Results of a multicentre randomised controlled trial of statistical process control charts and structured diagnostic tools to reduce ward-acquired meticillin-resistant Staphylococcus aureus: the CHART Project

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Summary  Statistical process control (SPC) charts have previously been advocated for infection control quality improvement. To determine their effectiveness, a multicentre randomised controlled trial was undertaken to explore whether monthly SPC feedback from infection control nurses (ICNs) to healthcare workers of ward-acquired meticillin-resistant Staphylococcus aureus (WA-MRSA) colonisation or infection rates would produce any reductions in incidence. Seventy-five wards in 24 hospitals in the UK were randomised into three arms: (1) wards receiving SPC chart feedback; (2) wards receiving SPC chart feedback in conjunction with structured diagnostic tools; and (3) control wards receiving neither type of feedback. Twenty-five months of pre-intervention WA-MRSA data were compared with 24 months of post-intervention data. Statistically significant and sustained decreases in WA-MRSA rates were identified in all three arms (% < 0.001; % = 0.015; % < 0.001). The mean percentage reduction was 32.3% for wards receiving SPC feedback, 19.6% for wards receiving SPC

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and diagnostic feedback, and 23.1% for control wards, but with no significant difference between the control and intervention arms \((P = 0.23)\). There were significantly more post-intervention ‘out-of-control’ episodes \((P = 0.021)\) in the control arm (averages of 0.60, 0.28, and 0.28 for Control, SPC and SPC + Tools wards, respectively). Participants identified SPC charts as an effective communication tool and valuable for disseminating WA-MRSA data.

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Introduction

Staphylococcus aureus is the single most important cause of hospital-associated bacteraemia.\(^1\)\(^-\)\(^2\) MRSA infections are seen as symptomatic of a failing healthcare system and the incidence of MRSA bacteraemia rose significantly during the 1990s in addition to cases involving meticillin-susceptible strains.\(^3\)\(^-\)\(^7\) Surveillance systems intended to reduce the incidence of WA-MRSA have had limited success.\(^8\)

The Study on the Efficacy of Nosocomial Infection Control demonstrated that surveillance with feedback is an effective infection prevention and control (IPC) activity and resulted in the establishment of local and national surveillance programmes.\(^9\)\(^-\)\(^11\) Some investigators have suggested that the quality of IPC practices can be improved by feeding back surveillance data to those involved in front-line patient care.\(^12\)\(^,\)\(^13\) Statistical process control (SPC) charts have been strongly recommended for this purpose.\(^14\)\(^-\)\(^18\) By analysing data over time, control charts can usually identify rate changes faster than if aggregated into larger samples and, additionally, can distinguish between two important types of variability.\(^19\) For processes with stable incidence rates (termed ‘in statistical control’) data vary in a consistent manner around the mean (centre line or CL), i.e. ‘natural variation’. For processes with unstable incidence rates (‘out of statistical control’) data vary in an inconsistent manner, i.e. ‘unnatural variation’. Unnatural variation indicates either the introduction of more communicable MRSA strains or deterioration in IPC practices.

To determine which type of variation exists, control charts plot monthly WA-MRSA data along with the CL and lower and upper control limits (LCL and UCL) that define the range of natural variation, assuming that causal processes remain unchanged. These limits are typically set at three standard deviations above and below the mean, with early warning limits sometimes set at two standard deviations from the CL.\(^15\)

In a previous study in one Glasgow hospital a 50% reduction in WA-MRSA incidence occurred after the introduction of SPC feedback.\(^20\) The infection control team (ICT) produced SPC charts to provide awareness of each ward’s natural and unnatural variation. These charts were found to be easy to produce, easy to produce feedback and helpful for communication and identification of infection control problems, providing a statistical rather than a subjective approach to identifying significant improvement or deterioration.

Once a problem is identified, quality improvement diagnostic tools such as Pareto and cause-and-effect charts may help to identify solutions. Fishbone cause-and-effect charts were developed to minimise transmission based on national MRSA guidelines and other publications that identify factors contributing to rate increases.\(^21\)\(^,\)\(^22\) Other investigators have also suggested that feedback of audits in the form of Pareto charts, which are based on the principle that typically the majority of problems are attributable to a minority of causes, can help practitioners focus their remedial actions.\(^23\)

The CHART study was undertaken to determine whether: (1) providing feedback in the form of SPC charts of WA-MRSA data to healthcare workers (HCWs) directly involved in patient care results in incidence reductions, suggesting improvement in infection control practices; and (2) additional use of cause-and-effect and Pareto charts as structured diagnostic tools promotes greater IPC improvements and incidence reductions.

