

The longitudinal prevalence of MRSA in care home residents and the effectiveness of improving infection prevention knowledge and practice on colonisation using a stepped wedge study design

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Complete List of Authors:	Horner, Carolyne; Leeds Teaching Hospitals NHS Trust, Microbiology Wilcox, Mark; Leeds Teaching Hospitals NHS Trust, Microbiology Barr, Ben; University of Liverpool, Division of Public Health Hall, David; NHS Leeds Hodgson, Gillian; Leeds Teaching Hospitals NHS Trust, Microbiology Parnell, Peter; Leeds Teaching Hospitals NHS Trust, Microbiology Tompkins, David; Health Protection Agency						
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ORION Checklist of items to include when reporting an outbreak or intervention study of a nosocomial organism

	ltem Number	Descriptor
Title & Abstract	1	Description of paper as outbreak report or intervention study.
		Design of intervention study (eg Randomised Controlled Trial, Cluster Randomised Controlled Trial, Interrupted Time Series, Cohort study etc).
		Brief description of intervention and main outcomes DONE
Introduction		Scientific and/or local clinical background and rationale.
Background	2	Description of organism as epidemic, endemic or epidemic becoming endemic DONE
Type of paper	3	Description of paper as Intervention study or an Outbreak Report.
.) he er herhet.	-	If an outbreak report, report the number of outbreaks DONE
Dates	4	Start and finish dates of the study or report DONE
Objectives	5	Objectives for outbreak reports. Hypotheses for intervention studies - DONE
Methods	-	Study design, Use of EPOC classification, recommended (BCT or CBCT, CBA, or ITS) - STEP WEDGE DESIGN
Design	6	Whether study was retrospective, prospective or ambidirectional
200.9.1	°	Whether decision to report or intervene, was promoted by any outcome data
		Whether study was formally implemented with predefined protocol and endpoints
Participants	7	Number of patients admitted in study or outbreak Summaries of distributions of are and lengths of stays. If possible proportion admitted from other wards, hospitals
1 antioipanto	,	nursing homes or from abrand Where relevant optimized of balances of age and insight of the provide the second sec
Setting	8	Description of the unit word or hospital and if a bospital the units included
Octung	0	Number of beds, the presence and staffing, levels of an infection control team - DONE
Interventions	9	Definition of pleases by major change in specific infection control practice (with start and stop dates). A summary table is strongly recommended, with pracise datails
	5	interventions how and when administered in each phase - DONE
Culturing & Typing	10	Details of culture media use of selective antibiotics and local and (or reference typing. Where relevant, details of environmental sampling - DONE
Infaction related	10	Clearly defined a manufactor of according to the second of
	11	clearly defined primary and secondary outcomes (egine derived on mechanic), bacteraemia) at regular time mechanics (egine derived on mechanic), bacteraemia) at regular time mechanics (egine derived on mechanic), bacteraemia) at regular time mechanics (egine derived on the der
outcomes		as totals for each priase, with at least three data points per priase and, for many two priase studies, r2 or more monthly data points per priase. Denominators (ega
		for information on admission and directly strike table motoling.
		For interction, colonisation on admission and directly attributable monanty.
Faanamia	10	For short studies of outpreak reports, use of crians with duration patient stary & dates organism detected may be useful (see text) - DONE
ECONOMIC	12	important accurations, with costs broken down to basic units, stating
Detential Threats	10	Important assumptions. NOT AFFEICADLE
Polenilar Inreals	13	semplinare orbitate values atrain and high and a second of adjusted for (eg. changes in length of stay, case mix, bed occupancy, stalling levels, hand-hygiene
to internal validity		Compliance, antibiolic use, strain type, processing or isolates, seasonanty).
Comula alma	14	Description of measures to avoid bias including binding a standardisation of outcome assessment a provision of care DONE
Sample size	14	Details of power calculations, where appropriate - ARE AVAILABLE IF REQUIRED
Statistical	15	Description of statistical methods to compare groups or phases. Methods for any subgroup of adjusted analyses, distinguishing between planned and unplanned
methods		(exploratory) analysis. Unless outcomes are independent, statistical approaches able to account for dependencies in the outcome data should be used, adjusting,
		where necessary, for potential contounders DONE
	10	For outbreak reports statistical analysis may be inappropriate.
Results	16	For relevant designs the dates defining periods of recruitment and follow-up. A flow diagram is recommended to describe participant flow in each stage of study
Recruitment		NOT APPLICABLE
	. –	
Outcomes &	17	For the main outcomes, the estimated effect size and its precision (usually using confidence intervals). A graphical summary of the outcome data is often appropriation
estimation		for dependent data (such as most time series) DONE
Ancillary analyses	18	Any subgroup analyses should be reported and it should be stated whether or not it was planned (specified in the protocol) and possible confounders adjusted for -
		DONE
Adverse events	19	Pre-specified categories of adverse events and occurrences of these in each intervention group. This might include drug side effects, crude or disease specific
		mortality in antibiotic policy studies or opportunity costs in isolation studies NOT APPLICABLE
Discussion		For intervention studies an assessment of evidence for/against hypotheses, accounting for potential threats to validity of inference including regression to mean effe
Interpretation	20	and reporting bias.
		For outbreak reports, consider clinical significance of observations and hypotheses generated to explain them NOT APPLICABLE
Generalisability	21	External validity of the findings of the intervention study i.e. to what degree can results be expected to generalise to different target populations or settings DONE
a	20	

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Abbreviations: RCT: randomised controlled trial CRCT : Cluster Randomised Controlled Trial CBA: controlled before and after study ITS: interrupted time series

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4 5 6	1	The longitudinal prevalence of MRSA in care home residents and the
7 8	2	effectiveness of improving infection prevention knowledge and practice
9 10 11	3	on colonisation using a stepped wedge study design
12 13 14	4	C Horner, M Wilcox, B Barr, D Hall, G Hodgson, P Parnell, & D Tompkins
15 16	5	C Horner Clinical Scientist Leeds Teaching Hospitals NHS Trust, Department of
17 18	6	Microbiology, Old Medical School, Leeds General Infirmary, Leeds, LS1 3EX
19 20 21	7	M Wilcox Consultant/Clinical Director of Microbiology/Pathology, Leeds Teaching
22 23	8	Hospitals NHS Trust, Department of Microbiology, Old Medical School, Leeds General
24 25	9	Infirmary, Leeds, LS1 3EX
20 27 28	10	B Barr Specialty Registrar in Public Health, University of Liverpool, Division of Public
29 30	11	Health, Whelan Building, Quadrangle, Liverpool, L69 3GB
31 32 33	12	D Hall Infection Prevention and Control Nurse NHS Leeds, Sycamore Lodge, 7a
34 35	13	Woodhouse Cliff, Leeds, LS6 2HF
36 37	14	G Hodgson Nurse Consultant Leeds Teaching Hospitals NHS Trust, Infection
38 39 40	15	Prevention and Control, Leeds General Infirmary, Leeds, LS1 3EX
41 42	16	P Parnell Senior Biomedical Scientist Department of Microbiology, Old Medical School,
43 44 45	17	Leeds General Infirmary, Leeds, LS1 3EX
46 47	18	D Tompkins Former Regional Microbiologist HPA Yorkshire and the Humber, Bridle
48 49 50	19	Path, York Road, Leeds, LS15 7TR
50 51 52	20	Corresponding author and address for reprints: Mark.wilcox@leedsth.nhs.uk.
53 54	21	Word count: 5220. The manuscript contains four tables (Tables 1-4) and one figure
55 56 57	22	(Figure 1).
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- 13 the previous three years; no other financial or non-financial relationships or interests
- 14 that that may be relevant to the submitted work.

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- 21 assistance in writing this manuscript.

22 Contributors

MW was the lead investigator and obtained funding for the study. All authors were involved in the study design and reviewed the draft of this report. CH coordinated the data management and drafted this report. GH and DT were integral to the setting up and management of the study. BB carried out the statistical analysis. PP was

- 1 responsible for laboratory protocol development. DH carried out the data collection
- 2 and the sampling of residents with assistance from other Infection Control Nurses,
- 3 North East Leeds PCT. MW is the guarantor of the study.

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8 Ethics approval

- 9 The study received approval from the East Leeds Research Ethics Committee: MREC
- 10 reference number 06/Q1206/162.

3 4	1	Article Summary
5 6	1	Antole Summary
7 8	2	1) Article Focus
9 10 11	3	To assess the effectiveness of an educational intervention on the prevalence of MRSA
12 13	4	in care homes for the elderly.
14 15 16	5	2) Key messages
17 18	6	• There was a high rate of MRSA colonisation in elderly residents of care homes
19 20 21	7	during the study period.
22 23	8	• The intervention improved the infection prevention knowledge and practice of
24 25	9	staff working in care homes, but did not reduce the prevalence of MRSA
26 27 28	10	colonisation of residents.
29 30 31	11	Additional measures are required to reduce endemic MRSA colonisation in care
32 33	12	homes.
34 35 36	13	3) Strengths and limitations of this study
37 38	14	• This is a large prospective study, including 65 homes and 2492 residents.
39 40 41	15	MRSA prevalence was monitored over a 28 month period.
42 43	16	• The intervention was plausible, unlikely to be harmful and the assessments of
44 45 46	17	the intervention were reasonable.
47 48	18	 A significant improvement was seen in scores for all three intervention
49 50 51	19 20	assessment methods; however, the intervention was associated with a small
52 53	20	but significant increase in MIRSA prevalence.
54 55	21	It was not possible to identify or control for the factors responsible for the
57 58 59 60	22	Increase in MRSA prevalence following the intervention.

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1 Abstract (249 words)

Objectives: To determine the prevalence and health outcomes of meticillin-resistant
 Staphylococcus aureus (MRSA) colonisation in elderly care home residents. To
 measure the effectiveness of improving infection prevention knowledge and practice on
 MRSA prevalence.

6 Setting: Care homes, with and without nursing capability, for elderly residents in
7 Leeds, UK.

8 **Participants:** Residents able to give informed consent.

9 **Design:** A controlled before and after intervention study, using a stepped-wedge 10 design, in three groups totalling 65 care homes. Baseline MRSA prevalence was 11 determined by screening the nares of residents (n = 2492). An intervention based 12 upon staff education and training on hand hygiene was delivered at three different 13 times according to group number. Scores for an audit of hand hygiene facilities, staff 14 hand hygiene observations, and an educational questionnaire were collected before 15 and after the intervention. After each group of homes received the intervention, all 16 participants were screened for MRSA nasal colonisation.

17 **Results:** MRSA prevalence was 20%, 19%, 22% and 21% in each survey,

18 respectively. There was a significant improvement in scores for all three assessment

19 methods (p <= 0.001) post-intervention. The intervention was associated with a small

20 but significant increase in MRSA prevalence (p = 0.023). MRSA colonisation was

21 associated with previous and subsequent MRSA infection, but was not significantly

22 associated with subsequent hospitalisation or mortality.

Conclusions: An intervention based on staff education and training did not result in a
 decrease in the prevalence of MRSA colonisation in care home residents. Additional
 measures will be required by reduce endemic MRSA colonisation in care homes.

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1 What is already known on this subject?

Residents of care homes are at risk of MRSA colonisation. The assessment of health outcomes of residents colonised with MRSA is not commonly reported. Robust data referring to strategies for preventing MRSA transmission in care homes are lacking and studies are needed to test infection prevention interventions that are deliverable in the care home setting.

7 What this study adds

There is a large reservoir of MRSA in care homes. MRSA colonisation is associated with previous and subsequent MRSA infection in residents of care homes; however, MRSA colonisation was not significantly associated with subsequent hospitalisation or mortality. The intervention improved staff education and hand hygiene (compliance and facility provision), but did not result in a decrease in prevalence of MRSA colonisation. Staff education and training alone cannot be expected to reduce levels of

14 MRSA colonisation in the care home residents.

1 Introduction

Meticillin-resistant *Staphylococcus aureus* is a significant cause of mortality and morbidity in both healthcare and community settings.^{1;2} Numerous surveillance schemes,^{3;4} recommendations,^{5;6} and guidelines^{7;8} have been developed with the aim of reducing levels of MRSA infection associated with healthcare. In the UK, mandatory surveillance of cases of MRSA bacteraemia was introduced in all acute NHS Trusts in England in 2001.³ Recently, levels of MRSA bacteraemia in hospitals have been decreasing markedly.⁹

The elderly population living in care homes often require frequent contact with healthcare. This situation, known as the 'revolving door' syndrome,¹⁰ when residents are admitted to hospital and then discharged back into a care home, means that care home residents are likely to be carriers of MRSA. Small studies in the UK during the 1990s identified levels of MRSA colonisation in care home residents between 0.8-17%.¹¹⁻¹³ More recently, our group¹⁴ and Baldwin et al. (2009) reported that MRSA colonisation levels among residents in care homes in the UK were greater than 20%.¹⁵ MRSA prevalence rates of greater than 36% have been reported in long-term care facilities in France and the USA.^{16;17} There is a paucity of large-scale, longitudinal studies monitoring the occurrence of MRSA in the care home setting^{14;15} and the assessment of health outcomes of residents colonised with MRSA are not commonly reported.

