% in the 2nd 20 minute period and by 8.9% in the 4th remaining relatively stable until the last (12th) period. The
estimated odds ratio (95% Confidence Intervals) for compliance at individual hand hygiene moments were significantly higher in the 2nd 20 minute period compared to the 1st, at 1.42 (1.02,1.96; p=0.04) and in the 4th (1.63, 1.17-2.29; p=0.004), compared to the 1st, remaining relatively stable thereafter although there was substantial fluctuation in the last three 20 minute segments.

In summary, compliance rose by a small but significant amount (5%) over a four hour observation period. The rise began after the first 20 minutes but was mostly seen after the first hour of observation, after which compliance remained stable, although there was fluctuation during the fourth hour.

Possible explanations are improving performance over the shift, a delayed reactive effect or, in the fourth hour, observer fatigue resulting in poor attention to task. The optimal period of observation may depend on the clinical or research setting.

The implications of this study for the optimal period of observation depend on the clinical or research setting. The need for results unaffected by the act of observation has to be balanced with the requirement for sufficiently large and representative samples, and the resources available for observation. For the FIT trial, the decision was taken to observe for no more than one hour, and we would recommend this for most trials. Longer periods than this appear to have no advantage, may be influenced by reactivity, may be subject to fluctuations if as long as four hours, and would be very resource intensive.

For clinical audit, we would recommend 20 minutes observation with the HHOT, provided the number of hand hygiene moments reaches its established reliability criteria (4) (observing at least 15 moments with an observable hand hygiene behaviour of hand rub, soap or no action) (Appendix 4). This would not be unreasonable for trials as well but researchers should state and explain the period and frequency of observations in both grant application and publications. For both clinical audit and trials, frequent measurement of compliance, to establish time trends and changes, are required.
We are not aware of any other study in the literature that has examined this issue in this way. The full study, together with discussion of its strengths and weaknesses is presented in Appendix 12 in the form of a draft paper for presentation to either the American Journal of Infection Control. Its findings are reflected in clinical recommendations 8 & 10 and research recommendations 11.

3.5: Methodology- assessing how much soap and AHR patients and visitors use (appendix 13)

One underlying assumption of the decision to collect consumables procurement data as an outcome measure in both the NOSEC and FIT studies is that most or the AHR and soap is used by HCWs. However, with AHR placed at the entrance to many wards, and in some cases in hospital entrances, and with visitors and patients being encouraged to clean their hands, the possibility exists that any increase in use of consumables may be attributable to use by non-HCWs. Although hand hygiene consumables are often used in hand hygiene intervention studies to assess outcome, quantifying the use by non-HCWs has not previously been considered in other studies.

We therefore carried out a study to examine this issue in 27 wards in 9 hospitals from the FIT study. We carried out 36 hours of direct observation of bedside hand hygiene behaviours by healthcare workers (HCWs), patients and visitors by adding any patient or visitor use of AHR or soap to the HHOT observation sheet. AHR containers from 10 ward entrances were also collected for four days and the mean daily volume used was compared with mean daily volume procured. The study found that only 4% of bedside soap use was by visitors. Patients used neither. An average 21% (range 7-38%) of all AHR procured by wards was used at ward entrances.

We were unable to record how much AHR used at ward entrances was by HCWs compared to non HCWs as we did not have the time or resources. It is likely that more than half of this was by HCWs, given that visiting hours are limited for most patients. The study therefore suggests that nearly all soap usage (96%) and probably more than 85% of AHR procured by wards is used
by HCWs, with 75% of procurement representing use at the point of care or bedside. We concluded that non-HCW use of soap or AHR at the bedside was negligible and that use of AHR at ward entrance use of AHR is modest but varies.

The implications of the study include some reassurance that for the NOSEC study, the reported changes in trust level procurement of soap and to a very large extent AHR, reflect increased use by HCWs as opposed to patients and visitors. The other implication is that hand hygiene intervention studies using consumables as an outcome should assess and adjust for such usage, as a potential confounder. The full implications of this for clinical audit and research are discussed below under clinical recommendations 11 & 12 and research recommendations 14-17. Appendix 13 describes the study in full and takes the form of a paper accepted by the British Journal of Infection Control.
Section 4. Additional outputs - gloves as a barrier to hand hygiene compliance (Appendix 14)

It became apparent to observers on the FIT study, whilst monitoring hand hygiene compliance, that gloves were being worn when not indicated and vice versa, and that people may not disinfect their hands when wearing gloves. WHO guidelines mandate use of gloves when contact with body fluids is anticipated and when patients are to be managed with contact precautions (31). Gloves should be changed between patient contacts, and hands should be cleaned before putting on gloves and immediately after removing them. There was some suggestion in the literature that HCWs might be less likely to clean their hands when they wore gloves, although studies differed regarding. However, these studies have been small and used non standardised assessments and indications for hand hygiene.

