

The ORION statement: guidelines for transparent reporting of Outbreak Reports and Intervention studies Of Nosocomial infection

S. P. Stone^{1*}, B. S. Cooper¹, C. C. Kibbler¹, B. D. Cookson², J. A. Roberts³, G. F. Medley⁴,
G. Duckworth², R. Lai¹, S. Ebrahim³, E. M. Brown⁵, P. J. Wiffen⁶ and P. G. Davey⁷

¹Royal Free and University College Medical School, Rowland Hill Street, London NW3 2PF, UK; ²Health Protection Agency, Centre for Infections, Colindale Avenue, Colindale, London NW9 5EQ, UK; ³London School of Hygiene and Tropical Medicine, Keppel Street London WC1E 7HT, UK; ⁴Warwick University, Coventry CV4 7AL, UK; ⁵Frenchay Hospital, Bristol BS16 1LE, UK; ⁶UK Cochrane Centre, Summertown Pavilion, Middle Way, Oxford OX2 7LG, UK; ⁷University of Dundee Medical School Mackenzie Building, Kirsty Semple Way, Dundee DD2 4BF, Scotland, UK

The quality of research in hospital epidemiology (infection control) must be improved to be robust enough to influence policy and practice. In order to raise the standards of research and publication, a CONSORT equivalent for these largely quasi-experimental studies has been prepared by the authors of two relevant systematic reviews, following consultation with learned societies, editors of journals and researchers. It consists of a 22 item checklist, and a summary table. The emphasis is on transparency to improve the quality of reporting and on the use of appropriate statistical techniques. The statement has been endorsed by a number of professional special interest groups and societies. Like CONSORT, ORION should be considered a 'work in progress', which requires ongoing dialogue for successful promotion and dissemination. The statement is therefore offered for further public discussion. Journals and research councils are strongly recommended to incorporate it into their submission and reviewing processes. Feedback to the authors is encouraged and the statement will be revised in 2 years.

Keywords: healthcare-associated infections, hospital epidemiology, evidence-based medicine

Introduction

The move towards evidence-based medicine has gained momentum this last decade. The publication of the CONSORT (Consolidated Standards of Reporting Trials) statement in 1996,¹ its revision in 2001² and extension in 2004,³ which sought to improve the quality of reports of randomized controlled trials (RCTs), has contributed to this. Through its insistence on complete transparency of reporting, the statement has enabled editors and readers to understand exactly why and how an individual RCT was designed, conducted and analysed, and to assess the threats to the validity of its results.

The recent publication of the TREND statement (Transparent Reporting of Evaluations of Nonrandomized Designs) sought to do for public health interventions, most of which are described in non-randomized studies, what CONSORT has achieved for the RCT.⁴ It adapted the CONSORT statement, its checklist of descriptors and its flow diagram, but with revisions relevant to

non-randomized designs and some important enhancements relevant to RCTs evaluating public health interventions. Transparency was key to improving the quality of reporting so that information critical to synthesis of research was not missing.⁵ The current STROBE initiative (Strengthening the Reporting of Observational studies in Epidemiology) seeks to do the same for epidemiological research, especially for cohort, case control and cross-sectional studies (www.strobe-statement.org).

Hospital interventions to control the rising levels of antimicrobial resistance (AMR) and healthcare-associated (nosocomial) infections form a large body of non-randomized studies. Systematic reviews of isolation policies in the hospital management of methicillin-resistant *Staphylococcus aureus* (MRSA)^{6,7} and of interventions to improve antibiotic prescribing to hospital inpatients^{8,9} revealed major methodological weaknesses and inadequate reporting in published research. These included lack of details on study design, as others have noted,¹⁰ the timing and nature of interventions, failure to consider threats to validity

*Corresponding author. Tel: +44-7801258061; Fax: +44-2078302378; E-mail: s.stone@medsch.ucl.ac.uk

of inference in the form of potential confounders and biases, and inappropriate statistical analyses. Studies were largely quasi-experimental and often basic information such as the number of isolation beds, criteria to diagnose infection, culture and typing of organisms, or the timing of interventions were missing. Guidelines for the publication of future outbreak reports and intervention studies were produced,⁶ informed by theoretical considerations¹¹ but, although available on-line (www.hta.nhsweb.nhs.uk), these refer primarily to MRSA and are not as user-friendly as the revised CONSORT statement with its 22 item checklist and flow diagram. Moreover, the CONSORT, TREND and STROBE statements do not provide items or descriptors easily translatable into the wide variety of interventions, settings, designs and statistical issues relating to infectious diseases.