The research described here is the main component of a multiple-method study that includes a descriptive component undertaken concurrently. It is the authors’ intention that the descriptive component of the study will be the subject of future publications. In the interim a detailed account of the study is available to interested readers in the form of a full report made to the Department of Health from Dr P. Harper at the Richard Wells Research Centre.
Methods

ICTs were invited to take part in this project through mailings and presentations at the 2001 Infection Control Nurses Association annual conference. ICTs who expressed interest were asked to complete an application form and entered into the trial if their facilities met inclusion criteria. In order to be eligible to participate in the study all participating wards in each hospital were required to:

- have not used SPC, Fishbone or Pareto charts before the study;
- be stable in terms of size (past and future);
- be stable in terms of bed occupancy (past and future);
- be similar in focus, i.e. patient types/treatments;
- be similar in design, e.g. bays and single-bedded rooms;
- be able to provide WA-MRSA incidence data for 25 months before the start of the study;
- have a monthly WA-MRSA incidence average \( \geq 1 \) as measured over the 12 months before the start of the study.

Twenty-three of the 24 selected hospitals provided three participating wards each, while one hospital provided two sets of three wards, giving a total of 75 wards. One ward in each set was randomly assigned to each of three study arms: wards receiving SPC chart feedback (SPC arm), wards receiving SPC feedback together with structured diagnostic tools (SPC + Tools arm); and wards receiving no new feedback of either type (Control arm). A list of all participating centres along with the names of the three wards to be randomised within each centre was given to the trial statistician, who had no access to any other information about the wards. A sequence of random digits was generated using the Minitab\textsuperscript{\textregistered} statistical package and used to allocate the three wards within each centre to the Control group, the SPC group or the SPC + Tools group. When the data were analysed at the end of the trial the allocated group for each ward was checked against the original list to verify that the randomisation sequence had been correctly followed.

The pre-intervention period ran from March 2002 to March 2004. Feedback occurred monthly from April 2004 through March 2006 in all but one centre which started feedback in August 2004. In two other centres the post-intervention data for the SPC + Tools wards were not complete, with 19 months and 16 (rather than 24) months of post-intervention data.

The outcome measure for the experimental phase of the study was the monthly MRSA colonisation and infection rate for each of the participating wards. Each centre was required to supply the research team with a copy of the local protocols used for calculating WA-MRSA (including laboratory procedures) during the pre-intervention period and to undertake to use the same protocols during the intervention period. Local protocols were verified by the senior microbiologist on the research team and by one of the lead investigators with expertise in clinical infection control.

Participating centres submitted WA-MRSA data at the end of each month. For the intervention wards, SPC charts were updated, annotated and sent to the wards. The annotation was typically one or two sentences describing the observed variation and any out-of-control episodes or trends to be aware of. Poisson-based 'c' type of control charts with initial centre lines and three standard deviation control limits were calculated from the 25 months of baseline data supplied by each ward. Data were not adjusted for patient acuity or volume for reporting simplicity and because monthly census and patient populations were fairly constant within wards.

The CL was lowered or raised if the chart exhibited eight consecutive months below or above the CL, and an annotation added to the chart. Warning signals, e.g. four to seven consecutive months above the CL, were noted with annotations that continuation of this pattern would indicate an infection rate increase.\textsuperscript{15} The ICN met monthly with each ward manager to discuss the results. Intervention wards received only their own data and were not informed of other wards' WA-MRSA rates until the study ended.

For the SPC + Tools wards, ICNs conducted audits of IPC practices at the end of months 4, 10, 17 and 22. The research team prepared separate Pareto charts of these results for each ward for the ICNs to review with their ward managers. For control wards, SPC charts were constructed and reviewed only after the study ended. The cause-and-effect chart is based on published guidance as to what might cause cross-transmission. The audits were based on these tools and consequently the Pareto charts were published as errors from the audits. Locally the ICT could use the cause-and-effect chart to discuss with the ward team what they thought were causing problems or what changes could be made to reduce the risk of cross-transmission. Training was provided to all participating ICTs. Examples of annotated SPC, and Pareto charts are shown in Figure 1.
After the study ended, all control charts were reviewed independently by two members of the research team, one of whom was blinded to wards and arms, to assess ward stability and out-of-control episodes. Three aggregate control charts were constructed from all 24 wards in each study arm, omitting data from the late starting centre (which was, however, included in between-centre statistical analyses). Reductions in WA-MRSA rates (pre-versus post-intervention) were compared between arms. Power calculations required 22 centres (assuming a WA-MRSA reduction of 25% using SPC+Tools, 10% in the control arm, and a standard deviation of WA-MRSA reduction of 15% in each arm) for 90% power at $P = 0.05$. This estimate does not consider between-ward correlation in MRSA rates within each centre; any correlation is likely to be positive, which would increase power. No attempt was made to undertake subgroup analyses on possible differences in WA-MRSAs or between different types of hospitals, wards, etc.