It was therefore decided to take advantage of the FIT trial to carry out a study of glove usage and associated hand-hygiene behaviours in a convenience sample of 56 wards in 16 trusts in England and Wales to observe whether gloves were worn when indicated and to determine whether hand-hygiene compliance was different when gloves were, or were not worn. The HHOT observation tool was amended to record whether gloves were worn or not. Gloves practice could not be observed in patients undergoing contact precautions because the decision had been taken previously not to observe hand hygiene in side rooms for FIT, because of concerns regarding patient privacy and the possibility of maximising the Hawthorn effect. It also proved too difficult to record whether HCWs changed gloves between patient contacts whilst documenting other aspects of hand hygiene behaviour, so this was not done.

Nearly 250 hours of observation were undertaken, covering nearly 7600 patient contacts. The study found that gloves were used in 26% of patient contacts, in 17% of low-risk contacts (i.e. when not indicated), and not used in 21% of high-risk contacts (i.e. when indicated). Hand-hygiene compliance
with and without glove-use was 50.0% and 41.4% respectively. After adjusting for ward and HCW type, contact risk-level and whether the hand-hygiene opportunity occurred before or after a patient contact, glove-use was found to be strongly associated with lower levels of hand-hygiene compliance (adjusted odds ratio 0.65, 95% CI [0.54, 0.79], p<0.0001) (Table 5).

<table>
<thead>
<tr>
<th></th>
<th>Adjusted OR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gloves used</td>
<td>0.65 (0.54, 0.79)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>After contact</td>
<td>2.02 (1.69, 2.41)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>High-risk</td>
<td>1.34 (1.07, 1.68)</td>
<td>0.01</td>
</tr>
<tr>
<td>Nurse</td>
<td>2.21 (1.66, 2.94)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Other HCW</td>
<td>1.05 (0.76, 1.44)</td>
<td>0.78</td>
</tr>
<tr>
<td>ITU</td>
<td>1.25 (0.96, 1.63)</td>
<td>0.10</td>
</tr>
</tbody>
</table>

We concluded that glove usage was lower than the 40-93% reported in previous studies, that they were often worn when not indicated and vice versa, and that hand-hygiene was significantly worse when gloves were worn for all types of patient contact. We postulated that lax hand hygiene when wearing gloves may contribute to the spread of nosocomial infection and that wearing gloves might be a barrier to effective hand hygiene.

On the basis of our figures above, the rise in hand-hygiene compliance that would be achieved by limiting glove-use to high-risk contacts and insisting that hand-hygiene preceded and followed such moments, would be modest (47.7% to 57.9%). However modelling studies indicate that such a rise could be highly significant in raising compliance levels above the threshold required to reduce transmission of infection (32, 33). We postulated that if the field of hand hygiene improvement were to focus now on improving glove use and its associated hand hygiene, this might prove a more effective hand-hygiene improvement strategy than aiming for 90-100% overall compliance.

The clinical implications regarding hand hygiene guidelines, hand hygiene campaigns and the potential impact improving hand hygiene associated
with gloving could have on reducing the spread of infection are detailed below under clinical recommendations 14-16. So too are the research implications for standardising assessment of gloving practice, and developing interventions to improve it (see research recommendations 18-20). The full study is described in Appendix 14 which takes the form of a paper submitted to the BMJ. Their review, although favourable, declined the paper on the basis that it was a convenience sample, and suggested presentation to a more specialist journal. We have sent it to the Annals of Internal Medicine as they have previously published on hand hygiene practices based on single hospital studies, and may not be deterred by the theoretical problem of a convenience sample given that so many wards, in hospitals across England and Wales were studied. The paper has now been accepted by Infection Control and Hospital Epidemiology and will be the subject of a special press release as they believe it highlights a significant problem
Section 5. Additional outputs: Partnerships -

a. NPSA

As outlined above, the NPSA carried the HHOT as a recommended tool for trusts to use to assess hand hygiene through direct observation on its website, which featured the tool and an abbreviated version of the standard operating procedures (Appendix 5). There was also a link to the NOSEC/FIT website which carried the full SOPs (Appendix 6).