The authors of the two systematic reviews of isolation⁶ and antibiotic prescribing,⁸ therefore modified previously guidelines⁶ for the publication of MRSA outbreak reports and intervention studies to make them relevant to nosocomial organisms in general and to take account of issues pertinent to evaluation of interventions to change hospital antibiotic prescribing.^{8,9} The resultant ORION (Outbreak Reports and Intervention studies of Nosocomial infection) statement is written in the spirit of the CONSORT and TREND statements, taking into account the variety of interventions, settings, designs and statistical issues pertinent to healthcare-associated infections (HCAI), with team members reaching consensus agreement through repeated e-mail correspondence and phone conversations. The statement was then put out to consultation with learned societies, editors of journals and many researchers, acknowledged below, whose responses have been taken into account in the revised statement. The statement is designed especially for quasi-experimental (i.e. non-randomized) study designs commonly used in hospital epidemiology: interrupted time series with and without control groups, and outbreak reports.

The interrupted time series is the predominant study design for infectious disease epidemiology, especially in the hospital setting. Outcome measures are not independent, which introduces specific threats to the validity of inferences which have had to be addressed. Much research into nosocomial infections blurs the distinction between formal studies and outbreak reports, planned and unplanned comparisons. The guidelines attempt to address this problem by emphasizing precision and thoroughness in reporting: as well as the usual *what was done* and *when it was done*, for such quasi-experimental research, it is also important to know *why* interventions and particular comparisons were made. As in the TREND statement 'transparency is key' and the ORION items and descriptors 'type of paper', 'design' and 'dates' have been added to ensure this as even such basic details are often lacking in the hospital infection literature.⁶⁻⁹

Our aims in producing these guidelines are to raise the standards of research and publication in hospital epidemiology, to facilitate synthesis of evidence and promote transparency of reporting, to enable readers to relate studies to their own experience and assess the degree to which results can be generalized to other settings. They are aimed at researchers, editors, reviewers, and grant assessment panels. It is intended that they facilitate well-designed interventional studies to help choose which methods are effective in reducing AMR or HCAI.

ORION components

ORION consists of a 22 item checklist (Table 1). A summary table is strongly recommended for description of the population, clinical setting, and the precise nature and timing of all interventions and outcomes (Table 2) and a graphical summary of the main results is recommended when outcomes are not independent. For intervention studies, such as cross-over studies, but also for interrupted time series where the primary outcome is a patient outcome such as infection and where there are exclusions, we recommend a flow chart to track participants through each stage of the study.

The items and descriptors in Table 1 are largely self-explanatory. We restrict further detailed comment in this paper to those items and descriptors concerning the difference between outbreak reports and intervention studies, the rationale and aim of studies, the description of interventions, the documentation of potential threats to validity of inference from biases and confounders, and the choice of appropriate statistical techniques to minimize threats to statistical conclusion validity. We also make brief comments on economic evaluation, the adverse effects of interventions, and the relationship between ORION and CONSORT in the design, analysis and reporting of RCTs in infection control.

(i) Outbreak reports and intervention studies

The hospital infection literature frequently blurs the distinction between outbreak reports (and the subsequent interventions adopted to control the outbreak) and planned studies of the effectiveness of interventions. Because many important biases may be in operation and several interventions are often made simultaneously, outbreak reports are of limited value for assessing the effectiveness of interventions.¹² They can, however, be important for generating hypotheses or describing new phenomena. The objective of an outbreak report should therefore be stated in the introduction, examples being to report a new epidemic strain,¹³ to quantify or describe the resources used to control the outbreak,^{13,14} or to describe obstacles to outbreak control encountered.¹³ The essential components of an outbreak investigation and report have been listed elsewhere.¹⁵ We recommend that these be adhered to and have incorporated them into our guidelines.

(ii) Aim and rationale of studies

The aim of an intervention study should be stated in the introduction and its design should be referred to in the abstract and title. It should be stated whether a study is prospective (i.e. looking forward, and typically using data collected for the purpose of the study) or retrospective (using historical data collected for purposes other than the study), or whether it is ambidirectional (using both prospectively and retrospectively collected data).