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Guidance for infection control in care homes was issued by the Department of Health in 2006.⁸ These guidelines comprised recommendations rather than statutory requirements, and were not specific for the control of MRSA. In a recent Care Quality Commission survey, however, 25% of participating care homes were not using the Department of Health guidance,⁸ including specific requirements that all staff should receive training in infection prevention and control.¹⁰ Most evidence for the

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> effectiveness of infection control strategies has been generated in the acute healthcare setting.^{7;18} Although some infection prevention recommendations designed for acute healthcare may be applicable to other settings,⁷ successful translation to the care home environment cannot be assumed.¹⁰ During compilation of a Cochrane review of infection control strategies for preventing MRSA transmission in nursing homes, no studies met the systematic selection criteria.¹⁸ Robust data referring to strategies for preventing MRSA transmission in care homes are lacking, and studies are needed to test infection prevention interventions that are deliverable in the care home setting.¹⁸

9 The objectives of this study were to determine prospectively the prevalence and 10 risk factors for MRSA colonisation in a large sample of elderly residents of care homes 11 in Leeds Primary Care Trust (PCT), and to determine whether training and education of 12 care home staff in the area of infection prevention, in particular hand hygiene, can 13 minimise the risk of MRSA transmission. Health outcomes (rates of subsequent 14 hospitalisation, infection and mortality) of residents according to MRSA colonisation 15 were also examined.

1 Methods

2 Setting

According to the Care Standards Act (2000), a care home is defined as 'any home that provides accommodation, together with nursing or personal care, for any person who is, or has been ill, or is disabled or infirm'.¹⁹ In the UK, all homes that meet the definition of a care home are registered with the Care Quality Commission, formerly known as the Commission for Social Care Inspection.²⁰ Care homes may be owned by the local authority or by independent providers. All care homes, with 20 or more beds, registered in Leeds, UK were eligible to take part in the study, excluding those that provided care for people with mental, physical or learning disabilities. Ninety of the 186 registered care homes met the study criteria and were invited to participate. Leeds Teaching Hospitals Trust (LTHT) was the main acute care provider for all the care homes included in the study.

14 Data collection

Each participating care home was given a unique identifying number and was anonymised to laboratory staff. Details such as home owner, number of beds, and whether or not a home had nursing capability were recorded for each home. Each resident who was considered to be eligible to participate by the care home staff was verbally given information about the nature of the study. In the first instance, written consent was obtained, followed by verbal consent if the resident agreed to participate in subsequent surveys. The sampling process was anonymised, with no specific infection prevention interventions being initiated on the identification of a resident who was colonised. At each survey the total number of residents present in the home and the number of residents able to consent was collected by age and sex category. Data pertaining to the age, sex and presence of an invasive device were collected per participant, per survey.

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> Once the collection of swabs had been completed, further data were collected. The Microbiology Laboratory Information Management System (LIMS) was used to determine whether each resident had a record of clinical samples being sent for microbiological investigation and whether or not MRSA had been isolated before or after each survey. For the purposes of this study, MRSA infection was defined as a record of MRSA isolated from any invasive sample type (*i.e.* blood culture, tissue, bone, bronchoalveolar lavage) or MRSA isolated as pure culture from a non-invasive sample type (*i.e.* swab, sputum, urine). MRSA colonisation was defined as a record of MRSA isolated from a urine sample collected via a catheter, or MRSA isolated from a non-invasive sample type in the presence of other bacteria. Data regarding contact with healthcare facilities were collected using the Patient Administration System (PAS) for LTHT. This included the total number of hospital days spent in LTHT during the 12 months before a screening swab was collected, and the number of hospital admissions prior to this period. Any attendance at out-patient clinics was also recorded. All-cause mortality data were collected both from PAS and from a database held by Leeds Primary Care Trust.

17 Study design

This study was a controlled before and after intervention study and followed a stepped-wedge design (Table 1).²¹ After an initial MRSA prevalence survey, care homes were randomly allocated into three groups. Random allocation was stratified by number of beds and baseline MRSA prevalence. Implementation of staff training and education intervention was dependent on the group to which the home had been allocated. Homes in Group One received the intervention between January-October 2007; homes in Group Two between November 2007-February 2008; and homes in Group Three between July-September 2008. Scores for audits of hand hygiene

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1 facilities, staff hand hygiene observations, and an educational questionnaire were

2 collected before and after the intervention.

3 Table 1. Intervention schedules for stepped wedge design; "0" represents a

4 pre-intervention survey, "1" represents surveys occurring post-intervention.

	Survey/Period of Collection								
	1	2	3	4					
Group	Nov-Dec 2006	Oct-Nov 2007	May-Jun 2008	Jan-Feb 2009					
1	0	1	1	1					
2	0	0	1	1					
3	0	0	0	1					

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5 Intervention

An intervention based on staff training and education on the topic of infection prevention and effective hand hygiene was used to assess the effect on MRSA prevalence. The intervention consisted of a structured session of education, combined with two audits that assessed hand hygiene practice and facilities in the care home. Scores for the educational questionnaire and for audit of hand hygiene facilities and staff hand hygiene observations were collected before and after the training session. Written feedback concerning the results of the audits that took place before the training session was returned to each home. Specific suggestions for improvement were included when necessary.

The education session, lead by an Infection Control Nurse employed by Leeds
 PCT, lasted approximately 45 minutes, and was delivered using a Microsoft Office

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PowerPoint presentation with strictly controlled content. Topics included how and when to wash hands and barriers to effective hand washing. The use of alcohol gel and personal protective equipment were also included. A DVD outlining correct hand hygiene procedures was shown during the training. Attendees participated in a practical demonstration of good hand hygiene technique by using hand cream containing ultra-violet responsive particles and a UV light box. A questionnaire comprising 12 short answer questions was completed, directly before (pre-) and after (post-) the educational session, by personnel who attended the training. Approximately four weeks after the training was completed, three members of staff were chosen at random to complete the same questionnaire; this is referred to as the extended-time questionnaire. The same materials and session format were used for all intervention groups. The study aimed to deliver the educational input to at least 80% of the whole-time equivalent (WTE) staff.

An audit of the hand hygiene practice and facilities was carried out for each home at the beginning of the relevant intervention period, using an audit tool from the Infection Control Nurses Association.²² Issues such as staff education, compliance with requirements relating to uniform policy, and provision of liquid soap and paper towels were assessed. The same audit was carried out after written feedback had been given to the home. The Lewisham hand hygiene assessment tool²³ was used to perform observational audits of hand hygiene practice before and, a minimum of four weeks, after the educational input for each intervention group. During each of these audits, three care home staff members, selected at random, were shadowed for a period of 20 minutes each. A comparison between the number of times hand decontamination occurred versus the number of hand washing opportunities arising was determined to give a percentage figure for compliance.

26 Statistical analysis

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Statistical analysis was carried out using Stata data analysis and statistical software (StataCorp, Texas, USA). Chi-squared tests were used to compare resident and care home characteristics. Descriptive statistics were used to compare home characteristics between the three groups into which homes were allocated and to compare those homes participating in the study to those not consenting to take part. Chi-squared tests were used to compare proportions, t-tests for comparing continuous variables between two groups and ANOVA for comparing continuous data between more than two groups. Analytical approaches used in stepped-wedge designs are susceptible to separate time trends within subgroups;²¹ therefore, the presence of a significant time trend within subgroups of care homes and residents was investigated. The impact of the intervention was then investigated using a random effects logistic regression model controlling for resident characteristics and subgroup by time trend interactions. A χ^2 test was used to compared hand hygiene proportions and a t-test to compare educational scores. Scores from the audit of hand hygiene facilities were not normally distributed and a Wilcoxon signed rank test was used for comparison. To investigate whether being identified with an infection was associated with prior MRSA carriage, survival analysis was performed using a Cox proportional hazards model. Residents that had a record of an MRSA infection prior to entering the study were excluded from this analysis. The analysis investigated the time from the resident entering the survey to the time of identification of an MRSA infection or until the 09/08/2009. A random effects logistic regression model was used to assess whether mortality was associated with prior MRSA carriage. For all analyses, statistical significance was defined as p < 0.05.

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24 Microbiological methods

Amies' Transport swabs (Barloworld Scientific, Stone, Staffordshire, UK) were
 used to sample the anterior nares of consenting residents during four periods:

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16 th November 2006-13 th December 2006 (Survey One); 1 st October
2007-12 th November 2007 (Survey Two); 1 st May 2008-26 th June 2008 (Survey Three)
and 5 th January-12 th February 2009 (Survey Four). Each swab was used to inoculate a
single MRSA Select agar plate (Bio-Rad, Marnes la Coquette, France), which was
incubated for 18-24 hours at 37 °C. Bright, fuchsia-pink colonies were considered
presumptive MRSA. Presumptive MRSA colonies were confirmed to be <i>S. aureus</i> by
DNAse agar testing and positive agglutination reaction using the Pastorex [™] Staph plus
kit (Bio-Rad, Marnes la Coquette, France). Meticillin resistance was confirmed by
breakpoint susceptibility testing using Iso-Sensitest agar (Oxoid, Basingstoke,
Hampshire, UK) supplemented with 4 mg/L, 8 mg/L and 12 mg/L methicillin,
respectively (Medical Wire and Equipment Co. Ltd., Corsham, Wiltshire, UK) or 4 mg/L
cefoxitin (Mast Diagnostics, Bootle, Merseyside, UK). Isolates that had an equivocal
meticillin susceptibility result by breakpoint method were analysed further using the
Mastalex™ MRSA kit (MAST Diagnostics, Bootle, Merseyside, UK).
Meticillin-susceptible S. aureus strain NCTC 6571 and MRSA strain NCTC 10442 were
used as control organisms.

1 Results

2 Participating Care Homes

Of the 90 homes that were invited, 68 homes participated in the first part of the study. There was no significant difference in the homes taking part and those that refused in terms of the number of residents (p = 0.15, t-test), the proportion with nursing capability (p = 0.62, χ^2) or the proportion that were owned by the local authority (p = 0.18, χ^2). After the initial survey, the 68 homes that participated were randomly allocated into three groups. The number of homes that were in each group and their characteristics are shown in Table 2.

10	Table 2.	Home characterist	ics	according to	Intervention	Group.

		Group	
		2	3
Total Homes (n)	28	18	22
Mean number of places per home (n)	44	39	42
Homes with nursing capability (n)	14	8	10
Local authority homes (n)	8	1	6

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11 There was no significant difference between homes allocated to different 12 intervention groups with respect to the number of homes that provided nursing care 13 $(p = 0.9, \chi^2)$, the mean number of beds per home (p = 0.6, ANOVA), and the owner of 14 the home $(p = 0.12, \chi^2)$. There were no significant differences in mean age $(p = 0.9, \chi^2)$ 15 ANOVA), sex distribution $(p = 0.4, \chi^2)$ or overall number of residents (p = 0.43, t-test)16 between the three intervention groups; however, there were fewer residents in homes

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owned by the local authority in Group Two. Following the first survey, two homes withdrew from the study leaving 66 homes in the second survey. A further home withdrew following Survey Two leaving 65 homes in Surveys Three and Four. The following analyses report data from those homes that participated in all four surveys. The 65 homes that participated in all four surveys had 2772 beds. Fourteen homes were operated by the local authority, none of which had nursing capability (n = 463 beds; range 20-40; mean 33). Fifty one homes were owned by independent providers (n = 2309 beds; range 20-180; mean 44); 31 homes (n = 1648 beds) had

9 nursing capability. Homes with nursing capability comprised 48% (n = 30) of the 10 homes in this study and housed 59% (n = 1621) of the beds.

11 Participating residents and swabs collected

In total, 4327 swabs were collected; 1210 from Survey One, 1067 from Survey Two, 1023 from Survey Three and 1027 from Survey Four. Two swabs were removed from Survey Four due to participant duplication (n = 1) and incomplete data, leaving 4325 swabs suitable for analysis. The number of swabs collected from individual care homes during any survey ranged from 5-93. On average, 46% of residents that were present in homes at the time of a survey were swabbed (*i.e.* able to provide consent and available for swabbing).