In addition the PI was asked to sit on the external reference group for the NPSA providing advice on the Patient Empowerment Pilot which the NPSA had commissioned from Central Office of Information. The aim of this research was to develop patient empowerment further so that patients reminding HCWs to clean their hands was a widespread feature of hand hygiene culture in the NHS. This group considered the research to date and recommended that further work needed to be undertaken with respect to staff perspectives on the intervention. It also called for further research to be carried out in patient groups more likely to have high levels of HCAI than the elective patients studied to date, but who might be too unwell and confused to play a role in patient empowerment, such as the elderly or patients in ITU. It was suggested that consideration be given to focussing on the family visiting such patients to act as their advocates and request HCWs to clean their hands. However, the group was very concerned that the evidence in favour of patient empowerment was not strong, with the current research suggesting that the barriers to its implementation outweighed the facilitators, that it was the least successfully implemented component of the CYHC, and that there was, as yet, no convincing behavioural framework to inform an intervention able to overcome these. A report was sent to the Chief Medical Officer expressing these views and the research was abandoned.

The PI and research fellow were both invited to join the external reference group, which already included one member of the investigating team (Barry Cookson) on the future strategy of the CYHC. This group included all the major stakeholders in the campaign. Our advice to the group was based on
our research findings and was that the campaign should become a centre for specialist advice on hand hygiene. We suggested focussing on audit and feedback, emphasising that accurate observation of compliance was a technique that needs to be properly studied and practiced, with the NPSA providing on-line teaching materials and videos, that took into account our own workshop teaching materials for using the HHOT. This was accepted, as was our view that trusts should monitor their monthly consumables procurement, as close to ward level as possible, and that this should be required by inspection teams such as the then healthcare commission (see clinical recommendations 5 & 7). However, after the spending review the decision was taken to close the NPSA and to move patient safety elsewhere within the NHS. It is currently unclear where that will be. Although CYHC materials will still be available for trusts to use, the other recommendations have not been taken up.

b. Infection Prevention Society (IPS) (Appendix 8 & 9)
As part of its teaching materials, the NPSA decided to adopt the WHO’s “Five Moments for hand hygiene” to teach and remind HCWs which hand hygiene opportunities necessitated hand hygiene. The Infection Prevention Society had been tasked by the DoH to produce audit tools for infection control which would become the national standard for all four home nations. Amongst the tools would be one for hand hygiene and the NPSA suggested that the NOSEC/FIT group work with the IPS to produce it. The IPS were happy to base the tool on the HHOT but requested that the terminology of the HHOT should reflect that of the “Five Moments”. We therefore revised the SOPs so that they were consistent with “Five moments” (Appendix 8) and entered a formal agreement with IPS relating to ownership of the tool (Appendix 9). The national audit tools were to be released in May 2010 but have been delayed.

c. Joint Commission
The NOSEC/FIT team were approached by the Joint Commission in America to submit our hand hygiene tool to critical scrutiny for inclusion in their monograph on measuring hand hygiene compliance. We submitted both the
HHOT and descriptions and analyses of the effect of the CYHC. The HHOT was published in full, one of the only tools published in the monograph, and was the only such tool to have full detailed SOPs published. There was also a detailed description of how reliability was tested. A synopsis of the near final results of the NOSEC study was also published within the monograph. The final monograph, which we also helped proof read and comment on, is the most up to date and detailed summary of research on hand hygiene methodology. Publication of the HHOT in the monograph makes it easily accessible to a wide international range of researchers in the field, and aids in its dissemination (16).

**d. National Audit Office (34)**

NOSEC questionnaire response rates fell over the first five questionnaires. The final questionnaire was to be released at about the same time as the NAO mandatory questionnaire on infection control. In line with a national agreement to avoid questionnaire “overload” for hospitals, the National Audit Office agreed to include the NOSEC questions in their own questionnaire, for those hospitals which had failed to respond to the final voluntary NOSEC questionnaire. In return, the NOSEC/FIT group helped with the development of the NAO questionnaire, in particular sections on hand hygiene, which had not been included in past questionnaires, isolation, antibiotic stewardship and cleaning. The group also piloted the full NAO questionnaire in several hospitals so that it could be “road tested” by chief executives, Directors of Infection Prevention and Control and Infection Control Teams before being released.
Section 6. Additional outputs - workshops