When reporting studies evaluating interventions authors have often failed to explicitly document the reasons behind the decision to intervene at a certain point in time.⁶ This is important, as studies where interventions are introduced because of unusual levels of infection are likely to be vulnerable to regression to the mean artefacts and must be interpreted with caution.¹⁶ It should therefore be made clear whether any part of the study data prompted the decision to intervene. Similarly, the

Review

Table 1. Checklist of items to include when reporting an outbreak or intervention study of a nosocomial organism

	Item Number	Descriptor
Title & Abstract	1	Description of paper as outbreak report or intervention study. Design of intervention study (e.g. ITS with or without control group, cross-over study). Brief description of intervention and main outcomes.
Introduction	2	Scientific and/or local clinical background and rationale.
Background		Description of organism as epidemic, endemic or epidemic becoming endemic.
Type of paper	3	Description of paper as intervention study or an outbreak report. If an outbreak report, report the number of outbreaks.
Dates	4	Start and finish dates of the study or report.
Objectives	5	Objectives for outbreak reports. Hypotheses for intervention studies.
Methods	6	Study design. Use of EPOC classification ²⁹ recommended (CBA, or ITS).
Design		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 during the 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 report.
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.
Interventions	9	Definition of phases by major change in specific infection control practice (with start and stop dates). A summary table is strongly recommended (see Table 2) with precise details of interventions, how and when administered in each phase.
Culturing and typing	10	Details of culture media, use of selective antibiotics and local and/or reference typing. Where relevant, details of environmental sampling.
Infection-related outcomes	11	Clearly defined primary and secondary outcomes (e.g. incidence of infection, colonization, bacteraemia) at regular time intervals (e.g. daily, weekly, monthly) rather than as totals for each phase, with at least three data points per phase ²⁹ and, for many two phase studies, 12 or more monthly data points per phase. ²⁰ Denominators (e.g. numbers of admissions or discharges, patient bed days). If possible, prevalence of organism and incidence of colonization on admission at same time intervals. Criteria for infection, colonization on admission and directly attributable mortality. All cause mortality. For short studies or outbreak reports, use of charts with duration patient stay and dates organism detected may be useful (see text).
Economic outcomes	12	If a formal economic study was done, definition of outcomes to be reported, description of resources used in interventions, with costs broken down to basic units, stating important assumptions.
Potential threats to internal validity	13	Which potential confounders were considered, recorded or adjusted for (e.g. changes in length of stay, case mix, bed occupancy, staffing levels, hand-hygiene compliance, antibiotic use, strain type, processing of isolates, seasonality). Description of measures to avoid bias including blinding and standardization of outcome assessment and provision of care.
Sample size	14	Details of power calculations, where appropriate.
Statistical methods	15	Description of statistical methods to compare groups or phases. Methods for any subgroup or adjusted analyses, distinguishing between planned and unplanned (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. For outbreak reports statistical analysis may be inappropriate.
Results	16	For relevant designs, such as cross-over studies, ³⁰ or where there are exclusions of groups of patients, the dates defining the periods of recruitment and follow-up, with a flow diagram describing participant flow in each phase.
Recruitment		
Outcomes and 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).

Continued

Review

Table 1. *Continued*

	Item Number	Descriptor
Ancillary analyses	18	Any subgroup analysis should be reported and it should be stated whether or not it was planned (i.e. specified in the protocol) and adjusted for possible confounders.
Harms	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.
Discussion Interpretation	20	For intervention studies an assessment of evidence for/against hypotheses, accounting for potential threats to validity of inference including regression to mean effects and reporting bias. For outbreak reports, consider clinical significance of observations and hypotheses generated to explain them.
Generalizability	21	External validity of the findings of the intervention study, i.e. to what degree can results be expected to generalize to different target populations or settings. Feasibility of maintaining an intervention long term.
Overall evidence	22	General interpretation of results in context of current evidence.

CBA, controlled before and after study; ITS, interrupted time series.

Table 2. Example of summary table of population, clinical setting, nature and timing of interventions¹⁷

Setting: three acute care of elderly wards (78 beds) in 1200 bed tertiary hospital with 0.3 WTE ICD & 4.5 WTE ICNs

Dates: 1st Sep 1999–31st March 2003

Population characteristics: 6129 unselected acute consecutive elderly medical admissions (80 years plus). Monthly length of stay 11.93–13.53 days. Endemic CDI and E-MRSA 15 & 16. No inter-hospital transfers.

Major infection control changes during the study: change from “cephalosporin restrictive” antibiotic policy with feedback every 2–3 months (phase 1: 1st Sept 1999–30th Jun 2001; 21 months) to “narrow spectrum” antibiotic policy with feedback as before and provision of laminated pocket-sized card with policy written on it (phase 2: 1st July 2001–31st March 2003; 21 months).