Results

Within-arm MRSA rate stability

Figure 2 compares the aggregate control charts for each arm. As shown, the WA-MRSA rate for the SPC arm is stable during the baseline period (although six consecutive data above the CL just before the study began indicate a possibly increasing rate) and exhibits a one-time and sustained decrease from a monthly average of 48 cases during the baseline period to 30 cases per month post intervention. No post-intervention rate increases are evident at the aggregate level although individually one ward experienced a significant increase in December 2005.

By contrast, the SPC+Tools arm exhibits one pre-intervention out-of-control episode (November 2005) and continuous post-intervention improvements from 50 (pre-intervention baseline) to 26 WA-MRSA cases per month, experiencing three separate CL recalculations.

The Control arm exhibited a slight pre-intervention reduction in the WA-MRSA rate (11 consecutive months below the CL) and a more significant post-intervention reduction from an average of 49 cases per month for the 12 pre-intervention months to 36 per month. By contrast with the experimental arms, a rate increase occurred near the end of the intervention period in January 2006 (above UCL), with six of the last seven months above the CL also suggesting that the earlier reduction was not sustained and that the MRSA rate may be increasing.

Percentage rate reductions

For each arm, Table I summarizes the mean (SD) number of new cases in each ward before and after the intervention, the average percentage reduction and the mean number of post-intervention monthly data above the UCL (indicating inconsistent cause or prevention processes). Since the post-intervention data include months immediately after the intervention was introduced, it could contain a learning trend (rather than a step-type of change), so the final 12 months pre-intervention and final 12 months post-intervention may offer a more meaningful comparison. In both cases (i.e. for all data and for the final 12 months only), 95% confidence intervals and $P$ values (paired t-tests) indicate that all three arms experienced statistically significant WA-MRSA reductions. However, repeated measures analysis of variance (ANOVA) found no significant difference [$P = 0.23$ (all data) and $P = 0.46$ (final 12 months)] between the mean percentage reductions of each arm, as also suggested by the overlapping confidence intervals.

Out-of-control episodes

The mean number of months exhibiting unnatural variation above the UCL (i.e. out-of-control episodes) was 0.60 for control wards versus 0.28 for both SPC and SPC+Tools wards, a statistically significant difference (Friedman’s test, $P = 0.021$). Of the control wards, 56% experienced at least one out-of-control episode versus 16% for both the SPC and SPC+Tools arms. If this comparison is restricted to the final 12 months pre and post intervention, the mean numbers of out-of-control episodes are 0.32 for Control, 0.12 for SPC and 0.08 for SPC+Tools (Friedman’s test, $P = 0.032$).

Discussion

This study explored whether monthly feedback to front-line HCWs of WA-MRSA data using SPC charts would result in reductions in colonisation and infection rates, and whether additional use of cause-and-effect and Pareto charts as diagnostic aids would result in further reductions. Although each arm experienced statistically significant reductions in the mean number of new WA-MRSA cases per month, there were no significant differences between arms either for actual or for proportional reductions. If participating wards are representative, these reductions suggest ~25%
Sample chart for an SPC + Tools ward at the end of the study

Out-of-control episode

Chart comment March 2006 - This chart continues stable and in control around the lowered centre line - Well Done

Centre Line lowered in March 2005 after 8 consecutive results less than 1.

Sample Pareto chart 10-month isolation audit

Total observed criteria =136
Total errors criteria =11

Compliance with isolation procedures has improved from 70% on earlier audit to 91% on current audit - Well done.

(Quoting D Berwick, please remember, ‘Feedback is for improvement not judgement’ - well done)

Figure 1   Examples of annotated statistical process control (SPC) and Pareto charts. Diamonds/solid line: total; dashed line: centre line (mean); dotted lines: upper and lower control limits.
Figure 2  Summary control charts for the statistical process control (SPC), SPC + Tools and Control arms. Diamonds/solid line: total; dashed line: centre line (mean); dotted lines: upper and lower control limits.
decrease in WA-MRSA throughout UK hospitals between April 2004 and March 2006.

Confounders such as length of stay, case mix, bed occupancy, staffing levels, hand hygiene compliance, antibiotic use, strain type and processing of isolates were in effect the current working conditions individual to each context. Details of any changes of policy were requested quarterly throughout the study and none were reported by the participants. Changes in bed occupancy or ward purpose were also requested and where relevant annotated on the charts. None of these could explain the sustained decreases in WA-MRSA noted throughout the study. All of these factors were included on the cause-and-effect chart, the main purpose of which is to involve the ICT and ward staff in discussions regarding significant changes as indicated by out-of-control episodes in the SPC charts.