a. Hand hygiene Observation Tool workshops (Appendix 7)
After presentation of the HHOT study at scientific meetings and the publication of the paper, there were requests for workshops to teach the method to Infection Control Teams. Appendix 7 contains the training materials, which were developed from the training we gave to hand hygiene observers for the FIT study. They took the format of the FIT team explaining the SOPs of the HHOT, and illustrating each hand hygiene moment with a scenario that was acted out by members of the team. Attendees were required to assess whether there was a hand hygiene moment and to classify the associated hand hygiene behaviour of the actors. They were then required to feedback their findings to the person co-ordinating the workshop, who then commented on them, inviting further discussion or comment from the group. Each workshop took about 90 minutes. They were held at the Sheffield HIS “Don’t Panic” Conference in 2008 and 2009, for the Infection Control team at Beaumont Hospital, Royal College of Surgeons of Ireland (2008) and for infection control link nurses at the Royal Marsden Hospital (2008).

b. Feedback Intervention workshop (Appendix 10)
The training materials to equip the ward implementers to deliver the intervention, giving feedback to both individuals and groups, and helping HCWs to decide their own hand hygiene goals, were modified to provide a workshop for the infection control team at Beaumont Hospital, Royal College of Surgeons of Ireland, who were interested in acquiring the technique. Again, these took the format of scenarios acted out by the FIT team, with interactive feedback from the attendees.
Section 7. Dissemination

a. Conference presentations (Appendix 15)
Throughout the study, the research team made regular presentations to infection control, public health and microbiology conferences in the UK, America (SHEA; Society for Hospital Epidemiology of America) and Europe (EECMID- European Conference for Clinical Microbiology and Infectious Diseases). In particular these featured the presentation of the final results of the NOSEC study at ECCMID 2009, HPA 2009, with invited presentations at the Welsh Assembly 2009 and the combined ECDC-DOH conference October 2009 and late breaker presentations of the first results of NOSEC and the penultimate results at SHEA 2007 and 2009. The full list of oral presentations in 2011 and conference poster presentations are listed in Appendix 15. The FIT study was selected for a plenary session of SHEA as one of the four best abstracts submitted to the meeting.

b. Publications (Appendix 16)
As soon as results started coming through, the NOSEC/FIT studies have prepared publications, beginning in 2007 with an “early communication” on the initial stages of the clean your hands campaign in Journal Of Hospital Infection (Appendix 17), continuing with the Hand Hygiene Observation Tool study in 2008, followed by the blinding study (Appendix 11) and that on use of AHR at ward entrances and of AHR and soap by patients and visitors at the bedside in 2010 (Appendix 13). “The dirty hand in the latex glove” (Appendix 14) has been accepted by Infection Control and Hospital Epidemiology who wish to run a press release on it. To date these represent the five main publications, with the paper on the NOSEC study (Appendix 1) out to the BMJ at present being resubmitted. The FIT study (Appendix 2) has been sent to PloS Medicine who have suggested slight revision and then sending it to PLOS. The American Journal of Infection Control is considering “What is the ideal period for direct observation of hand hygiene compliance?” (Appendix 12), which is out to referees.
In addition there have been two letters, one on the CYHC (Appendix 18) and another on the theory of feedback (Appendix 19) and four abstracts from conferences published in a supplement. Appendix 16 lists all publications. The PhD based on the pilot trial of FIT was submitted to the University of London on 1st December 2010.

c. Health Select Committee March 2009
We were asked to present a summary of the NOSEC study to the Parliamentary Health Select Committee of March 2009. These related in particular to the uptake of the campaign and the relationship between AHE use and MRSAB reductions. These are given in the relevant parliamentary records.

d. National Audit Office and the Parliamentary Accounts Committee 2009 (34, 35)
We were asked to submit evidence to the NAO’s third report on infection control in English hospitals (34). Our summary of the NOSEC study of the CYHC was published in their report as one of four case studies. The evidence was referred to in the resultant PAC response to the NAO in November 2009 (35).
Section 8. Limitations of the studies

The limitations of the studies are considered here because from these derive the research, and to some extent the clinical, recommendations of this report. The main limitations of the NOSEC study have been described briefly above (section 2.1) and are dealt with in full in Appendix 1. They concern principally the difficulties of carrying out an ecological study to evaluate a mandatory national infection control intervention when participation in the evaluation is not mandatory and when some important data are either unavailable or not routinely available. These are reflected in research recommendations 1-4, 6 and 21 and in clinical recommendations 1, 2, 7 and 17.