Antibiotic policy: phase 1 - cephalosporin restrictive policy (see below for details).
phase 2 - narrow-spectrum (see Figure 2 in reference 17) policy, written on portable pocket-sized laminated card.

Feedback (both phases): 2–3 monthly feedback of antibiotic use in notional 7 day courses per 100 admissions per month and of monthly numbers of CDI and new MRSA cases.

Isolation policy CDI (both phases): all proven cases isolated in side rooms. Aprons and gloves worn for contact.

Isolation policy MRSA (both phases): all cases of colonization or infection isolated in side rooms or four-bedded cohort on one ward. Aprons and gloves worn for contact.

Cephalosporin restrictive antibiotic policy details (phase 1): Community acquired pneumonia (CAP), amoxicillin; urinary tract infection (UTI), trimethoprim; cellulitis, flucloxacillin and benzyl penicillin; community acquired aspiration pneumonia, benzyl penicillin and metronidazole. Ceftriaxone reserved for:
(i) severe CAP; (ii) hospital-acquired aspiration pneumonia; (iii) UTI with renal failure. Gentamicin: UTI with shock, septicaemia with no apparent focus infection and intra-abdominal sepsis (with ampicillin and metronidazole); erythromycin: penicillin allergy.

Isolation details (both phases): 10 side rooms available on the three wards. One four-bedded MRSA cohort on one ward. All other beds configured in four-bedded bays. Wall-mounted liquid soap and alcohol handrub dispenser and sink in each side room. One sink for each four-bedded bay with liquid soap and, from January 2002, one wall-mounted alcohol handrub dispenser per four-bedded bay.

MRSA screening policy (both phases): admission screening (nose, perineum, wounds and devices) of admissions from nursing homes and of those with a past history of MRSA, (both groups admitted to side room). Patients screened during admission if they had been in the same bay with a new case of MRSA.

MRSA eradication policy (both phases): intranasal mupirocin and chlorhexidine body washes and shampoo for patient with no wounds. Clearance defined as three consecutive negative weekly swabs.

Definition CDI (both phases): an episode of diarrhoea a sample of which was positive for toxin (1). No culture or typing performed.

Definition of new MRSA acquisition (both phases): cases found on screening or clinical specimens taken more than 48 h after admission. No routine typing performed but E-MRSA 15 and 16 endemic.

ICD, infection control doctor; ICN, infection control nurse; WTE, whole time equivalent; CDI, *Clostridium difficile* infection.

Review

reasons for choosing comparisons between certain groups or time periods should be clearly stated. When this choice could be influenced by knowledge of some part of the outcome data, the validity of inferences about the intervention is again threatened (for example by reporting bias, if the successful interventions are more likely to be reported than the unsuccessful). Measures taken to prevent such influence should therefore be reported. These problems with unplanned interventions and comparisons most commonly affect retrospective studies, but prospective studies can also be vulnerable if the study protocol contains insufficient detail about the implementation of interventions or the analysis. The extent to which different aspects of the study are specified by the protocol should therefore be clearly reported. Such aspects include the nature and timing of interventions, the groups to be compared, the start and endpoints of the study, and the analysis plan, including details of subgroup analyses. Deviations from the protocol should also be reported.

(iii) Summary table

Details on participants, setting and interventions are often insufficient and we recommend that a summary table be used to describe the populations, clinical settings, and the precise nature and timing of all interventions (see Table 2 for an example), defining each phase of the study by a major change in specific infection control practice. The patient isolation, screening and eradication policies and other interventions (for example, antibiotic restriction, hand-hygiene education or feedback, ward closures, feedback of surveillance or outcome data) should all be specified and clearly described in each phase. We have found it possible to do so in table form,^{6,17} in a way that we would suggest makes for both clarity and brevity, and we have written a companion paper that illustrates how to report an intervention study in an ORION-compliant way¹⁷ to help readers to understand the statement in operation.