The study included 2492 residents. The majority (n = 1405, 56%) of residents participated in a single survey, 550 (22%) participated in two surveys, 328 (13%) in three surveys and 209 (8%) participated in all four surveys. The majority (n = 1404) of residents had been admitted to hospital within the 12 months before being included in the study. Of those that did not have a record of hospital admission within 12 months of being sampled, 664 had a record of previous hospital admission according to LTHT PAS. There were 424 (17%) residents that had no record of hospital admission to LTHT; however 154 of these had a record of contact with out-patient clinics. There

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were 270 residents that did not have any record of contact with healthcare; of these, 18% were found to be MRSA positive in at least one survey. The corresponding proportion for those who had had healthcare contact was 28% (p < 0.001). Staff knowledge and behaviour There were significant improvements in the mean scores for staff knowledge following the intervention; 71%, scores after education vs. 43% before education (p < 0.001, t-test). The mean knowledge score achieved at the extended-time questionnaire was 57% (vs. baseline p < 0.001, t-test). There were significant improvements in the mean scores following the intervention for the audit of hand hygiene facilities (85% post-intervention vs. 69% pre-intervention; p < 0.001, Wilcoxon signed rank test) and observations of hand hygiene (82% of 455 opportunities after the intervention vs. 58% of 568 opportunities before; p < 0.001, χ^2 test). MRSA colonisation

A total of 888 swabs (21%) of anterior nares were MRSA positive; this comprised 238 participants in Survey One (20%); 204 in Survey Two (19%); 228 in Survey Three (22%), and 218 in Survey Four (21%). The prevalence of MRSA colonisation in residents within individual homes ranged from 0-60%. One home, a privately owned care home without nursing capability (n = 24 beds), with 21 participants, did not have any residents with nasal colonisation with MRSA identified in any of the four surveys. There was no significant difference in prevalence of MRSA between surveys (p = 0.28, χ^2) and there was no significant trend in MRSA prevalence overall (p = 0.15, ANOVA) across the four surveys. When other factors were controlled for (age, sex, hospital admissions, invasive devices), however, a significant increase in MRSA colonisation across the four surveys was identified (OR = 1.08, p = 0.031, logistic regression). In order to identify factors associated with the increasing trend, subgroup analyses (homes with nursing capability, privately owned homes or large

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homes (>35 beds) were performed. The increase in MRSA prevalence remained
 significant in homes with nursing capability (OR = 1.61, 95% CI 1.15-2.26, *p* = 0.006,
 logistic regression) and for residents in the >90 years age group (OR = 1.14, *p* = 0.044,
 logistic regression). Both trends were taken into account during multivariate analysis.

Multivariate analysis of risk factors for MRSA colonisation in residents showed that the intervention was associated with a small but significant increase in prevalence of MRSA (p = 0.02, logistic regression) (Table 3). Overall, MRSA prevalence prior to the intervention was 18.6%, which increased to 22.4% after the intervention. When analysed according to Group, there was a significant difference between MRSA prevalence before and after the intervention in Groups Two (p = 0.04, χ^2) and Three $(p = 0.02, \chi^2)$ but not in Group One $(p = 0.44, \chi^2)$ (Figure 1). The significant increase in prevalence occurred in the survey directly after the intervention but was not sustained in the group that had follow-up (Figure 1). The following factors were also significantly associated with MRSA colonisation: the number of hospital admissions in the last 12 months, the total number of days a participant spent in hospital in the 12 months before sampling, male sex, and having a record of an MRSA infection prior to entering the study (Table 3).

To investigate the increase in MRSA prevalence occurring after the intervention, care homes with and without nursing capability were analysed separately with controls (Table 3). This analysis showed that the intervention was no longer associated with an increase in MRSA prevalence in homes with nursing capability (p = 0.159, logistic regression); however, in care homes without nursing capability the intervention remained significantly associated with an increase in MRSA prevalence (p = 0.034, logistic regression). When the same analysis was performed only including participants who were present in at least two surveys (n = 1087), the intervention remained associated with an increase in MRSA prevalence in both care homes with

1 2 2		
3 4 5	1	nursing capability (OR = 2.07, 95% CI 1.22-3.52, $p = 0.007$, logistic regression) and
6 7	2	those without (OR = 2.55, 95% CI 1.3-4.97, $p = 0.006$, logistic regression).
$\begin{array}{c} 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ 21\\ 22\\ 32\\ 4\\ 25\\ 26\\ 27\\ 28\\ 29\\ 30\\ 31\\ 22\\ 33\\ 34\\ 35\\ 36\\ 37\\ 38\\ 39\\ 40\\ 41\\ 42\\ 43\\ 44\\ 546\\ 47\\ 48\\ 49\\ 50\\ 51\\ 52\\ 53\\ 54\\ 55\\ 67\\ 58\\ 960 \end{array}$	2	those without (OR = 2.55, 95% Cl 1.3-4.97, <i>p</i> = 0.006, logistic regression).

Table 3. Logistic regression of risk factors for colonisation with meticillin-resistant Staphylococcus aureus (MRSA) among 2492

residents of care homes in Leeds, United Kingdom, according to care home capability

			Overall				Care	e home		
	Comparison				With	out nursing c	apability	Wi	th nursing ca	oability
Risk factor	group	OR	CI	р	OR	CI	р	OR	CI	р
After intervention	No intervention	1.36	1.04-1.79	0.02	1.61	1.03-2.52	0.034	1.26	0.91-1.75	0.159
No. of hospital admissions in the last 12 months	106	1.18	1.11-1.26	<0.001	1.23	1.11-1.36	<0.001	1.14	1.05-1.24	0.001
No. of hospital admission days in the last 12 months	-	1.00	1.00-1.00	0.001	1.00	1.00-1.01	0.046	1.00	1.00-1.00	0.006
Presence of an invasive device	Absence of invasive device	2.36	1.70-3.29	<0.001	1.81	0.86-3.82	0.116	2.46	1.70-3.56	<0.001
Record of MRSA infection prior to study	No previous record	2.12	1.49-3.02	<0.001	3.73	1.78-7.82	<0.001	1.78	1.19-2.65	0.005
Age 80-89 years	<80 years	1.13	0.92-1.39	0.24	1.14	0.80-1.64	0.454	1.15	0.90-1.48	0.246
Age 90+ years	<80 years	1.29	0.94-1.78	0.11	1.54	0.91-2.6	0.101	1.13	0.75-1.7	0.537
Male	Female	1.48	1.24-1.78	<0.001	1.37	1.0-1.87	0.042	1.55	1.25-1.93	<0.001

Key: OR, odds ratio; CI, 95% confidence interval.

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Pag	je 23 of 37 2	Residents were followed for a median 21 months to determine MRSA infection BMJ Open
-	3	and survival outcomes. The length of follow-up varied significantly according to the
1 2	4	survey in which the resident participated; residents in the first survey had a possible
3 4	5	follow-up of 33 months compared with those in the last survey, who had possible
5 6	6	follow-up of six months. Hospital admission data in the period 12 months after the date
7 8 0	7	of colonisation were collected for residents that participated in Survey One ($n = 1210$).
9 10 11	8	The relative risk for hospitalisation within 12 months of the date of colonisation was
12 13	9	1.27 ($p > 0.05$). Subsequent infection with MRSA was significantly associated with prior
14 15	10	MRSA colonisation when other factors were controlled for (OR = 2.5, 95%
16 17	11	CI = 1.2-5.24, p = 0.014, Cox proportional hazards model) (Table 4). Of the 2492
18 19	12	residents included in the study, 90 residents were recorded as having an MRSA
20 21 22	13	infection prior to entering the study, leaving 2442 suitable for further analysis. The
23 24	14	majority (n = 1800) of residents were not colonised with MRSA and had no record of an
25 26	15	MRSA infection. There were 612 residents who were colonised with MRSA but had no
27 28	16	record of MRSA infection, 16 residents had no MRSA colonisation and had a
29 30	17	subsequent record of an MRSA infection, and 14 residents were identified with
31 32 33	18	colonisation and had subsequently developed an MRSA infection. Eight residents had
33 35	19	a record of MRSA bacteraemia. Two percent of residents colonised with MRSA had a
36 37	20	record of MRSA infection subsequent to a survey, compared with 0.9% for those
38 39	21	residents without MRSA colonisation ($p = 0.008$, χ^2). Death was recorded for 897 of
40 41	22	the 2492 residents that participated. Colonisation with MRSA was not significantly
42 43	23	associated with mortality (OR = 1.16, 95% CI 0.95-1.41, $p = 1.32$, logistic regression);
44 45	24	however, mortality was significantly associated with advanced age, male sex, the
46	ation in the second	Protected by comprise including the less intervention and the less intervention of the second comprise of the second comprese of the seco
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- L entering the study to either MRSA infection or 09/08/2009, whichever occurred **BMJ Open**
- Page 24 of 37
- first and b) logistic regression model of mortality associated with prior MRSA
- carriage

	MRSA infection ^a			Mortality ^b		
Risk factor	Hazard	CI	р	OR	CI	р
	Ratio					
MRSA colonisation	2.51	1.2-5.24	0.014	1.16	0.95-1.41	0.132
during study						
Age	1.00	0.96-1.05	0.728	1.04	1.03-1.05	<0.001
Male	1.41	0.65-3.08	0.377	1.39	1.14-1.69	0.001
Presence of an	0.67	0.09-5.02	0.701	5.45	3.32-8.95	<0.001
invasive device						
No. of hospital	1.11	0.92-1.34	0.244	1.06	1.00-1.12	0.038
admissions in the						
previous 12 months						

Key: OR, Odds ratio; CI, 95% confidence interval.

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1 Discussion

To our knowledge, this is the largest prospective study that has monitored the level of nasal colonisation of MRSA in elderly residents of care homes in the UK. Sixty five homes and 2492 residents participated in the study which took place over a 28 month period (November 2006-February 2009). The study included a large proportion of care homes in the area served by Leeds Primary Care Trust, including homes of different sizes (n = 20-180 beds), homes owned by the local authority and by independent providers, and homes with and without nursing capability. In total, 888 MRSA isolates were identified from 4325 nasal swabs during the periods of screening stated. The mean level of MRSA colonisation was 20% (95% CI = 18-23%), which was higher than levels recorded during the 1990s but comparable to those reported recently (22-23%).^{14;17} Interestingly, a recent survey of 748 residents in 51 care homes in Gloucestershire and Bristol found that only 7.9% residents were positive for MRSA by nasal screening, indicating marked geographical variation in MRSA prevalence in care homes.²⁴

The health outcomes of residents are not commonly included in studies of MRSA prevalence in the care home.^{17;25;26} The findings of the present study support the hypothesis that although MRSA infections in the care home setting are infrequent. colonised residents have an increased risk of developing an infection.^{15,27} MRSA colonisation was associated with previous and subsequent MRSA infection; residents colonised with MRSA were two and a half times more likely to develop a MRSA infection than non-carriers. Notably, however, MRSA colonisation was not significantly associated with mortality in a logistic regression model, a finding which has been reported by others, albeit in a lower prevalence setting.²⁸

The intervention applied in the present study was intended to improve
 awareness of good practice and knowledge of infection control in care homes, with an

emphasis on hand hygiene. The present study assessed the infection prevention knowledge of over 1000 members of staff and the infection prevention practice of more than 300 individuals. The stepped-wedge design allowed measurement of MRSA prevalence before the intervention, directly after the intervention, and further follow-up in two out of three study groups. Participating residents and staff in each group of homes acted as controls for each other. Three established methods were used to measure staff knowledge and behaviour following the intervention and scores improved after the intervention for all three assessments. Overall, no significant difference in MRSA prevalence was identified during the survey periods. Directly following the

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intervention, however, there was a significant increase in MRSA prevalence, although this returned to baseline levels in one group that had follow-up. Stepped-wedge designs are particularly susceptible to trends within subgroups, but when the subgroups were adjusted for linear trends, the increase in MRSA prevalence after the intervention remained significant. It is possible that other confounding factors resulted in a non-linear trend in MRSA prevalence in certain homes. It has not been possible to identify or control for these factors. MRSA infections are unlikely to be independent events and a cluster of MRSA cases may explain temporary increases in prevalence following the intervention in some homes.

Other studies have used a similar intervention strategy in care homes.²⁹⁻³¹ A study based in Taiwan introduced a programme of hand hygiene training into three care homes and identified significant improvements in scores for staff knowledge and behaviour after the training; difference between hand hygiene knowledge pre- and post-intervention, p < 0.001; difference between hand hygiene observations pre-and post-intervention, p = 0.001.³⁰ Although no direct measure of microbiological outcome was included, rates of infection based on the total number of urinary tract infections, lower respiratory infections and rates of influenza recorded by each facility, were

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significantly lower following the intervention (1.52%) compared with rates recorded for two periods before the intervention; December 2004-February 2005 (1.74%) and June-August 2005 (2.04%) (p < 0.001). Around the same time as the present study, Baldwin et al. (2010) implemented an infection control education and training programme in nursing homes in the Belfast area of Northern Ireland.²⁹ The study screened 793 residents and 338 members of staff for MRSA colonisation. The education programme, occurring at baseline and at three and six months, consisted of multiple training sessions for staff. An existing member of staff in each intervention home was assigned the role of infection control link worker, the role of which was to reinforce good infection control practice in the home. Practice was observed and recorded, with feedback, for an audit of ten specified infection control standards involving the following subject areas: cleanliness, decontamination (hand and environment), waste management, personal protective equipment and the management of wounds, urinary catheters and enteral feeding.