The lack of between-arm differences in MRSA rate reductions and the improvements seen on the control wards may have various explanations. One is that the null hypothesis is true and that SPC feedback and the diagnostic tools are ineffective in facilitating WA-MRSA rate reductions. Another is that the study was conducted during a period of unprecedented government and media focus on healthcare-associated infections (HCAIs), with multiple interventions throughout the National Health Service (such as the National Patient Safety Agency’s ‘Clean your hands’ campaign) producing significant IPC improvements in all three arms.

The continuous improvement trend of the SPC + Tools wards, in contrast with the one-time rate reductions of the other two arms, and the improved stability in both intervention arms (i.e. fewer out-of-control episodes) are interesting observations that warrant further research. For example, it is possible that the combination of feedback and diagnostic tools results in improvement of a different type, indicative of a culture of continuous improvement and process standardization.

The mean number of out-of-control episodes per month (post intervention) for the SPC and SPC + Tools arms was lower than for the Control arm, suggesting more consistent IPC practices due to SPC feedback, although the difference was only moderately significant. Such standardization is an important achievement in process

<table>
<thead>
<tr>
<th>Table I</th>
<th>Mean number of out-of-control months after intervention and mean (SD) number of new MRSA cases per month per ward before and after intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm</td>
<td>No. of wards</td>
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<tr>
<td>All data</td>
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<tr>
<td>SPC only</td>
<td>25</td>
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<td>SPC + Tools</td>
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<td>Control</td>
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<tr>
<td>Final 12 months before and after intervention</td>
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<tr>
<td>SPC only</td>
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<td>SPC + Tools</td>
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<td>Control</td>
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MRSA, meticillin-resistant Staphylococcus aureus; SPC, statistical process control.
improvement work, indicating that processes are consistently followed.

Several additional benefits of SPC feedback (with or without the diagnostic tools) were evident during this study. Control charts identified rate changes within wards in all three arms that would not have been detected as quickly, helping ICTs to direct their attention to where more urgent action is required. Furthermore, if SPC charts continue to be used the impact of hypothesised improvements could be measured, e.g., changes in antibiotic policy or increased placement of alcohol hand gels, an iterative introduction and assessment quality improvement approach that follows Berwick and Nolan’s ‘model for improvement’.24

ICNs and ward managers also appreciated SPC as a communication tool. The monthly delivery and review of control charts to discuss IPC performance created a process somewhat akin to ‘quality circles’, i.e., small regular meetings to discuss improving the quality of care delivered to patients. Other investigators have previously demonstrated the benefit of quality circles in IPC.25 Some ICTs also used control charts to promote and demonstrate their quality and commitment to IPC. Some even received pressure near the end of the study to implement SPC across their institutions.

Control charts were felt to add a helpful statistical approach to defining and detecting significant rate changes and outbreaks. Wenzel et al. described a consensus definition of a significant MRSA increase as a 25% increase above the baseline, three or more new cases per month in any unit, or one case per month in a unit previously without cases.26 Control limits and other rules for statistical significance can complement this definition.

It should also be noted that the prevalence of patients with MRSA on the wards would be subject to natural variation. If a ward went out of control the possible causes would include an increase in the prevalence of MRSA cases and an inability to isolate. An out-of-control situation does not always denote that the staff are doing something wrong – they might be doing well given current working conditions and available resources. The SPC chart in this instance would give them the opportunity to illustrate specific challenges to the system.

No additional resources were provided locally to undertake this work. Updating a chart when new monthly data became available took only minutes. The participants were trained to update the charts such that when the central analysis stopped they would be able to carry on.

This approach might be beneficial for other HCAIs, since WA-MRSA prevention and control precautions are similar to those for other HCAIs.8,20,22 In addition, SPC feedback satisfies criteria for a useful IPC quality marker in that it reflects performance; is easy to interpret; is continuously collected and fed back in real time; distinguishes between natural and unnatural variation; and is communicated to multiple individuals responsible for supporting infection control practices.

In conclusion, this study demonstrated the utility of using control charts to monitor and feedback WA-MRSA rates to front-line HCWs. If SPC charts were used nationally, comparative feedback on WA-MRSA rates and stability could be useful in improving and sustaining IPC improvements. SPC monitoring of WA-MRSA may also serve as a proxy for IPC monitoring more broadly.

The study highlighted a number of additional benefits:

- identifying when and where ICTs should focus their efforts to investigate causes of WA-MRSA increases;
- assisting in determining the hospital epidemiology of antimicrobial-resistant alert organisms;
- improving communication between ICTs and ward managers regarding IPC performance;
- promoting and demonstrating commitment to IPC.

All participants valued using SPC as a feedback system and many stated that they would continue using it after the study ended to help monitor and feedback infection data. National agencies should use WA-MRSA control charts to monitor the impact of national programmes aimed at reducing the incidence of HCAI and to help determine the epidemiology of antibiotic-resistant organisms at ward, hospital and national levels.

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Conflicts of interest statement
None declared.

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References