(iv) Description of interventions

We recommend avoiding the use of terms such as contact or strict isolation, barrier nursing, enteric or skin precautions to describe isolation interventions, as these may not be universally understood to have the same meaning. Even when accompanied by a reference to, for example, national guidelines, these may not be easily accessible or relevant, especially internationally. We therefore recommend the use of more descriptive terms such as isolation ward, cohort (on a general ward) with designated staff, cohort without designated staff, single room, use of aprons or gowns and gloves only, or no measures taken. Similarly, we recommend avoiding descriptions of interventions such as 'according to UK National Working Party Guidelines'. This provides insufficient detail, for example the most recent UK guidelines¹⁸ have in-built flexibility, that require further detail to be given in reporting an outbreak or intervention study. Terms such as 'search and destroy' or 'Scutari',¹⁹ similarly lack clarity, although they remain useful concepts in general discussion. A glossary, as published elsewhere,⁶ may be helpful to avoid confusion but we recommend precise description of isolation, eradication, screening, antibiotic, hand-hygiene and other policies as detailed in Appendix 1. Again, the companion paper¹⁷ gives an example of this in practice.

(v) Documentation of potential confounders and biases

Attention should be paid to describing, minimizing and adjusting for plausible threats to the validity of inference from biases and confounders.^{6,7} Measures taken to prevent bias should be considered in the study design, and reported in detail. Potential bias in studies with comparison groups should be sought in the usual way¹ with attention paid to method of allocation and possible selection bias. Blinding may be as relevant to non-RCT designs as to RCTs and, even when it is impossible to blind the care provider or patient, it may be possible to blind the outcome assessor. When blinding is not possible, this should be stated. Possible confounders or effect modifiers should be acknowledged and, where possible, quantified and adjusted for in the analysis. Such factors may include changes to length of stay, case mix, bed occupancy, staffing levels or workloads, and seasonal effects. Similarly, changes in antibiotic use, hand-hygiene and ward closures, unless part of the intervention under investigation, are all potential confounders.

Variations in laboratory practices may also affect both the ability to make valid inferences about an intervention and the ability to generalize results to other settings. The fact that variants of the same pathogen species may have very different properties poses further challenges for reporting and interpreting results and for generalizing findings. This consideration led to the inclusion of pathogen typing as a separate item on the checklist. For longer studies, changes in the properties of the pathogens may be important, and where information is available these should be described.

When accurate data on potential confounders are unavailable, descriptive summaries should still be provided, for example, whether or not there were believed to be changes in patient characteristics, processing of isolates, antibiotic or screening policies etc.

(vi) Appropriate statistical analysis

Threats to statistical conclusion validity should be minimized in intervention studies by seeking advice from a statistician with epidemiological expertise (and ideally knowledge of special issues relating to infectious diseases) prior to conducting the study. Typically, statistical approaches assuming independence of outcomes relating to infection or colonization will be inappropriate, since for a communicable disease the risk to one patient will depend on the status of other patients. Incorrect use of approaches that assume independence (which include the χ^2 test, Fisher's Exact test, linear regression, etc.) can lead to false inferences.

All outcome data should be clearly described in the methods, as should the statistical methods. These might include survival analysis or time series methods for interrupted time series. Unless it is reasonable to assume outcomes to be independent, analysis of aggregated data should be avoided when disaggregated data are available: in general, for interrupted time series designs the outcome data (which may include both infection-related outcomes and indirect or behavioural outcomes such as antibiotic use or hand-hygiene compliance) should be presented as time series rather than averages in the pre- and post-interventions phase, as the latter do not provide information about trends over time, and regression to mean effects may operate.^{6,8,9,16} Before and after studies should either have a contemporary control (no intervention) group or there should be

Review

sufficient observations for analysis as an interrupted time series.^{8,9} The absolute minimum number of data points is three before and three after the intervention. Uncontrolled before and after studies with fewer data points than this are unacceptable. A general pragmatic recommendation is for at least 12 monthly data points before and 12 monthly points after the intervention, although more data points and longer study periods provide even stronger evidence because trends, seasonal effects and natural stochastic variability can be better identified.²⁰ Unnecessary aggregation of data such as reporting yearly or six-monthly rather than monthly or weekly, loses information, weakens the evidence, and should be avoided. Graphical summaries of the main outcomes are often useful for presenting time series data in a condensed and informative manner.

For short studies or outbreak reports, charts showing the duration of individual patient stays and dates of detection of organisms, including data on exposed patients who did not acquire the organism are often informative. Formal statistical analysis is not required for outbreak reports, and may sometimes be inappropriate, an exception to this being appropriate analysis of a case control study performed within the outbreak report.