Using a cluster randomised controlled study design, audit scores and MRSA colonisation of residents and staff were compared for homes in the intervention group (n = 16) with those homes in the control group (n = 16); homes in the control group did not receive training or feedback. While scores for the infection control audits significantly improved in eight of the ten standards (82% *vs.* 64% in intervention and control homes, respectively, p < 0.0001), levels of MRSA colonisation did not change over the 12 month study period in either residents or staff. Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

In contrast, Gopal *et al.* (2009) evaluated whether enhanced infection control
support in nursing homes had an impact on improving infection control practice.³¹ The
intervention included extensive support from a dedicated infection control team,
including an infection control nurse, infection control nurse specialist and an infection
control doctor. Twelve homes were included in the study and were divided into two

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groups of six, an intervention group and a control group, based on the number of residents. The study found no statistical difference between the control group and the group of homes that received the intervention at baseline and final assessment for hand hygiene facilities (p = 0.69), environmental cleanliness (p = 0.43) and disposal of clinical waste (p = 0.96). There was no microbiological investigation included in this evaluation.

In principle, the intervention applied in the present study was plausible and unlikely to be harmful. The assessments were reasonable, albeit focussed on short-term effects; however, the following limitations of the study must be acknowledged. It is likely that the prevalence reported here is an underestimation of the true level of MRSA colonisation because of the use of nasal screening alone. To achieve a high-level of sensitivity of detection (>90%) of MRSA carriers, multiple sites (e.g. axilla, groin, nose and throat) need to be screened.^{32;33} Screening urethral catheters, legs ulcers and pressure sores would have increased the sensitivity of MRSA detection and may have provided further information regarding the infection status of the resident. Although pooling swabs from multiple sites could have been done at the same cost, screening the anterior nares as a single site using chromagar as a growth medium was a compromise, taking into account the difficulties of obtaining consent and practical issues associated with more extensive sampling of a predominantly frail, elderly population and the need for a cost-effective approach. The study aimed to deliver educational input to at least 80% whole-time equivalent staff. As only one individual is required to break the chain of infection control; the study ought to have included all full- and part-time employees, or as a minimum included all key personnel, in terms of influencing practice, in each setting. Although observational methods of assessing hand hygiene compliance are considered the gold standard,³⁴ increased productivity due to observation, known as the

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Hawthorne effect, must be considered.^{35;36} Despite long-term microbiological follow-up
(8-25 months), the duration of follow-up with regards to staff knowledge and behaviour
remained short (approximately four weeks). While the anonymous design of the
present study kept assessment of the intervention informal, it did not enable the
long-term follow-up of knowledge and practice in individual staff.

6 The intervention applied in the present study focused on a particular area of 7 infection prevention, that of hand hygiene, skin care and personal protective 8 equipment. Hand hygiene is considered to be an educational priority; however, there is 9 little evidence to suggest that improvements in hand hygiene alone result in a significant reduction in MRSA infection or colonisation.³⁷ Additional educational topics 10 11 may include risk factors for infection and how to identify residents at risk, care of 12 wounds and invasive devices, and education about the judicious use of antibiotics.³⁸ 13 Implementation of an intervention in a setting such as that of the care home, which 14 experiences a high level of change, in terms of employee and resident throughput, 15 cannot be expected to last long-term without regular input. A single session of 16 education per staff member is unlikely to make a large difference to long-term practice. 17 Alternative training and education strategies may include more frequent educational 18 sessions, with additional learning resources, such as e-learning. Others have reported, 19 however, that the introduction of multiple training sessions did not result in a decrease in MRSA prevalence,²⁹ and cares homes that had access to extensive infection control 20 support failed to show improvements in audit scores.³¹ 21

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The use of interventions that focus on screening and decolonisation of residents and/or staff may reduce MRSA prevalence in care homes. Given the difficulty of achieving MRSA decolonisation in individuals with multiple risk factors for persistence, this would be a considerable undertaking, and may risk resistance selection. Control of risk factors for MRSA colonisation, such as improved management of wounds and

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invasive devices may be beneficial.³⁸ Evaluation would be required to assess the cost *versus* benefit of interventions involving screening and decolonisation in the care home setting, along with consideration about the source of funding if such approaches were to be recommended,^{39;40} Given the large recent and continuing decreases in incidence of invasive MRSA infection in England,⁹ it remains possible that control measures in the secondary care setting will lead to reduced MRSA carriage in care home residents.

7 Conclusion

8 These results reinforce previous reports of high MRSA colonisation rates in 9 elderly residents of care homes. The intervention applied in the present study 10 improved staff practice and knowledge but did not reduce MRSA prevalence in 11 residents. These data provide an important baseline for future surveillance of MRSA in 12 the care home setting. Further work is needed regarding screening, decolonisation 13 and re-entry to the care home and continued surveillance is needed to understand the 14 interaction between MRSA in care homes and hospitals.

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8	Legend for Figure 1.
9	Changes in MRSA prevalence by Intervention Group per survey, before and after
10	the intervention.
11	



Changes in MRSA prevalence by Intervention Group per survey, before and after the intervention. 83x135mm (96 x 96 DPI)

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The longitudinal prevalence of MRSA in care home residents and the effectiveness of improving infection prevention knowledge and practice on colonisation using a stepped wedge study design

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Keywords:	carriage, transmission, intervention

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ORION Checklist of items to include when reporting an outbreak or intervention study of a nosocomial organism

	ltem Number	Descriptor	
Title & Abstract	1	Description of paper as outbreak report or intervention study. Design of intervention study (eg Randomised Controlled Trial, Cluster Randomised Controlled Trial, Interrupted Time Series, Cohort study etc).	
Brief description of intervention and ma		Brief description of intervention and main outcomes DONE	
Introduction		Scientific and/or local clinical background and rationale.	
Background	2	Description of organism as epidemic, endemic or epidemic becoming endemic DONE	
Type of paper	3	If an outbreak report, report the number of outbreaks DONE	
Dates	4	Start and finish dates of the study or report DONE	
Objectives	5	Objectives for outbreak reports. Hypotheses for intervention studies - DONE	
Methods		Study design. Use of EPOC classification recommended (RCT or CRCT, CBA, or ITS) - STEP WEDGE DESIGN	
Design	6	Whether study was retrospective, prospective or ambidirectional.	
		Whether decision to report or intervene was prompted by any outcome data.	
		Whether study was formally implemented with predefined protocol and endpoints.	
Participants	7	Number of patients admitted in study or outbreak. Summaries of distributions of age and lengths of stays. If possible, proportion admitted from other wards, hospitals, nursing homes or from abroad. Where relevant, potential risk factors for acquiring the organism. Eligibility criteria for study. Case definitions for outbreak reportDON	
Setting	8	Description of the unit, ward or hospital and, if a hospital, the units included. Number of beds, the presence and staffing, levels of an infection control team, - DONE	
Interventions	9	Definition of phases by major change in specific infection control practice (with start and stop dates). A summary table is strongly recommended with precise details interventions how and when administered in each phase - DONE	
Culturing & Typing	10	Details of culture media use of selective antibiotics and local and loc reference typing. Where relevant, details of environmental sampling - DONE	
Infection_related	10	Clearly defined primary and escendary outcomes and hold and or reference (yping, where relevant, defand or removimentary and pseudowy monthly) rather that	
outcomes		as totals for each phase, with at least three data points per phase and, for many two phase studies, 12 or more monthly data points per phase. Denominators (eg numbers admissions or discharges, patient bed days). If possible, prevalence of organism and incidence of colonisation on admission at same time intervals. Criteria for infection, colonisation on admission and directly attributable mortality.	
Economic	12	For short studies of outpreak reports, use of charts with obtaining patient stay & dates organism detected may be useful (sector bolice) - DONE	
	12	important assumptions - NOT APPLICABLE	
Potential Threats	13	Which notantial confounders were considered recorded or adjusted for (an changes in length of stay, case mix, bed occupancy, staffing levels, hand-hygiene	
to internal validity	10	compliance, antibiotic use, strain type, processing of isolates, seasonality).	
Sampla ciza	14	Description of measures to avoid bias including billinging a standardisation of outcome assessment a provision of care Done	
Statiatical	14	Details of power calculations, where appropriate - And Available in negotined	
methods	15	(exploratory) analysis. Unless outcomes are independent, statistical approaches able to account for dependencies in the outcome data should be used, adjusting, where necessary, for potential confounders DONE For outbreak reports statistical analysis may be inappropriate.	
Results Recruitment	16	For relevant designs the dates defining periods of recruitment and follow-up. A flow diagram is recommended to describe participant flow in each stage of study. NOT APPLICABLE	
Outcomes & estimation	17	For the main outcomes, the estimated effect size and its precision (usually using confidence intervals). A graphical summary of the outcome data is often appropriate for dependent data (such as most time series) DONE	
Ancillary analyses	18	Any subgroup analyses should be reported and it should be stated whether or not it was planned (specified in the protocol) and possible confounders adjusted for - DONE	
Adverse events	19	Pre-specified categories of adverse events and occurrences of these in each intervention group. This might include drug side effects, crude or disease specific mortality in antibiotic policy studies or opportunity costs in isolation studies NOT APPLICABLE	
Discussion		For intervention studies an assessment of evidence for/against hypotheses, accounting for potential threats to validity of inference including regression to mean effect	
Interpretation	20	and reporting bias. For outbreak reports, consider, clinical significance of observations and hypotheses generated to explain them NOT APPLICABLE	
Generalisability	21	External validity of the findings of the intervention study i.e. to what degree can results be expected to generalise to different target populations or settings - DONF	
		General interview of results in contrast of current evidence - DONE	

Abbreviations: RCT: randomised controlled trial CRCT : Cluster Randomised Controlled Trial CBA: controlled before and after study ITS: interrupted time series

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1	The longitudinal prevalence of MRSA in care home residents and the
2	effectiveness of improving infection prevention knowledge and practice
3	on colonisation using a stepped wedge study design
4	C Horner, M Wilcox, B Barr, D Hall, G Hodgson, P Parnell, & D Tompkins
5	C Horner Clinical Scientist, Leeds Teaching Hospitals NHS Trust, Department of
6	Microbiology, Old Medical School, Leeds General Infirmary, Leeds, LS1 3EX
7	M Wilcox Consultant/Clinical Director of Microbiology/Pathology, Leeds Teaching
8	Hospitals NHS Trust, Department of Microbiology, Old Medical School, Leeds General
9	Infirmary, Leeds, LS1 3EX
10	B Barr Specialty Registrar in Public Health, University of Liverpool, Division of Public
11	Health, Whelan Building, Quadrangle, Liverpool, L69 3GB
12	D Hall Infection Prevention and Control Nurse, NHS Leeds, Sycamore Lodge, 7a
13	Woodhouse Cliff, Leeds, LS6 2HF
14	G Hodgson Nurse Consultant Leeds Teaching Hospitals NHS Trust, Infection
15	Prevention and Control, Leeds General Infirmary, Leeds, LS1 3EX
16	P Parnell Senior Biomedical Scientist, Department of Microbiology, Old Medical
17	School, Leeds General Infirmary, Leeds, LS1 3EX
18	D Tompkins Former Regional Microbiologist, HPA Yorkshire and the Humber, Bridle
19	Path, York Road, Leeds, LS15 7TR
20	Corresponding author and address for reprints: Mark.wilcox@leedsth.nhs.uk.
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22	Contributors
23	MW was the lead investigator and obtained funding for the study. All authors were
24	involved in the study design and reviewed the draft of this report. CH coordinated the
25	data management and drafted this report. GH and DT were integral to the setting up
26	and management of the study. BB carried out the statistical analysis. PP was

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3 4 5	1	responsible for laboratory protocol development. DH carried out the data collection
5 6 7	2	and the sampling of residents with assistance from other Infection Control Nurses,
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1	Article Summary
2	1) Article Focus
3	To assess the effectiveness of an educational intervention on the prevalence of MRSA
4	in care homes for the elderly.
5	2) Key messages
6	There was a high rate of MRSA colonisation in elderly residents of care homes
7	during the study period.
8	The intervention improved the infection prevention knowledge and practice of
9	staff working in care homes, but did not reduce the prevalence of MRSA
10	colonisation of residents.
11	MRSA colonisation was associated with previous and subsequent MRSA
12	infection, but was not significantly associated with subsequent
13	hospitalisation or mortality.
14	Additional measures are required to reduce endemic MRSA colonisation in care
15	homes.
16	3) Strengths and limitations of this study
17	• This is a large prospective study, including 65 homes and 2492 residents.
18	MRSA prevalence was monitored over a 28 month period.
19	• The intervention was plausible, unlikely to be harmful and the assessments of
20	the intervention were reasonable.
21	A significant improvement was seen in scores for all three intervention
22	assessment methods; however, the intervention was associated with a small
23	but significant increase in MRSA prevalence.