An additional criticism of the NOSEC study made by some of the Lancet referees and addressed in the resubmission, concerns the lack of any directly observed hand hygiene compliance data. Although we argue that this was not a real limitation of the study for the following reasons. The first reason that direct observation of hand hygiene was not considered for the NOSEC study was pragmatic. It might have been ideal to supplement hand hygiene consumables data with directly observed hand hygiene data from a small number (10-20) of sentinel hospitals, but there were insufficient research funds and time to recruit and train observers to assess this with a rigorously validated method, and as noted above (section 3.1) there was no such measure available at the time. Once trained, observers would have needed to measure compliance in a wide sample of wards, for example, an ITU, a general surgical, general medical/ACE, an obstetric, paediatric, CCU and A/E ward in each hospital, in order to provide representative and comparable data across all hospitals, repeated at regular intervals (16). This would be better done, for the purposes of an independent evaluation, by research staff blinded to what hand hygiene interventions were ongoing at each sentinel hospital, which might introduce bias, than by a member of the infection control team.

The second reason why compliance data was not collected was that an alternative source of data, suggested by referees, namely asking hospitals for
their own compliance data collected as part of CYHC, was considered unreliable. This was because of the variety of audit tools used, which lack standard operating procedures and the proven reliability (27, 28, Appendix 4) required to ensure inter- and intra-hospital consistency. Moreover, implementation of audit and feedback was low in the early stages of the campaign and would not have been done on the same wards in each trust. In addition there was also no routinely available hospital level compliance data prior to CYHC to allow pre and post comparison.

There is substantial debate as to the relative merits of directly observed compliance and measurement of consumables (16). Although traditionally considered the gold standard for assessing hand hygiene, direct observation may be subject to reactive effects and suffer from selection bias due to the relatively small sample of hand hygiene moments and behaviours possible to observe in a trial such as this. Measurement of consumables however, is not subject to reactive effects, reflects 24 hour seven days a week use, is unaffected by bias and is easier to collect, especially hospital wide. The literature differs widely regarding the association between directly observed compliance and procurement data (16), with the most detailed recent study showing that direct observation over-estimates by a factor of nearly three that calculated from consumables use (36). Current opinion, advanced by those now attempting to assess hand hygiene campaigns in Europe, seems to endorse the decision of the NOSEC study, by favouring measurement of consumables as a practical and more reliable way to assess quantitative change in hand-hygiene behaviour and compare hospitals (37). Consumables can only be a proxy for compliance, because they may be used when there is no actual hand hygiene moment, and because they can be used by non-HCWs, although our work indicates (see section 3.5 above) that the latter is relatively small. One can overcome the main limitation of procurement data, procurement spikes caused by infrequent bulk orders, by using smoothing techniques, as in the NOSEC study. However, it is important to note that consumables are only a proxy indicator of the behavioural target of interest, hand hygiene behaviours.
Our experience of measuring hand hygiene by both means in NOSEC and FIT informs our recommendations for its measurement in both clinical and research settings (see clinical recommendations 5-10 & 13 and research recommendations 11, 12, 14-17).
Section 9. Clinical/service recommendations/implications

The cleanyourhands campaign
1. NOSEC has provided evidence that a multicomponent national campaign can achieve sustained improvements in hand hygiene and through the more frequent use or procurement of AHR and soap has lead to an associated reduction in some nosocomial infections.

2. The cleanyourhands campaign, having achieved substantial change in hand hygiene behaviour in England and Wales, should be maintained because when successful behavioural interventions stop behaviour often relapses. The campaign should however change its focus so that the NPSA or its successor, through the campaign, becomes a centre for specialist advice on hand hygiene. The campaign should focus more on audit and feedback, emphasising that accurate observation is a technique that needs to be taught, learnt and practiced according to standard operating criteria. The campaign should provide on-line teaching materials and videos, and workshops to facilitate this, drawing on the experience of the HHOT workshops. This recommendation is in line with the NPSA’s external expert reference group’s advice and that of external advice commissioned by the NPSA and should be supported by both the new NHS Commissioning Board and the new Department of Public Health.