(vii) Economics

'Economic outcomes' have been included, although they are not obligatory. They do not appear in CONSORT but are often highly relevant to complex interventions,²¹ such as infection control interventions, and systematic review has established a lack of robust economic evaluation in this field.⁶⁻⁹ To be useful however, economic evaluations should attempt to adopt an approach that is comprehensive in so far as it documents and measures all resources used (such as hours or minutes of physician or nurse time, number of extra agarose plates) and costs these resources using cost vectors that are available and transparent to other researchers. Such resources should be precisely described (e.g. minutes or hours of nurse or physician time, number of extra swabs etc.) to help with generalizability. Moreover, any change in practice consumes resources that could have been used for other purposes and therefore has an opportunity cost.²² Care should be taken when attributing the costs to ensure that the attribution is appropriate. If no economic analysis was done, this should be clearly stated. Advice should be sought from a health economist, ideally, one with knowledge of the special issues^{23,24} relating to nosocomial infection, prior to conducting the study.

(viii) Harms

All potential harms should be specified beforehand.²⁵ These might include measures of clinical outcome such as mortality (all-cause mortality should be routinely reported), re-admissions or length of stay. Such measures may need to be monitored after interventions intended to reduce antibiotic prescribing in order to provide evidence about unintended adverse effects, as might the use of empirical antibiotic treatment shown later not to match the sensitivity of the isolated organism. There may often be no explicit evidence directly linking recommended policies with clinical outcomes²² and this may be especially true for local antibiotic policies.²⁶ In certain studies, different unintended adverse effects, such as operations cancelled or isolation beds that could have been used for other purposes, or the

adverse effects of isolation, will require pre-specification and assessment.

(ix) ORION and RCTs in infection control

The statement does not address issues specific to the conduct, description and analysis of RCTs (including those with cluster-randomization) because the CONSORT statement already covers these. However, when cluster RCTs are used to evaluate infection control interventions, ORION may be useful to identify potential confounders and to ensure sufficient detail is reported to maximize transparency and enable assessments of external validity to be made. Examples are those items or, more often, descriptors, relating to culture and typing, participants, interventions, infection-related outcomes and harms. Similarly, for cohort or case control studies STROBE should apply, although ORION may be helpful in similar respects.

Dissemination, enforcement, feedback, revision and evaluation

CONSORT and TREND consider themselves 'work in progress'. We regard ORION in the same light, realizing that such guidelines require dissemination, endorsement, enforcement, feedback, revision and evaluation.²⁷ Dissemination of ORION by joint publication, conference presentations and workshops, and open access to its own website (www.idrn.org/orion.php) is being allied to MSc or post-graduate diploma teaching in infectious diseases, infection control and pharmacy. The statement has been endorsed by the Association of Medical Microbiologists, who have placed it on their web site, and welcomed by the Infection Control Nurses' Association Research and Development Group. The British Society for Antimicrobial Chemotherapy has placed it on their website (www.bsac.org.uk), intends to incorporate it into their grant assessment process, and their journal intends to trial its incorporation into its instructions to authors and reviewers. We strongly recommend that other journals and research councils follow suit. Feedback directly through the website and through post-graduate teaching will be stored for a revision meeting in two years. Evaluation will be through an electronic search strategy for citations of ORION in relevant published studies and, following precedent with CONSORT,²⁸ a controlled before and after study comparing adopter with non-adopter journals, in the first five years of its publication.

Acknowledgements

We thank the following institutions and individuals for their helpful comments during drafting of the ORION statement: British Society for Antimicrobial Chemotherapy, Association of Medical Microbiologists (UK), Infection Control Nurses Association (Research and Development Group) (UK), Hospital Infection Society (UK); The Lancet Infectious Diseases, Journal of Antimicrobial Chemotherapy, Journal of Hospital Infection, British Medical Journal, BMC (BioMed Central Ltd), Annals of Internal Medicine, New England Journal of Medicine, Lancet; Lindsay Nicolle (Health Sciences Centre, Winnipeg, Canada); Anthony Harris (University Of Maryland, Baltimore, USA); W. Charles Huskins (Mayo Clinic College of Medicine, Rochester, Minnesota, USA); Kathy Orr (Freeman Hospital,

Review

Newcastle, UK); Claire Kilpatrick (Health Protection, Scotland); and the three anonymous referees, who provided informed constructive suggestions.

Transparency declarations

S. S. has received research grant contributions and expenses for conference attendance from GOJO Industries, manufacturers of Purell Hand-Rub. P. G. D. has received sponsorship for speaking at meetings from Aventis, Pfizer, and Wyeth, and research funding from GlaxoSmithKline, Pfizer, and Boehringer Ingelheim. He is also a member of the Johnson & Johnson Global Anti-infectives Advisory Board. All other authors have none to declare.