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4	 It was not possible to identify or control for the factors responsible for the
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6	2 increase in MRSA prevalence following the intervention.
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> 1 Abstract (250 words) 2 Objectives: To determine the prevalence and health outcomes of meticillin-resistant 3 Staphylococcus aureus (MRSA) colonisation in elderly care home residents. To 4 measure the effectiveness of improving infection prevention knowledge and practice on 5 MRSA prevalence. 6 Setting: Care homes for elderly residents in Leeds, UK. 7 Participants: Residents able to give informed consent. 8 **Design:** A controlled intervention study, using a stepped-wedge design, comprising 65 9 homes divided into three groups. Baseline MRSA prevalence was determined by 10 screening the nares of residents (n = 2492). An intervention based upon staff 11 education and training on hand hygiene was delivered at three different times 12 according to group number. Scores for three assessment methods, an audit of 13 hand hygiene facilities, staff hand hygiene observations, and an educational 14 questionnaire, were collected before and after the intervention. After each group 15 of homes received the intervention, all participants were screened for MRSA nasal 16 colonisation. In total, four surveys took place between November 2006 and 17 February 2009. 18 Results: MRSA prevalence was 20%, 19%, 22% and 21% in each survey, 19 respectively. There was a significant improvement in scores for all three assessment 20 methods post-intervention ($p \le 0.001$). The intervention was associated with a small 21 but significant increase in MRSA prevalence (p = 0.023). MRSA colonisation was

- 22 associated with previous and subsequent MRSA infection, but was not significantly
- $23 \qquad \text{associated with subsequent hospitalisation or mortality}.$
- 24 **Conclusions:** The intervention did not result in a decrease in the prevalence of MRSA
- 25 colonisation in care home residents. Additional measures will be required **to** reduce



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1 Introduction

Meticillin-resistant *Staphylococcus aureus* is a significant cause of mortality and morbidity in both healthcare and community settings.^{1;2} Numerous surveillance schemes,^{3;4} recommendations,^{5;6} and guidelines^{7;8} have been developed with the aim of reducing levels of MRSA infection associated with healthcare. In the UK, mandatory surveillance of cases of MRSA bacteraemia was introduced in all acute NHS Trusts in England in 2001.³ Recently, levels of MRSA bacteraemia in hospitals have been decreasing markedly.⁹

The elderly population living in care homes often require frequent contact with healthcare. This situation, known as the 'revolving door' syndrome,¹⁰ when residents are admitted to hospital and then discharged back into a care home, means that care home residents are more likely to be carriers of MRSA. Small studies in the UK during the 1990s identified levels of MRSA colonisation in care home residents between 0.8-17%.¹¹⁻¹³ More recently, our group¹⁴ and Baldwin *et al.* (2009) reported that MRSA colonisation levels among residents in care homes in the UK were greater than 20%.¹⁵ MRSA prevalence rates of greater than 36% have been reported in long-term care facilities in France and the USA.^{16;17} There is a paucity of large-scale, longitudinal studies monitoring the occurrence of MRSA in the care home setting^{14;15} and the assessment of health outcomes of residents colonised with MRSA are not commonly reported.

Guidance for infection control in care homes was issued by the Department of Health in 2006.⁸ These guidelines comprised recommendations rather than statutory requirements, and were not specific for the control of MRSA. In a recent Care Quality Commission survey, however, 25% of participating care homes were not using the Department of Health guidance,⁸ including specific requirements that all staff should receive training in infection prevention and control.¹⁰ Most evidence for the

effectiveness of infection control strategies has been generated in the acute healthcare setting.^{7;18} Although some infection prevention recommendations designed for acute healthcare may be applicable to other settings,⁷ successful translation to the care home environment cannot be assumed.¹⁰ During compilation of a Cochrane review of infection control strategies for preventing MRSA transmission in nursing homes, no studies met the systematic selection criteria.¹⁸ Robust data referring to strategies for preventing MRSA transmission in care homes are lacking, and studies are needed to test infection prevention interventions that are deliverable in the care home setting.¹⁸

9 The objectives of this study were to determine prospectively the prevalence and 10 risk factors for MRSA colonisation in a large sample of elderly residents of care homes 11 in Leeds Primary Care Trust (PCT), and to determine whether training and education of 12 care home staff in the area of infection prevention, in particular hand hygiene, can 13 minimise the risk of MRSA transmission. Health outcomes (rates of subsequent 14 hospitalisation, infection and mortality) of residents according to MRSA colonisation 15 were also examined.

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1 Methods

2 Setting

According to the Care Standards Act (2000), a care home is defined as 'any home that provides accommodation, together with nursing or personal care, for any person who is, or has been ill, or is disabled or infirm'.¹⁹ In the UK, all homes that meet the definition of a care home are registered with the Care Quality Commission (CQC), formerly known as the Commission for Social Care Inspection.²⁰ Care homes may be owned by the local authority or by independent providers. A care home without nursing capability was defined as a home that provided residents with accommodation, social and personal care. A home with nursing capability was defined as a home that employed registered nurses and provided nursing care in addition to accommodation, social and personal care to residents. Care homes with nursing capability were listed on the CQC register as a nursing home. All care homes, with 20 or more beds, registered in Leeds, UK were eligible to take part in the study, excluding those that provided care for people with mental, physical or learning disabilities. Ninety of the 186 registered care homes met the study criteria and were invited to participate. Leeds Teaching Hospitals Trust (LTHT) was the main acute care provider for all the care homes included in the study.

19 Data collection

Each participating care home was given a unique identifying number and was anonymised to laboratory staff. Details such as home owner, number of beds, and whether or not a home had nursing capability were recorded for each home. Each resident who was considered to be eligible to participate by the care home staff was verbally given information about the nature of the study. In the first instance, written consent was obtained, followed by verbal consent if the resident agreed to participate in subsequent surveys. The sampling process was anonymised, with no specific

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1	infection prevention interventions being initiated on the identification of a resident who
2	was colonised. At each survey the total number of residents present in the home and
3	the number of residents able to consent was collected by age and sex category. Data
4	pertaining to the age, sex and presence of an invasive device were collected per
5	participant, per survey.
6	Once the collection of swabs had been completed, further data were collected.
7	The Microbiology Laboratory Information Management System (LIMS) was used to
8	determine whether each resident had a record of clinical samples being sent for
9	microbiological investigation and whether or not MRSA had been isolated before or
10	after each survey. For the purposes of this study, MRSA infection was defined as a
11	record of MRSA isolated from any invasive sample type (<i>i.e.</i> blood culture, tissue,
12	bone, bronchoalveolar lavage) or MRSA isolated as pure culture from a non-invasive
13	sample type (<i>i.e.</i> swab, sputum, urine). MRSA colonisation was defined as a record of
14	MRSA isolated from a urine sample collected via a catheter, or MRSA isolated from a
15	non-invasive sample type in the presence of other bacteria. Data regarding contact
16	with healthcare facilities were collected using the Patient Administration System (PAS)
17	for LTHT. This included the total number of hospital days spent in LTHT during the 12
18	months before a screening swab was collected, and the number of hospital admissions
19	prior to this period. Any attendance at out-patient clinics was also recorded. All-cause
20	mortality data were collected both from PAS and from a database held by Leeds
21	Primary Care Trust.
22	Study design
23	This study was a controlled before and after intervention study and followed a
24	stepped-wedge design (Table 1). ²¹ After an initial MRSA prevalence survey, care
25	homes were randomly allocated into three groups. Random allocation was stratified by
26	number of beds and baseline MRSA prevalence. Implementation of staff training and

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education intervention was dependent on the group to which the home had been
allocated. Homes in Group One received the intervention between January-October
2007; homes in Group Two between November 2007-February 2008; and homes in
Group Three between July-September 2008. Scores for audits of hand hygiene
facilities, staff hand hygiene observations, and an educational questionnaire were
collected before and after the intervention.

7 Table 1. Intervention schedules for stepped wedge design; "Pre" represents a

8 pre-intervention survey, "Post" represents surveys occurring post-intervention.

	Survey/Period of Collection			
	1	2	3	4
Group	Nov-Dec 2006	Oct-Nov 2007	May-Jun 2008	Jan-Feb 2009
1	Pre	Post	Post	Post
2	Pre	Pre	Post	Post
3	Pre	Pre	Pre	Post

9 Intervention

An intervention based on staff training and education on the topic of infection prevention and effective hand hygiene was used to assess the effect on MRSA prevalence. The intervention consisted of a structured session of education, combined with two audits that assessed hand hygiene practice and facilities in the care home. Scores for the educational questionnaire and for audit of hand hygiene facilities and staff hand hygiene observations were collected before and after the training session. Written feedback concerning the results of the audits that took place before the training

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session was returned to each home. Specific suggestions for improvement were included when necessary.

The education session, lead by an Infection Control Nurse employed by Leeds PCT, lasted approximately 45 minutes, and was delivered using a Microsoft Office PowerPoint presentation with strictly controlled content. Topics included how and when to wash hands and barriers to effective hand washing. The use of alcohol gel and personal protective equipment were also included. A DVD outlining correct hand hygiene procedures was shown during the training. Attendees participated in a practical demonstration of good hand hygiene technique by using hand cream containing ultra-violet responsive particles and a UV light box. A guestionnaire comprising 12 short answer questions was completed, directly before (pre-) and after (post-) the educational session, by personnel who attended the training. Approximately four weeks after the training was completed, three members of staff were chosen at random to complete the same questionnaire; this is referred to as the extended-time questionnaire. The same materials and session format were used for all intervention groups. The study aimed to deliver the educational input to at least 80% of the whole-time equivalent (WTE) staff.

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An audit of the hand hygiene practice and facilities was carried out for each home at the beginning of the relevant intervention period, using an audit tool from the Infection Control Nurses Association.²² Issues such as staff education, compliance with requirements relating to uniform policy, and provision of liquid soap and paper towels were assessed. The same audit was carried out after written feedback had been given to the home. The Lewisham hand hygiene assessment tool²³ was used to perform observational audits of hand hygiene practice before and, a minimum of four weeks, after the educational input for each intervention group. During each of these audits, three care home staff members, selected at random, were shadowed for a

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period of 20 minutes each. A comparison between the number of times hand
 decontamination occurred *versus* the number of hand washing opportunities arising

3 was determined to give a percentage figure for compliance.

4 Statistical analysis

5 Statistical analysis was carried out using Stata data analysis and statistical 6 software (StataCorp, Texas, USA). Chi-squared tests were used to compare resident 7 and care home characteristics. Descriptive statistics were used to compare home 8 characteristics between the three groups into which homes were allocated and to 9 compare those homes participating in the study to those not consenting to take part. 10 Chi-squared tests were used to compare proportions, t-tests for comparing continuous 11 variables between two groups and ANOVA for comparing continuous data between 12 more than two groups. Analytical approaches used in stepped-wedge designs are susceptible to separate time trends within subgroups:²¹ therefore, the presence of a 13 14 significant time trend within subgroups of care homes and residents was investigated. 15 The impact of the intervention was then investigated using a random effects logistic 16 regression model controlling for resident characteristics and subgroup by time trend 17 interactions. A χ^2 test was used to compared hand hygiene proportions and a t-test to 18 compare educational scores. Scores from the audit of hand hygiene facilities were not 19 normally distributed and a Wilcoxon signed rank test was used for comparison. To 20 investigate whether being identified with an infection was associated with prior MRSA 21 carriage, survival analysis was performed using a Cox proportional hazards model. 22 Residents that had a record of an MRSA infection prior to entering the study were 23 excluded from this analysis. The analysis investigated the time from the resident 24 entering the survey to the time of identification of an MRSA infection or until the 25 09/08/2009. A random effects logistic regression model was used to assess whether

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1	mortality was associated with prior MRSA carriage. For all analyses, statistical
2	significance was defined as $p < 0.05$.
3	Microbiological methods
4	Amies' Transport swabs (Barloworld Scientific, Stone, Staffordshire, UK) were
5	used to sample the anterior nares of consenting residents during four periods:
6	16 th November 2006-13 th December 2006 (Survey One); 1 st October
7	2007-12 th November 2007 (Survey Two); 1 st May 2008-26 th June 2008 (Survey Three)
8	and 5 th January-12 th February 2009 (Survey Four). Each swab was used to inoculate a
9	single MRSA Select agar plate (Bio-Rad, Marnes la Coquette, France), which was
10	incubated for 18-24 hours at 37°C. Bright, fuchsia-pink colonies were considered
11	presumptive MRSA. Presumptive MRSA colonies were confirmed to be S. aureus by
12	DNAse agar testing and positive agglutination reaction using the Pastorex [™] Staph plus
13	kit (Bio-Rad, Marnes la Coquette, France). Meticillin resistance was confirmed by
14	breakpoint susceptibility testing using Iso-Sensitest agar (Oxoid, Basingstoke,
15	Hampshire, UK) supplemented with 4 mg/L, 8 mg/L and 12 mg/L methicillin,
16	respectively (Medical Wire and Equipment Co. Ltd., Corsham, Wiltshire, UK) or 4 mg/L
17	cefoxitin (Mast Diagnostics, Bootle, Merseyside, UK). Isolates that had an equivocal
18	meticillin susceptibility result by breakpoint method were analysed further using the
19	Mastalex™ MRSA kit (MAST Diagnostics, Bootle, Merseyside, UK).
20	Meticillin-susceptible S. aureus strain NCTC 6571 and MRSA strain NCTC 10442 were
21	used as control organisms.
22	

1 Results

2 Participating Care Homes

Of the 90 homes that were invited, 68 homes participated in the first part of the study. There was no significant difference in the homes taking part and those that refused in terms of the number of residents (p = 0.15, t-test), the proportion with nursing capability (p = 0.62, χ^2) or the proportion that were owned by the local authority (p = 0.18, χ^2). After the initial survey, the 68 homes that participated were randomly allocated into three groups. The number of homes that were in each group and their characteristics are shown in Table 2.