3. The announcement of the campaign’s closure in December 2010 has been a cause for considerable concern amongst healthcare professionals, patients and their representatives. Without a clear national policy and strategy for hand hygiene, the gains of recent years may be lost and opportunities to improve practice still further will be missed. Although patient safety will lie within the brief of the new NHS Commissioning Board, it is not clear to what extent hand hygiene will be covered. However, the coalition government’s vision for clinical ownership of healthcare delivery and the “Big
"Society" provides an opportunity to keep hand hygiene as an essential prerequisite of Patient Safety, demanded by patients and expected of healthcare workers. These two groups of stakeholders should work together to engage and work with the new Department of Public Health, the new NHS Commissioning Board, and with local commissioners, inspectors, regulators, product developers, procurement agencies and research councils to ensure that the Health Service provides the best standard of hand hygiene based on the best available evidence. An alliance of patients and healthcare workers for hand hygiene has recently been formed to do this (44; www.idrn.org/alliance) and should take account of the recommendations in this report.

4. Some caution should be exercised in generalising from the NOSEC findings as the campaign and the study took place in the context of a high profile political drive to reduce MRSAB and CDI. It is not known whether this will generalise to other HCAIs or to other nations.

5. The following are likely to have been factors in securing sustained implementation of the campaign’s key components and should be considered by nations, states, regions or even individual hospitals in adopting the CYHC intervention:

(i) piloting of the CYHC intervention in a small number of hospitals
(ii) evaluation of that pilot prior to roll out
(iii) the preceding patient safety alert
(iv) the three month preparation time given to infection control teams to engage their institution
(v) the ongoing support given by a dedicated national CYH team that also co-ordinated two “relaunches” of the campaign.

6. Replicating the CYHC’s success in the 139 nations that have signed up to the WHO’s “SAVE LIVES: cleanyourhands” (38) initiative, which offers an intervention very like the CYHC, may therefore depend on countries’ ability to fund, co-ordinate and maintain the intervention. This is likely to vary with local health service structures, available resources, and the priority given to it by
policy makers but the CYHC provides a model for other countries to adopt or adapt to implement the WHO initiative (39).

**Hand hygiene assessment & measurement**

7. Clinical audit of hand hygiene compliance should use both direct observation and consumables data, with the latter using occupied bed days as the denominator. NICE (the National Institute for Clinical Excellence) should support this as a quality measure or statement. Observation sessions should be at least 20 minutes and cover at least 15 hand hygiene moments. They should not be longer than one hour.

8. The Hand hygiene Observation Tool should be adopted as the national tool for assessing and auditing hand hygiene as part of the IPS national, infection-control audit tools in order to standardise and improve practice across the NHS.

9. Hand hygiene consumables procurement data should be routinely available from hospitals at hospital, specialty and ward level irrespective of supplier, and be available for clinical audit and feedback, and for inspection teams such as the Care Quality Commission to facilitate inter hospital comparison and identification of outliers. NICE (the National Institute for Clinical Excellence) and the new NHS Commissioning Board should support this as a routine performance indicator.

10. Observational data is useful for informing feedback to HCWs about their HHB performance. Consideration should be given by infection control staff to employing the Feedback Intervention Trial intervention using the same cycle and principles. It is likely to be more effectively implemented and therefore be more effective if included as a regular part of the ward’s audit programme and carried out by infection control or ward staff who already have responsibility for assessing and appraising staff. The teaching materials for FIT could be used to train staff.
11. Group observational data to measure ward and hospital compliance should sample widely and frequently enough to provide representative data and to measure change over time. Like the JCO and WHO we recommend assessment of approximately 20 data-points each with around 15 opportunities for hand-hygiene. (31)

12. Hospitals should be discouraged from placing AHR dispensers at hospital entrances, as these are not clinically indicated being far removed from the point of care. If they are retained, their requisition point should be separately identified from those of clinical areas and removed from the hospital procurement data in order to provide a more accurate estimate of use at the point of care by healthcare workers.

13. Although use of AHR at the entrance to a ward is not included in the WHO 5 moments for hand hygiene or in the standard operating procedures of the HHOT, it can be argued that such use by HCWs is appropriate in that it not only reduces transient carriage of pathogens on their hands before entering a clinical area, but inculcates a culture of hand hygiene by “ritualising” their entrance to the ward. We would therefore recommend including a short period of observation of hand hygiene behaviour by HCWs at ward entrances as an additional measure of hand hygiene compliance during clinical audit. With the emergence of the swine flu (H1N1) pandemic, since the end of the NOSEC study, and WHO advice with its subsequent high profile focus on hand hygiene, it is unlikely that hospitals will remove AHR from entrances to their wards (40, 41).