Simultaneous publication

This article also appears in *The Lancet Infectious Diseases* (2007; 7: 282–8).

References

1. Begg CB, Cho MK, Eastwood S *et al.* Improving the quality of reporting of randomized controlled trials: the CONSORT statement. *JAMA* 1996; **276**: 637–9.
2. Moher D, Schulz KF, Altman DG for the CONSORT group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *Lancet* 2001; **357**: 1191–4.
3. Campbell MK, Elbourne DR, Altman DG for the CONSORT group. CONSORT statement: extension to cluster randomised trials. *BMJ* 2004; **328**: 702–8.
4. Des Jarlais DC, Lyles C, Crepaz N *et al.* Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: the TREND statement. *Am J Pub Health* 2004; **94**: 361–6.
5. Kirkwood B. Making public health interventions more evidence based. *BMJ* 2004; **328**: 966–7.
6. Cooper BS, Stone SP, Kibbler CC *et al.* Systematic review of isolation policies in the hospital management of methicillin-resistant *Staphylococcus aureus*: a review of the literature with epidemiological and economic modelling. *Health Technol Assess* 2003; **7**: 1–194.
7. Cooper BS, Stone SP, Kibbler CC *et al.* Isolation measures in the hospital management of MRSA: a systematic review of the literature. *BMJ* 2004; **329**: 533–8.
8. Ramsay C, Brown E, Hartman G *et al.* Room for improvement: a systematic review of the quality of evaluations of interventions to improve hospital antibiotic prescribing. *J Antimicrob Chemother* 2003; **52**: 764–71.
9. Davey P, Brown E, Hartman G *et al.* Interventions to improve antibiotic prescribing practices for hospital inpatients. *Cochrane Database Syst Rev* 2005; issue 4: CD003543. DOI: 10.1002/14651858.CD003543.pub2 (16 November 2006, date last accessed).
10. Harris AD, Lautenbach E, Perencevich EN. A systematic review of quasi-experimental study designs in the fields of infection control and antibiotic resistance. *Clin Infect Dis* 2005; **41**: 77–82.
11. Cook TD, Campbell DT. *Quasi Experimentation. Design & Analysis Issues for Field Settings*. First Edition. Boston, USA: Houghton Mifflin Company, 1979; 1–405.
12. Grimes DA, Schulz KF. Descriptive studies: what they can and cannot do. *Lancet* 2002; **359**: 145–9.
13. Cox RA, Conquest C, Mallaghan C *et al.* A major outbreak of methicillin-resistant *Staphylococcus aureus* caused by a new phage-type (EMRSA-16). *J Hosp Infect* 1995; **29**: 87–106.
14. Cartmill TD, Panigrahi H, Worsley MA *et al.* Management and control of a large outbreak of diarrhoea due to *Clostridium difficile*. *J Hosp Infect* 1994; **27**: 1–15.
15. Reingold AL. Outbreak investigations - a perspective. *Emerg Infect Dis* 1998; **4**: 21–7.
16. Morton V, Torgerson DJ. Effect of regression to the mean on decision making in health care. *BMJ* 2003; **326**: 1083–4.
17. Fowler S, Webber A, Cooper BS *et al.* Successful use of feedback to improve antibiotic prescribing and reduce *Clostridium difficile* infection: a controlled interrupted times series. *J Antimicrob Chemother* 2007; doi:10.1093/jac/dkm014.
18. Coia JE, Duckworth GJ, Edwards DI *et al.* Guidelines for the control and prevention of methicillin-resistant *Staphylococcus aureus* (MRSA) in healthcare facilities. *J Hosp Infect* 2006; **46** Suppl 1: S1–S44.
19. Bell SM. Recommendations for control of the spread of methicillin-resistant *Staphylococcus aureus* infection based on 18 years' experience in a group of teaching hospitals. *Med J Aust* 1982; **1**: 472–4.
20. Wagner AK, Soumerai SB, Zhang F *et al.* Segmented regression analysis of interrupted time series studies in medication use research. *J Clin Pharm Ther* 2002; **27**: 299–309.
21. MRC Health Services and Public Health Research Board. *A Framework for Development and Evaluation of RCTs for Complex Interventions to Improve Health 2000*. <http://www.mrc.ac.uk/> (16 November 2006, date last accessed).
22. Grimshaw JM, Thomas RE, MacLennan G *et al.* Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess* 2004; **8**: 1–72.
23. Plowman RP, Graves N, Griffin MAS *et al.* The rate and cost of hospital-acquired infections occurring in patients admitted to selected specialties of a district general hospital in England and the national burden imposed. *J Hosp Infect* 2001; **47**: 198–209.
24. Graves N. Economics and preventing hospital-acquired infection. *Emerg Infect Dis* 2004; **10**: 561–5.
25. Ioannidis JP, Evans SJ, Gotzsche PC *et al.* Better reporting of harms in randomised trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; **141**: 781–8.
26. Mayon-White RT, Wiffen P. Audit of antibiotic policies in the South East of England, 2004. *J Antimicrob Chemother* 2005; **56**: 204–7.
27. Altman DG, Moher D. Developing guidelines for reporting health-care research: scientific rationale and procedures. *Med Clin (Barc)* 2005; **125** Suppl 1: 8–13.
28. Moher D, Jones A, Lepage L for the CONSORT group. Use of the CONSORT statement and quality of reports of randomized trials: a comparative before and after evaluation. *JAMA* 2001; **285**: 1992–5.
29. Effective Practice Organisation of Care Group. <http://www.epoc.uottawa.ca/index.htm> (25 May 2006, date last accessed).
30. Cepeda JA, Whitehouse T, Cooper B *et al.* Isolation of patients in single rooms or cohorts to reduce spread of MRSA in intensive-care units: prospective two-centre study. *Lancet* 2005; **365**: 295–304.