		Group	
		2	3
Total Homes (n)	28	18	22
Mean number of places per home (n)	44	39	42
Homes with nursing capability (n)	14	8	10
Local authority homes (n)	8	1	6

10 Table 2. Home characteristics according to Intervention Group.

11 There was no significant difference between homes allocated to different 12 intervention groups with respect to the number of homes that provided nursing care 13 $(p = 0.9, \chi^2)$, the mean number of beds per home (p = 0.6, ANOVA), and the owner of 14 the home $(p = 0.12, \chi^2)$. There were no significant differences in mean age $(p = 0.9, \chi^2)$ 15 ANOVA), sex distribution $(p = 0.4, \chi^2)$ or overall number of residents (p = 0.43, t-test)16 between the three intervention groups; however, there were fewer residents in homes

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1 2		
3 4	1	owned by the local authority in Group Two. Following the first survey, two homes
5 6	2	withdrew from the study leaving 66 homes in the second survey. A further home
7 8	3	withdrew following Survey Two leaving 65 homes in Surveys Three and Four. The
9 10 11	4	following analyses report data from those homes that participated in all four surveys.
12 13	5	The 65 homes that participated in all four surveys had 2772 beds. Fourteen
14 15	6	homes were operated by the local authority, none of which had nursing capability
16 17	7	(n = 463 beds; range 20-40; mean 33). Fifty one homes were owned by independent
18 19	8	providers (n = 2309 beds; range 20-180; mean 44); 31 homes (n = 1648 beds) had
20 21	9	nursing capability. Homes with nursing capability comprised 48% (n = 30) of the
22 23	10	homes in this study and housed 59% (n = 1621) of the beds.
24 25 26	11	Participating residents and swabs collected
27 28	12	In total, 4327 swabs were collected; 1210 from Survey One, 1067 from Survey
29 30	13	Two 1023 from Survey Three and 1027 from Survey Four Two swahs were removed
31 32	14	from Survey Four due to participant duplication $(n = 1)$ and incomplete data leaving
33 34	15	4325 swabs suitable for analysis. The number of swabs collected from individual care
35 36	15	homes during any survey ranged from 5.03. On average 46% of residents that were
37	10	nomes during any survey ranged nom 5-95. On average, 46% of residents that were
38 39	17	present in homes at the time of a survey were swabbed (<i>i.e.</i> able to provide consent
40 41	18	and available for swabbing).
42 43	19	The study included 2492 residents. The majority (n = 1405, 56%) of residents
44 45	20	participated in a single survey, 550 (22%) participated in two surveys, 328 (13%) in
46 47	21	three surveys and 209 (8%) participated in all four surveys. The majority (n = 1404) of
48 49	22	residents had been admitted to hospital within the 12 months before being included in
50 51	23	the study. Of those that did not have a record of hospital admission within 12 months
52 53	24	of being sampled, 664 had a record of previous hospital admission according to LTHT
54 55	25	PAS. There were 424 (17%) residents that had no record of hospital admission to
56 57 58 59	26	LTHT; however 154 of these had a record of contact with out-patient clinics. There

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1	were 270 residents that did not have any record of contact with healthcare; of these,
2	18% were found to be MRSA positive in at least one survey. The corresponding
3	proportion for those who had had healthcare contact was 28% ($p < 0.001$).
4	Staff knowledge and behaviour
5	There were significant improvements in the mean scores for staff knowledge
6	following the intervention; 71%, scores after education vs . 43% before education
7	($p < 0.001$, t-test). The mean knowledge score achieved at the extended-time
8	questionnaire was 57% (vs. baseline $p < 0.001$, t-test). There were significant
9	improvements in the mean scores following the intervention for the audit of hand
10	hygiene facilities (85% post-intervention vs . 69% pre-intervention; $p < 0.001$, Wilcoxon
11	signed rank test) and observations of hand hygiene (82% of 455 opportunities after the
12	intervention vs. 58% of 568 opportunities before; $p < 0.001$, χ^2 test).
13	MRSA colonisation
14	A total of 888 swabs (21%) of anterior nares were MRSA positive; this
15	comprised 238 participants in Survey One (20%); 204 in Survey Two (19%); 228 in
16	Survey Three (22%), and 218 in Survey Four (21%). The prevalence of MRSA
17	colonisation in residents within individual homes ranged from 0-60%. One home, a
18	privately owned care home without nursing capability (n = 24 beds), with 21
19	participants, did not have any residents with nasal colonisation with MRSA identified in
20	any of the four surveys. There was no significant difference in prevalence of MRSA
21	between surveys ($p = 0.28$, χ^2) and there was no significant trend in MRSA prevalence
22	overall ($p = 0.15$, ANOVA) across the four surveys. When other factors were controlled
23	for (age, sex, hospital admissions, invasive devices), however, a significant increase in
24	MRSA colonisation across the four surveys was identified (OR = 1.08, p = 0.031,
25	logistic regression). In order to identify factors associated with the increasing trend,
26	subgroup analyses (homes with nursing capability, privately owned homes or large

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1	homes (>35 beds) were performed. The increase in MRSA prevalence remained
2	significant in homes with nursing capability (OR = 1.61, 95% CI 1.15-2.26, $p = 0.006$,
3	logistic regression) and for residents in the >90 years age group (OR = 1.14, p = 0.044,
4	logistic regression). Both trends were taken into account during multivariate analysis.
5	Multivariate analysis of risk factors for MRSA colonisation in residents showed
6	that the intervention was associated with a small but significant increase in prevalence
7	of MRSA ($p = 0.02$, logistic regression) (Table 3). Overall, MRSA prevalence prior to
8	the intervention was 18.6%, which increased to 22.4% after the intervention. When
9	analysed according to Group, there was a significant difference between MRSA
10	prevalence before and after the intervention in Groups Two ($p = 0.04$, χ^2) and Three
11	($p = 0.02$, χ^2) but not in Group One ($p = 0.44$, χ^2) (Figure 1). The significant increase in
12	prevalence occurred in the survey directly after the intervention but was not sustained
13	in the group that had follow-up (Figure 1). The following factors were also significantly
14	associated with MRSA colonisation: the number of hospital admissions in the last
15	12 months, the total number of days a participant spent in hospital in the 12 months
16	before sampling, male sex, and having a record of an MRSA infection prior to entering
17	the study (Table 3).

18 To investigate the increase in MRSA prevalence occurring after the 19 intervention, care homes with and without nursing capability were analysed separately 20 with controls (Table 3). This analysis showed that the intervention was no longer 21 associated with an increase in MRSA prevalence in homes with nursing capability 22 (p = 0.159, logistic regression); however, in care homes without nursing capability the 23 intervention remained significantly associated with an increase in MRSA prevalence 24 (p = 0.034, logistic regression). When the same analysis was performed only including 25 participants who were present in at least two surveys (n = 1087), the intervention 26 remained associated with an increase in MRSA prevalence in both care homes with

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4	1	nursing capability (OR = 2.07, 95% Cl 1.22-3.52, p = 0.007, logistic regression) and
6	2	those without (OR = 2.55, 95% CI 1.3-4.97, p = 0.006, logistic regression).
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Table 3. Logistic regression of risk factors for colonisation with meticillin-resistant Staphylococcus aureus (MRSA) among 2492

residents of care homes in Leeds, United Kingdom, according to care home capability

			Overall				Care	e home		
	Comparison				With	out nursing c	apability	Wi	th nursing cap	bability
Risk factor	group	OR	CI	p	OR	CI	p	OR	CI	p
After intervention	No intervention	1.36	1.04-1.79	0.02	1.61	1.03-2.52	0.034	1.26	0.91-1.75	0.159
No. of hospital admissions in the last 12 months		1.18	1.11-1.26	<0.001	1.23	1.11-1.36	<0.001	1.14	1.05-1.24	0.001
No. of hospital admission days in the last 12 months	-	1.00	1.00-1.00	0.001	1.00	1.00-1.01	0.046	1.00	1.00-1.00	0.006
Presence of an invasive device	Absence of invasive device	2.36	1.70-3.29	<0.001	1.81	0.86-3.82	0.116	2.46	1.70-3.56	<0.001
Record of MRSA infection prior to study	No previous record	2.12	1.49-3.02	<0.001	3.73	1.78-7.82	<0.001	1.78	1.19-2.65	0.005
Age 80-89 years	<80 years	1.13	0.92-1.39	0.24	1.14	0.80-1.64	0.454	1.15	0.90-1.48	0.246
Age 90+ years	<80 years	1.29	0.94-1.78	0.11	1.54	0.91-2.6	0.101	1.13	0.75-1.7	0.537
Male	Female	1.48	1.24-1.78	<0.001	1.37	1.0-1.87	0.042	1.55	1.25-1.93	<0.001

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2	Residents were followed for a median 21 months to determine MRSA infection BMJ Open	Page 24 of 71
3	and survival outcomes. The length of follow-up varied significantly according to the	
4	survey in which the resident participated; residents in the first survey had a possible	
5	follow-up of 33 months compared with those in the last survey, who had possible	
6	follow-up of six months. Hospital admission data in the period 12 months after the date	
7	of colonisation were collected for residents that participated in Survey One (n = 1210).	
8	The relative risk for hospitalisation within 12 months of the date of colonisation was	
9	1.27 ($p > 0.05$). Subsequent infection with MRSA was significantly associated with prior	
10	MRSA colonisation when other factors were controlled for (OR = $2.5, 95\%$	
11	CI = 1.2-5.24, p = 0.014, Cox proportional hazards model) (Table 4). Of the 2492	
12	residents included in the study, 90 residents were recorded as having an MRSA	
13	infection prior to entering the study, leaving 2442 suitable for further analysis. The	
14	majority (n = 1800) of residents were not colonised with MRSA and had no record of an	
15	MRSA infection. There were 612 residents who were colonised with MRSA but had no	
16	record of MRSA infection, 16 residents had no MRSA colonisation and had a	
17	subsequent record of an MRSA infection, and 14 residents were identified with	
18	colonisation and had subsequently developed an MRSA infection. Eight residents had	
19	a record of MRSA bacteraemia. Two percent of residents colonised with MRSA had a	
20	record of MRSA infection subsequent to a survey, compared with 0.9% for those	
21	residents without MRSA colonisation ($p = 0.008$, χ^2). Death was recorded for 897 of	
22	the 2492 residents that participated. Colonisation with MRSA was not significantly	
23	associated with mortality (OR = 1.16, 95% CI 0.95-1.41, p = 1.32, logistic regression);	
24	however, mortality was significantly associated with advanced age, male sex, the	
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- entering the study to either MRSA infection or 09/08/2009, whichever occurred BMJ Open
- first and b) logistic regression model of mortality associated with prior MRSA
- carriage

	MR	SA infectior	۱ ^а		Mortality ^t)
Risk factor	Hazard	CI	р	OR	CI	p
	Ratio					
MRSA colonisation	2.51	1.2-5.24	0.014	1.16	0.95-1.41	0.132
during study						
Age	1.00	0.96-1.05	0.728	1.04	1.03-1.05	<0.001
Male	1.41	0.65-3.08	0.377	1.39	1.14-1.69	0.001
Presence of an	0.67	0.09-5.02	0.701	5.45	3.32-8.95	<0.001
invasive device						
No. of hospital	1.11	0.92-1.34	0.244	1.06	1.00-1.12	0.038
admissions in the						
previous 12 months						

Key: OR, Odds ratio; CI, 95% confidence interval.