14. Hospitals setting up a clinical programme to improve hand hygiene compliance should consider blinding observers or assessors to the presence and nature of any intervention in order to avoid biasing the observations. Current practice is for ward nurses or infection control nurses usually involved in the intervention to assess compliance but this introduces possible bias. Consideration should therefore be given to asking independent assessors, perhaps through mutual arrangements with neighbouring trusts infection control teams to assess compliance on request without being told what,
when and where the intervention is. Possibly this function could be entrusted to the clinical audit department who would have members of staff trained to assess compliance and to perform it regularly on request.

**Gloving practice**

15. Based on the findings (see section 4) that hand hygiene is poorer when gloves are worn, and that gloves are often worn when not indicated and vice versa, national and international campaigns such as the English and Welsh clean your hands campaign and the WHO Clean Care is Safer Care should consider emphasising better gloving practice and associated hand-hygiene.

16. Clinical audits of hand hygiene should therefore also consider examining hand hygiene practice associated with wearing gloves and adherence to WHO standards for glove use. Until a feasible unified measure of assessing hand hygiene and glove use simultaneously is produced and validated, the two practices should probably be assessed separately.

17. The field of hand hygiene improvement might also consider, on the basis of the above findings, a change in focus from trying to secure further improvements by aiming for 90-95% hand hygiene compliance and concentrate instead on improving gloving practice and its associated hand hygiene. This might prove a more effective hand-hygiene improvement strategy by raising overall compliance levels above the threshold required to reduce transmission of infection, and doing so by concentrating on those activities associated with particular risk of transmission of infection (after contacts with body fluids, before aseptic tasks or any contacts with isolated patients).

**Antibiotic prescribing**

18. A robust system to collect antibiotic data needs to be established in all hospitals able to give overall hospital, specialty and ward use. This has been a longstanding problem identified in all NAO reports on HCAI, highlighted in the 2009 report and the subsequent Parliamentary Accounts Committee response (34, 35).
Section 10. Research Implications

Evaluating national infection control interventions

1. NOSEC has implications for future studies evaluating national infection control and other patient safety interventions. It is essential that future national infection-control interventions are evaluated. NOSEC has shown how powerful the ecological design can be, even with the limitations imposed upon it at the time.

2. Consideration therefore should be given to making compliance with studies mandatory for hospitals undertaking such interventions, co-ordinating the timing of the intervention and the evaluation to balance the competing needs of implementation and evaluation. To facilitate this, future investigations should minimise the non routine data required from hospitals as much as possible, and steps should be taken to ensure that systems are in place for key data to be routinely collected.

3. Consideration should be given to extending the requirements for national reporting of MRSAB, MSSAB and CDI to other common hospital acquired infections, to procurement of hand hygiene consumables, and to antibiotic use as this will make it easier to evaluate interventions by measuring important potential confounders. The last two are national requirements in France (37). The clinical recommendation above regarding routine collection of hand hygiene consumables and antibiotic data at hospital, specialty and ward level will facilitate research not only into national interventions but trials such as FIT taking place at the ward or hospital level.

4. A preliminary economic model suggested that the campaign would prove cost effective if it reduced HCAI by 0.1% (42). A full economic analysis of the cost effectiveness of the CYHC is now underway, setting the costs of the campaign against the estimated savings on cases of MRSAB and CDI avoided (Appendix 20).
Feedback Intervention Trial—further research
5. A study of the predictors of fidelity to intervention in the FIT study will be carried out relating fidelity to the perceived barriers and facilitators. This will enable the intervention to be redesigned in order to maximise its potential effect.

6. A further trial of the re-designed intervention and its implementation is required before recommending widespread use. This should include a careful assessment of the staffing required to deliver the intervention long term.

Clinical trials of behavioural interventions in infection control
7. Future trials of behavioural interventions in infection control should follow FIT’s example in utilising behavioural evidence and theory as a basis for designing interventions, should measure implementation, and investigate its barriers and facilitators.