Appendix: Guidelines for description of interventions

(i) Isolation policy

The main isolation policy should be described according to intensity of isolation, that is, as 'isolation ward or unit', 'cohorting

Review

with designated nursing staff 'or 'cohorting without designated nursing staff', 'side room isolation', or 'none'. The use or non-use of gowns or aprons, gloves and masks should be specified, as this may be the only isolation policy in some settings.

It should be stated whether the capacity of the main isolation policy was sufficient to isolate all patients requiring isolation and, if not, the overflow policy should be described as above.

It should be stated clearly which patient groups were isolated. In the case of MRSA such groups may include: all MRSA-positive patients; infected patients only; other selected MRSA-positive patients (e.g. those with uncontrollable secretions); contacts of MRSA-positive patients; patients awaiting screening results; inter-hospital transfers; and admissions from nursing homes.

If an isolation ward or unit was used it should be specified whether the unit was used only for patients with particular organisms [such as MRSA, glycopeptide-resistant enterococcus (GRE) or *Clostridium difficile*] or also for other infectious disease, and whether or not it was purpose-built with negative-pressure ventilation. The number of beds should be stated, together with the number of single rooms in the unit.

When cohorting was used, with or without designated nursing staff, it should be stated whether cohorts were on open wards (i.e. in geographically defined but not physically separated sections of a general non-outbreak organism ward), or in open or closed bays.

The number of side rooms potentially available to the study population and whether or not these had negative pressure should also be stated.

(ii) Screening policy

This should specify who was screened; (e.g. all patients, contacts, healthcare workers, elective admissions, inter-hospital or

other transfers, patients with a history of infection or colonization with the organism under investigation, admissions from nursing homes), when (e.g. on admission, on discharge, weekly, once per phase, once per admission) and what sites (e.g. nose, perineum, throat, wounds, sores, ulcers or skin breaks; mid-stream urine or catheter specimen urine) were screened.

(iii) Eradication policy

This should specify whether eradication of colonization was attempted or not, whether it was topical or systemic or both, and which agents were used. The target group should be clearly described (e.g. 'all positive patients', 'all positive staff') and whether or not it was continued after discharge. Clearance of colonization should be clearly defined (e.g. negative swabs for three consecutive weekly tests).

(iv) Other interventions

The presence or absence of antibiotic restrictions, hand-hygiene education, surveillance and feedback of infection or colonization rates and use of ward closures should be stated, even if these are not the main interventions. Where an antibiotic policy has been introduced, the antibiotics targeted for reduced usage, those targeted for increased use and those not targeted for change in use should be specified and data regarding changes in use should be presented, or the absence of such data at least acknowledged. Where a hand-hygiene policy has been introduced, this should be clearly described and data on compliance or consumables usage should be presented, or the absence of such data at least acknowledged. Where education or feedback has been used, the frequency and format should be described.