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1 Discussion

2	To our knowledge, this is the largest prospective study that has monitored the
3	level of nasal colonisation of MRSA in elderly residents of care homes in the UK. Sixty
4	five homes and 2492 residents participated in the study which took place over a 28
5	month period (November 2006-February 2009). The study included a large proportion
6	of care homes in the area served by Leeds Primary Care Trust, including homes of
7	different sizes (n = 20-180 beds), homes owned by the local authority and by
8	independent providers, and homes with and without nursing capability. In total, 888
9	MRSA isolates were identified from 4325 nasal swabs during the periods of screening
10	stated. The mean level of MRSA colonisation was 20% (95% CI = 18-23%), which was
11	higher than levels recorded during the 1990s but comparable to those reported recently
12	(22-23%). ^{14;17} Interestingly, a recent survey of 748 residents in 51 care homes in
13	Gloucestershire and Bristol found that only 7.9% residents were positive for MRSA by
14	nasal screening, indicating marked geographical variation in MRSA prevalence in care
15	homes. ²⁴
15 16	homes. ²⁴ The health outcomes of residents are not commonly included in studies of
15 16 17	homes. ²⁴ The health outcomes of residents are not commonly included in studies of MRSA prevalence in the care home. ^{17;25;26} The findings of the present study support
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1	emphasis on hand hygiene. The present study assessed the infection prevention
2	knowledge of over 1000 members of staff and the infection prevention practice of more
3	than 300 individuals. The stepped-wedge design allowed measurement of MRSA
4	prevalence before the intervention, directly after the intervention, and further follow-up
5	in two out of three study groups. Participating residents and staff in each group of
6	homes acted as controls for each other. Three established methods were used to
7	measure staff knowledge and behaviour following the intervention and scores improved
8	after the intervention for all three assessments.
9	Overall, no significant difference in MRSA prevalence was identified during the
10	survey periods. Directly following the intervention, however, there was a significant
11	increase in MRSA prevalence, although this returned to baseline levels in one group
12	that had follow-up. Stepped-wedge designs are particularly susceptible to trends within
13	subgroups, but when the subgroups were adjusted for linear trends, the increase in
14	MRSA prevalence after the intervention remained significant. It is possible that other
15	confounding factors resulted in a non-linear trend in MRSA prevalence in certain
16	homes. It has not been possible to identify or control for these factors. MRSA
17	infections are unlikely to be independent events and a cluster of MRSA cases may
18	explain temporary increases in prevalence following the intervention in some homes.
19	Leeds Teaching Hospitals Trust (LTHT) was the main acute care provider for all
20	the homes in the study. The small increase in MRSA prevalence following the
21	intervention is unlikely to relate to the extent of MRSA infection in LTHT as
22	during the period of the study, there was a decreasing trend in the MRSA
23	bacteraemia rates reported by LTHT. ³
24	Other studies have used a similar intervention strategy in care homes. ²⁹⁻³¹ A
25	study based in Taiwan introduced a programme of hand hygiene training into three
26	care homes and identified significant improvements in scores for staff knowledge and
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1 behaviour after the training; difference between hand hygiene knowledge pre- and 2 post-intervention, p < 0.001; difference between hand hygiene observations pre-and 3 post-intervention, p = 0.001.³⁰ Although no direct measure of microbiological outcome 4 was included, rates of infection based on the total number of urinary tract infections, 5 lower respiratory infections and rates of influenza recorded by each facility, were 6 significantly lower following the intervention (1.52%) compared with rates recorded for 7 two periods before the intervention; December 2004-February 2005 (1.74%) and 8 June-August 2005 (2.04%) (p < 0.001).

9 Around the same time as the present study, Baldwin et al. (2010) implemented 10 an infection control education and training programme in nursing homes in the Belfast area of Northern Ireland.²⁹ The study screened 793 residents and 338 members of 11 12 staff for MRSA colonisation. The education programme, occurring at baseline and at 13 three and six months, consisted of multiple training sessions for staff. An existing 14 member of staff in each intervention home was assigned the role of infection control 15 link worker, the role of which was to reinforce good infection control practice in the 16 home. Practice was observed and recorded, with feedback, for an audit of ten 17 specified infection control standards involving the following subject areas: cleanliness, 18 decontamination (hand and environment), waste management, personal protective 19 equipment and the management of wounds, urinary catheters and enteral feeding. 20 Using a cluster randomised controlled study design, audit scores and MRSA 21 colonisation of residents and staff were compared for homes in the intervention group 22 (n = 16) with those homes in the control group (n = 16); homes in the control group did 23 not receive training or feedback. While scores for the infection control audits 24 significantly improved in eight of the ten standards (82% vs. 64% in intervention and 25 control homes, respectively, p < 0.0001), levels of MRSA colonisation did not change 26 over the 12 month study period in either residents or staff.

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1	In contrast, Gopal et al. (2009) evaluated whether enhanced infection control
2	support in nursing homes had an impact on improving infection control practice. ³¹ The
3	intervention included extensive support from a dedicated infection control team,
4	including an infection control nurse, infection control nurse specialist and an infection
5	control doctor. Twelve homes were included in the study and were divided into two
6	groups of six, an intervention group and a control group, based on the number of
7	residents. The study found no statistical difference between the control group and the
8	group of homes that received the intervention at baseline and final assessment for
9	hand hygiene facilities ($p = 0.69$), environmental cleanliness ($p = 0.43$) and disposal of
10	clinical waste ($p = 0.96$). There was no microbiological investigation included in this
11	evaluation.
12	In principle, the intervention applied in the present study was plausible and
13	unlikely to be harmful. The assessments were reasonable, albeit focussed on
14	short-term effects; however, the following limitations of the study must be
15	acknowledged. It is likely that the prevalence reported here is an underestimation of
16	the true level of MRSA colonisation because of the use of nasal screening alone. To
17	achieve a high-level of sensitivity of detection (>90%) of MRSA carriers, multiple sites
18	(e.g. axilla, groin, nose and throat) need to be screened. ^{32;33} Screening urethral
19	catheters, legs ulcers and pressure sores would have increased the sensitivity of
20	MRSA detection and may have provided further information regarding the infection
21	status of the resident. Although pooling swabs from multiple sites could have been
22	done at the same cost, screening the anterior nares as a single site using chromagar
23	as a growth medium was a compromise, taking into account the difficulties of obtaining
24	consent and practical issues associated with more extensive sampling of a
25	predominantly frail, elderly population and the need for a cost-effective approach.
26	Participation of residents was voluntary and on average 46% of the residents

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> were tested for MRSA colonisation. Reasons for non-participation of residents were not collected; care homes for people with dementia were not specifically excluded from the study, but residents with dementia were excluded. It is acknowledged that residents who were not considered eligible to participate due to their level of dependency may be at a greater risk of MRSA colonisation.

6 Other potentially informative data were not collected. For example, the 7 type of room available per resident (*i.e.* single, shared, en-suite), local cleaning 8 policies (routine and incident-related), laundry provision, and the uniform policy 9 of the home would have provided a fuller description of the care home setting. 10 Staff turnover in each care home was assessed at baseline, but more frequent 11 data collection may have enabled a better assessment of the effect of the 12 intervention. We did not collect information about length of stay of each 13 resident, movement of individuals between homes, which we understand is 14 uncommon, the number of admissions per home, and sources of admission (*i.e.* 15 own home, hospital, other care home).

16 The study aimed to deliver educational input to at least 80% whole-time 17 equivalent staff, which was achieved in 32% of the homes. Resources were 18 available to provide each home with a maximum of three educational sessions, 19 although exceptions were made for those homes with >100 beds. Availability of 20 care home staff due to work demands or sickness, and closure of homes due to 21 outbreaks of norovirus were reasons for not achieving the educational target in 22 some homes. Such issues highlight the operational barriers to infection 23 prevention measures, especially those that require behavioural change.

Other challenges to a study of this design include the requirement for ethical approval, which may result in the inability to screen residents who cannot give consent, and the need to maintain the anonymity of participating residents and staff. Limited resources, home ownership, lack of isolation facilities, the high throughput of employees and a high resident-to-carer ratio may influence the effectiveness of infection control strategies in care homes.^{18, 34} In the absence of mandatory requirements relating to infection control in care homes, it may be difficult to implement infection prevention strategies in the primary care setting. Although observational methods of assessing hand hygiene compliance are considered the gold standard,³⁵ increased productivity due to observation, known as the Hawthorne effect, must be considered.^{36;37} Despite long-term microbiological follow-up (8-25 months), the duration of follow-up with regards to staff knowledge and behaviour remained short (approximately four weeks). While the anonymous design of the present study kept assessment of the intervention informal, it did not enable the long-term follow-up of knowledge and practice in individual staff. The intervention applied in the present study focused on a particular area of infection prevention, that of hand hygiene, skin care and personal protective equipment. Hand hygiene is considered to be an educational priority; however, there is little evidence to suggest that improvements in hand hygiene alone result in a significant reduction in MRSA infection or colonisation.³⁸ Clearly, hand hygiene may still be beneficial, and without emphasis on such practice it is plausible that transmission of MRSA and other pathogens would increase. Reinforcement of message and/or use cognitive behavioural theory could be explored to optimise hand hygiene and thus its effectiveness. Additional educational topics may include risk factors for infection and how to identify residents at risk, care of wounds and

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1	invasive devices, and education about the judicious use of antibiotics. ³⁹
2	Implementation of an intervention in a setting such as that of the care home, which
3	experiences a high level of change, in terms of employee and resident throughput,
4	cannot be expected to last long-term without regular input. A single session of
5	education per staff member is unlikely to make a large difference to long-term practice.
6	Alternative training and education strategies may include more frequent educational
7	sessions, with additional learning resources, such as e-learning. Others have reported,
8	however, that the introduction of multiple training sessions did not result in a decrease
9	in MRSA prevalence, ²⁹ and cares homes that had access to extensive infection control
10	support failed to show improvements in audit scores. ³¹
11	The use of interventions that focus on screening and decolonisation of residents
12	and/or staff may reduce MRSA prevalence in care homes. Given the difficulty of
13	achieving MRSA decolonisation in individuals with multiple risk factors for persistence,
14	this would be a considerable undertaking, and may risk resistance selection. Control of
15	risk factors for MRSA colonisation, such as improved management of wounds and
16	invasive devices may be beneficial. ³⁹ Evaluation would be required to assess the cost
17	versus benefit of interventions involving screening and decolonisation in the care home
18	setting, along with consideration about the source of funding if such approaches were
19	to be recommended, ^{40,41} Given the large recent and continuing decreases in incidence
20	of invasive MRSA infection in England, ⁹ it remains possible that control measures in
21	the secondary care setting will lead to reduced MRSA carriage in care home residents.
22	Conclusion
23	These results reinforce previous reports of high MRSA colonisation rates in
24	elderly residents of care homes. The intervention applied in the present study
25	improved staff practice and knowledge but did not reduce MRSA prevalence in
26	residents. These data provide an important baseline for future surveillance of MRSA in

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the care home setting. Further work is needed regarding screening, decolonisation and re-entry to the care home and continued surveillance is needed to understand the interaction between MRSA in care homes and hospitals. Clear policy decisions need to be made about how to manage with the burden of MRSA colonisation in care home residents. The high burden of MRSA in residents has implications for other healthcare institutions who manage these individuals. Admission arrangements (isolation/screening, etc) of care home residents may need to be adjusted to take account the risk of MRSA colonisation for individuals. Reducing MRSA infection and possibly colonisation in hospital patients may in turn affect the prevalence of MRSA in care home residents.

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23 Northern Ireland. <i>J Am Geriatr Soc</i> 2009;57:620-626.	22		Staphylococcus aureus colonization in residents and staff in nursing homes in
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Changes in MRSA prevalence by Intervention Group per survey, before and after the intervention. 83x135mm (96 x 96 DPI)

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4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Name PROFESSOR MARK WILCOX
5. Manuscript Title The longitudinal prevalence of MRSA i knowledge and practice on colonisatic	n care home residents and	d the effectiveness of improving infection prevention
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Relevant financial activities out	side the	submit	ted work			
Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your Institution*	Entity	Comments	
						ADD
8. Patents (planned, pending or issued)	\checkmark					×
						ADD
9. Royalties	\checkmark					×
						ADD
10. Payment for development of educational presentations	\checkmark					×
						ADD
11. Stock/stock options	\checkmark					×
						ADD
12. Travel/accommodations/ meeting expenses unrelated to activities listed**	\checkmark					×
						ADD
13. Other (err on the side of full disclosure)	\checkmark					×
						ADD

* This means money that your institution received for your efforts.

** For example, if you report a consultancy above there is no need to report travel related to that consultancy on this line.

Section 4. Other relationships

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

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Hide All Table Rows Checked 'No'

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Instructions

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in four parts.

Identifying information.

Enter your full name. If you are NOT the corresponding author please check the box "no" and a space to enter the name of the corresponding author in the space that appears. Provide the requested manuscript information. Double-check the manuscript number and enter it.

The work under consideration for publication.

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Other relationships.

Use this section to report other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work.

Hodgson



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Continue 1		
Section I. Identifying Inform	mation	
1. Given Name (First Name) Gillian	2. Surname (Last Name) Hodgson	3. Effective Date (07-August-2008) 31-August-2011
4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Name PROFESSOR MARK WILCOX
5. Manuscript Title The longitudinal prevalence of MRSA in knowledge and practice on colonisatic	n care home residents an on	d the effectiveness of improving infection prevention
6. Manuscript Identifying Number (if you k BMJ.2011.000490	now it)	
Section 2. The Work Under C	Consideration for Pub	lication

Did you or your institution at any time receive payment or services from a third party for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc...)?

Complete each row by checking "No" or providing the requested information. If you have more than one relationship click the "Add" button to add a row. Excess rows can be removed by clicking the "X" button.

The Work Under Consideration f	or Pub	lication				
Туре	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
1. Grant			\checkmark	Department of Health		×
						ADD
2. Consulting fee or honorarium	\checkmark					×
						ADD
3. Support for travel to meetings for the study or other purposes	\checkmark					×
						ADD
 Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like 	✓					×
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5. Payment for writing or reviewing the manuscript	\checkmark					×
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 Provision of writing assistance, medicines, equipment, or administrative support 	✓					×
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The Work Under Consideration for Publication									
Туре	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**				
						ADD			
7. Other	\checkmark					×			
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* This means money that your institution received for your efforts on this study.