9. Such trials require greater staffing and, therefore, funds than were available for the FIT study. One research fellow and two junior research assistants, one of whom was occupied in blinded observation of compliance, to cover both NOSEC and FIT, meant that the research fellow, who had a nursing background in infection, was the only available and suitably qualified member of the team responsible for liaison with and encouraging the ward teams in all 16 hospitals. Additional research staff would have prevented delays in roll out of the FIT intervention, and increased the numbers implementing the intervention, by maximising the support given to the ward teams, and enabled sustainability to have been examined in more detail. The alternative strategy would have been for funding to have been provided to local infection control teams, to allow them to spend one day a week supporting or doing the intervention. Future trials should give serious consideration to this issue in their planning and funding.
Hand hygiene trials

10. Trials of hand hygiene interventions should consider carefully how many hand hygiene observers are required and how to employ them (see section 1.5). Such work is monotonous and we were fortunate to employ one observer who was able to observe for nearly all the implementation period. For large trials requiring regular assessment of hand hygiene compliance, ensuring a supply of blinded observers is important. We estimate that a 60 ward study requires two whole time equivalent observers, to allow regular monthly assessments. This might be best achieved using four part timers, depending on recruitment possibilities.

11. Trials of hand hygiene interventions should continue to use both direct observation and consumables data, with the latter using occupied bed days as the denominator. Observation sessions should be at least 20 minutes and cover at least 15 hand hygiene moments. They should not be longer than one hour. Researchers should state and explain the period and frequency of observations, which might vary with the setting, resources available for observation and the number of sites to be observed.

12. Future trials of hand hygiene should use the amended version of the HHOT for direct observation of hand hygiene compliance as this is the only available robustly validated assessment with easily accessible standard operating procedures consistent with the WHO “five moments” of hand hygiene.

13. All randomized controlled trials and other study designs evaluating hand hygiene interventions should blind observers and assess its efficacy. This needs to be written into trial protocols and grant applications.

Measuring procurement of consumables in hand hygiene trials

14. Future studies of hand hygiene interventions using ward procurement data as an additional or surrogate marker of compliance should incorporate some assessment of visitor and patient use at the bed side and ward entrances, especially as ward entrance use can vary widely between wards.
15. For clinical trials taking place on individual wards this can be achieved through adding assessment of patient and visitor use of consumables at the bed side to the hand hygiene assessment protocol, and adding a short period of observation of hand hygiene behaviour at ward entrances to the observation schedule. Quantifying the use of AHR at ward entrances should be done by ward or infection control staff as described in Appendix 12.

16. For studies such as NOSEC, which use total hospital procurement data as an outcome measure, assessing non HCW use of consumables, including that at ward entrances is more difficult. Consideration should be given to choosing sentinel hospitals and measuring use in a specified sample of wards in each sentinel hospital, for example on ITU, an acute medical or elderly ward, a surgical, paediatric, casualty and women’s health ward every quarter. An infection control nurse at the sentinel hospital would be required to do this, and the hospital paid for the time involved.

17. Hospitals involved in whole hospital studies of hand hygiene interventions who continue to site AHR at general entrances will require assessment of AHR use at these sites using a similar schedule to that described for ward entrances.

**Glove use**

18. A validated comprehensive assessment of glove-use and its associated hand-hygiene behaviours is needed. A study to develop this should also examine how such an assessment could feasibly be combined with the HHOT.

19. A study to investigate gloving practice and associated hand hygiene behaviours in staff caring for patients in isolation should be carried out.

20. Study of the behavioural and psychological predictors of gloving behaviour and their relationships to hand disinfection is warranted, and would be useful to help design an intervention to improve hand-hygiene when wearing gloves, and limit glove-use to those indications in the WHO
guidelines. This could in turn lead to a trial of the effectiveness of such an intervention.

**MRSA Infection outcomes for trials**

21. For clinical trials aiming to reduce MRSA, the best infectious outcome would be MRSA acquisition measured by admission and discharge screening. As trusts are routinely screening all admissions, and as prevalence screening is also common now, we have found this to be acceptable to ward staff in a current trial of isolation, whereas measuring MRSA prevalence in FIT was unacceptable to most staff.
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- Heatherwood and Wexham Park Hospitals NHS Trust
- Homerton University Hospital NHS Trust
- Medway Maritime Hospitals NHS Trust
- Plymouth Hospitals NHS Trust
- Poole Hospital NHS Trust
- Portsmouth Hospitals NHS Trust
- Queen Elizabeth Hospital NHS Trust
- Royal Free Hampstead NHS Trust.
- Royal Bournemouth and Christchurch NHS Trust
- Royal West Sussex NHS Trust
- Sussex & Surrey Healthcare NHS Trust
- UCH NHS Trust
- Whittington Hospital NHS Trust
- Winchester and Eastleigh Hospital NHS Trust
- York Hospitals NHS Trust
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