** Use this section to provide any needed explanation.

Section 3. Relevant financial activities outside the submitted work.

Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were present during the 36 months prior to submission.

Complete each row by checking "No" or providing the requested information. If you have more than one relationship click the "Add" button to add a row. Excess rows can be removed by clicking the "X" button.

Relevant financial activities outside the submitted work									
Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your Institution*	Entity	Comments				
1. Board membership	\checkmark					×			
						ADD			
2. Consultancy	\checkmark					×			
						ADD			
3. Employment	\checkmark					×			
						ADD			
4. Expert testimony	\checkmark					×			
						ADD			
5. Grants/grants pending	\checkmark					×			
						ADD			
Payment for lectures including service on speakers bureaus	\checkmark					×			
						ADD			
7. Payment for manuscript preparation	\checkmark					×			

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Relevant financial activities outs	ide the	submit	ted work			
Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your Institution*	Entity	Comments	
						ADD
 Patents (planned, pending or issued) 	\checkmark					×
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9. Royalties	\checkmark					×
						ADD
10. Payment for development of educational presentations	\checkmark					×
						ADD
11. Stock/stock options	\checkmark					×
						ADD
 Travel/accommodations/ meeting expenses unrelated to activities listed** 	\checkmark					×
						ADD
13. Other (err on the side of full disclosure)	\checkmark					×
						ADD

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Yes, the following relationships/conditions/circumstances are present (explain below):

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Instructions

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in four parts.

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Enter your full name. If you are NOT the corresponding author please check the box "no" and a space to enter the name of the corresponding author in the space that appears. Provide the requested manuscript information. Double-check the manuscript number and enter it.

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Relevant financial activities outside the submitted work.

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Other relationships.

Use this section to report other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work.

Wilcox



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Section 1.	Identifying Infor	mation	
1. Given Name (Fir Mark	st Name)	2. Surname (Last Name) Wilcox	3. Effective Date (07-August-2008) 31-August-2011
4. Are you the corr	esponding author?	✓ Yes No	
5. Manuscript Title The longitudinal knowledge and p	prevalence of MRSA i practice on colonisation	in care home residents and the effectiv on	eness of improving infection prevention
6. Manuscript Iden BMJ.2011.000490	tifying Number (if you l)	know it)	

Section 2. The Work Under Consideration for Publication

Did you or your institution at any time receive payment or services from a third party for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc...)?

Complete each row by checking "No" or providing the requested information. If you have more than one relationship click the "Add" button to add a row. Excess rows can be removed by clicking the "X" button.

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Туре	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
1. Grant			\checkmark	Department of Health		×
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2. Consulting fee or honorarium	\checkmark					×
						ADD
3. Support for travel to meetings for the study or other purposes	\checkmark					×
						ADD
 Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like 	\checkmark					×
						ADD
5. Payment for writing or reviewing the manuscript	\checkmark					×
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 Provision of writing assistance, medicines, equipment, or administrative support 	✓					×
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Wilcox

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Relevant financial activities outside the submitted work							
Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your Institution*	Entity	Comments		
						ADD	
8. Patents (planned, pending or issued)	\checkmark					×	
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9. Royalties	\checkmark					×	
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10. Payment for development of educational presentations	\checkmark					×	
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ICMJE Form for Disclosure of Potential Conflicts of Interest

Instructions

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in four parts.

Identifying information.

Enter your full name. If you are NOT the corresponding author please check the box "no" and a space to enter the name of the corresponding author in the space that appears. Provide the requested manuscript information. Double-check the manuscript number and enter it.

The work under consideration for publication.

This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present. The requested information is about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. Checking "No" means that you did the work without receiving any financial support from any third party -- that is, the work was supported by funds from the same institution that pays your salary and that institution did not receive third-party funds with which to pay you. If you or your institution received funds from a third party to support the work, such as a government granting agency, charitable foundation or commercial sponsor, check "Yes". Then complete the appropriate boxes to indicate the type of support and whether the payment went to you, or to your institution, or both.

Relevant financial activities outside the submitted work.

This section asks about your financial relationships with entities in the bio-medical arena that could be perceived to influence, or that give the appearance of potentially influencing, what you wrote in the submitted work. You should disclose interactions with ANY entity that could be considered broadly relevant to the work. For example, if your article is about testing an epidermal growth factor receptor (EGFR) antagonist in lung cancer, you should report all associations with entities pursuing diagnostic or therapeutic strategies in cancer in general, not just in the area of EGFR or lung cancer.

Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research. Please note that your interactions with the work's sponsor that are outside the submitted work should also be listed here. If there is any question, it is usually better to disclose a relationship than not to do so.

For grants you have received for work outside the submitted work, you should disclose support ONLY from entities that could be perceived to be affected financially by the published work, such as drug companies, or foundations supported by entities that could be perceived to have a financial stake in the outcome. Public funding sources, such as government agencies, charitable foundations or academic institutions, need not be disclosed. For example, if a government agency sponsored a study in which you have been involved and drugs were provided by a pharmaceutical company, you need only list the pharmaceutical company.

Other relationships.

Use this section to report other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work.



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Section 1. Identifying Infor 1. Given Name (First Name) Benjamin	mation 2. Surname (Last Name) Barr	3. Effective Date (07-August-2008) 31-August-2011
4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Name PROFESSOR MARK WILCOX
5. Manuscript Title The longitudinal prevalence of MRSA knowledge and practice on colonisati	in care home residents an on	d the effectiveness of improving infection prevention
6. Manuscript Identifying Number (if you BMJ.2011.000490	know it)	
Section 2. The Work Under	Consideration for Pub	lication

Did you or your institution at any time receive payment or services from a third party for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc...)?

Complete each row by checking "No" or providing the requested information. If you have more than one relationship click the "Add" button to add a row. Excess rows can be removed by clicking the "X" button.

The Work Under Consideration for Publication						
Туре	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
1. Grant			\checkmark	Department of Health		×
						ADD
2. Consulting fee or honorarium	\checkmark					×
						ADD
3. Support for travel to meetings for the study or other purposes	\checkmark					×
						ADD
 Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like 	✓					×
						ADD
Payment for writing or reviewing the manuscript	\checkmark					×
						ADD
 Provision of writing assistance, medicines, equipment, or administrative support 	✓					×
Barr						2

Barr

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The Work Under Consideration for Publication								
Туре	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**			
						ADD		
7. Other	\checkmark					×		
						ADD		

* This means money that your institution received for your efforts on this study.

** Use this section to provide any needed explanation.

Section 3. Relevant financial activities outside the submitted work.

Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were present during the 36 months prior to submission.

Complete each row by checking "No" or providing the requested information. If you have more than one relationship click the "Add" button to add a row. Excess rows can be removed by clicking the "X" button.

Relevant financial activities outside the submitted work						
Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your Institution*	Entity	Comments	
1. Board membership	\checkmark					×
						ADD
2. Consultancy	\checkmark					×
						ADD
3. Employment	\checkmark					×
						ADD
4. Expert testimony	\checkmark					×
						ADD
5. Grants/grants pending	\checkmark					×
						ADD
Payment for lectures including service on speakers bureaus	\checkmark					×
						ADD
7. Payment for manuscript preparation	\checkmark					×

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Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your Institution*	Entity	Comments		
						ADD	
 Patents (planned, pending or issued) 	\checkmark					×	
						ADD	
9. Royalties	\checkmark					×	
						ADD	
10. Payment for development of educational presentations	\checkmark					×	
						ADD	
11. Stock/stock options	\checkmark					×	
						ADD	
 Travel/accommodations/ meeting expenses unrelated to activities listed** 	\checkmark					×	
						ADD	
13. Other (err on the side of full disclosure)	\checkmark					×	
						ADD	

* This means money that your institution received for your efforts.

** For example, if you report a consultancy above there is no need to report travel related to that consultancy on this line.

Section 4. Other relationships

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

✓ No other relationships/conditions/circumstances that present a potential conflict of interest

Yes, the following relationships/conditions/circumstances are present (explain below):

At the time of manuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. On occasion, journals may ask authors to disclose further information about reported relationships.

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Evaluation and Feedback

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 Please visit http://www.icmje.org/cgi-bin/feedback to provide feedback on your experience with completing this form.

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Parnell



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Section 1.	Identifying Inform	mation	
1. Given Name (First Name) Peter		2. Surname (Last Nam Parnell	e) 3. Effective Date (07-August-2008) 31-August-2011
4. Are you the co	rresponding author?	Yes 🖌 No	Corresponding Author's Name PROFESSOR MARK WILCOX
5. Manuscript Titl The longitudina knowledge and	e l prevalence of MRSA i practice on colonisatio	in care home residents a	and the effectiveness of improving infection prevention
6. Manuscript Ide BMJ.2011.00049	ntifying Number (if you l 00	know it)	
Section 2.	The Work Under 0	Consideration for Pu	blication

Did you or your institution at any time receive payment or services from a third party for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc...)?

Complete each row by checking "No" or providing the requested information. If you have more than one relationship click the "Add" button to add a row. Excess rows can be removed by clicking the "X" button.

The Work Under Consideration	for Pub	lication				
Туре	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
1. Grant			\checkmark	Department of Health		×
						ADD
2. Consulting fee or honorarium	\checkmark					×
						ADD
3. Support for travel to meetings for the study or other purposes	\checkmark					×
						ADD
 Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like 	✓					×
						ADD
Payment for writing or reviewing the manuscript	\checkmark					×
						ADD
 Provision of writing assistance, medicines, equipment, or administrative support 	✓					×
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Parnell

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ICMJE Form for Disclos	ure o	f Pote	ntial Con	flicts of Intere	est		
The Work Under Consideration Type	for Pub	Money Paid	Money to Your	Name of Entity	Comments**		
		to You	Institution*			ADD	
7. Other	\checkmark					X	
						ADD	
* This means money that your institution	n received	l for your ef	forts on this stud	у.			
Use this section to provide any neede							
Section 3. Relevant financ	ial activ	vities out	side the subr	nitted work.			
clicking the "Add +" box. You should report relationships that were present during the 36 months prior to submission. Complete each row by checking "No" or providing the requested information. If you have more than one relationship click the "Add" button to add a row. Excess rows can be removed by clicking the "X" button. Relevant financial activities outside the submitted work							
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Type of Relationship (in alphabetical order)	No	e submit Money Paid to You	ted work Money to Your Institution*	Entity	Comments		
Type of Relationship (in alphabetical order) 1. Board membership	No ✓	e submit Money Paid to You	ted work Money to Your Institution*	Entity	Comments	×	
Type of Relationship (in alphabetical order) 1. Board membership	No	e submit Money Paid to You	ted work Money to Your Institution*	Entity	Comments	× ADD	
Type of Relationship (in alphabetical order) 1. Board membership 2. Consultancy	No ✓	e submit Money Paid to You	ted work Money to Your Institution*	Entity	Comments	× ADD ×	
Type of Relationship (in alphabetical order) 1. Board membership 2. Consultancy 3. Employment	No	e submit	ted work Money to Your Institution*	Entity	Comments	ADD X ADD X ADD	
Type of Relationship (in alphabetical order) 1. Board membership 2. Consultancy 3. Employment	No ✓	e submit Money Paid to You	ted work Money to Your Institution*	Entity	Comments	ADD X ADD X ADD X ADD	
Type of Relationship (in alphabetical order) 1. Board membership 2. Consultancy 3. Employment 4. Expert testimony	No	e submiti Money Paid to You	ted work Money to Your Institution*	Entity	Comments	ADD X ADD X ADD X ADD X	
Type of Relationship (in alphabetical order) 1. Board membership 2. Consultancy 3. Employment 4. Expert testimony	No	e submiti Money Paid to You	ted work Money to Your Institution*	Entity	Comments	ADD X ADD X ADD X ADD X ADD	
Type of Relationship (in alphabetical order) 1. Board membership 2. Consultancy 3. Employment 4. Expert testimony 5. Grants/grants pending	No	e submit Money Paid to You	ted work Money to Your Institution*	Entity	Comments	ADD X ADD X ADD X ADD X ADD X ADD	
Type of Relationship (in alphabetical order) 1. Board membership 2. Consultancy 3. Employment 4. Expert testimony 5. Grants/grants pending	No	e submit Money Paid to You	ted work Money to Your Institution*	Entity	Comments	ADD X ADD X ADD X ADD X ADD X ADD X	
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Type of Relationship (in alphabetical order) 1. Board membership 2. Consultancy 3. Employment 4. Expert testimony 5. Grants/grants pending 6. Payment for lectures including service on speakers bureaus	No	e submit Money Paid to You	ted work Money to Your Institution*	Entity	Comments	ADD X ADD X ADD X ADD X ADD X ADD X ADD	
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						ADD
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						ADD
9. Royalties	\checkmark					×
						ADD
10. Payment for development of educational presentations	\checkmark					×
						ADD
11. Stock/stock options	\checkmark					×
						ADD
 Travel/accommodations/ meeting expenses unrelated to activities listed** 	\checkmark					×
						ADD
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Hide All Table Rows Checked 'No'

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