Appropriate and inappropriate use of publication guidelines for transparent reporting of observational, intervention and outbreak studies

Using the short "ORION" , "CONSORT"and "STROBE" Abstracts for conference and journal abstract submission & review

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On behalf of ORION group

Question 1

1. STROBE is a tool to help the interpretation of randomised controlled trials
2. STROBE does not yet have a www site to support its use
3. STROBE unfortunately does not yet have an abstract tool version

1) All are correct 2) 1 is correct 3) 2 is correct 4) 3 is correct 5) All are wrong

Question 2

1. CONSORT is a tool to help the interpretation of randomised controlled trials
2. CONSORT does have a www site to support its use
3. CONSORT does have an abstract tool version

1) All are correct 2) 1 is correct 3) 2 is correct 4) 3 is correct 5) All are wrong

Question 3

1. ORION is a tool to help the interpretation of randomised controlled trials and observational studies
2. ORION has a www site to support its use
3. ORION has no abstract tool version

1) All are correct 2) 1 is correct 3) 2 is correct 4) 3 is correct 5) All are wrong

ECCMID 2012 & 2013
Guidelines for submission of abstracts

ESCMID strongly support the improvements of reporting of study results. For this reason, all Authors submitting randomised clinical trial (RCT), infection control interventional study, outbreak report of nosocomial infections, and observational study in epidemiology are kindly requested to consult the following abstract checklists (please click on the respective link to download the document) for reporting their research results:

CONSORT (RCT)

STROBE (observational study in epidemiology)

ORION (outbreak report or interventional study)

EQUATOR NETWORK

www.equator-network.org

Too often, good research evidence is undermined by poor quality reporting.

The EQUATOR Network is an international initiative that seeks to improve reliability and value of medical research literature by promoting transparent and accurate reporting of research studies.

Pan American Health Organization

CIHR IRSC

MRC Medical Research Council

CHIEF SCIENTIST OFFICE

NHS National Institute for Health Research

The ORION statement:

Guidelines for transparent reporting of

***O**utbreak **R**eports & **I**ntervention studies **O**f **N**osocomial **I**nfection*

A CONSORT equivalent for Infection Control Studies

Funded by Health Technology Assessement Board

Stone et al Lancet Infect Dis 2007; J Antimicrob Chemother 2007

www.idrn.org/orion.php

Co-authors & Collaborating Institutions

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- GeorgiaDuckworth *Public Health*
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Question 4

Interventions in infection control often:

1. lack details e.g. on interventions & timings
2. do not address issues of confounders/ biases
3. have inadequate numbers of data points
4. fail to account for dependencies of infectious outcomes

1) All are correct 2) 1 is correct 3) 2 is correct 4) 3 is correct 5) only 4 is wrong

Evidence Base for Infection Control Interventions

Davey et al Cochrane 2005;Cooper et al BMJ 2004

- Cochrane review of interventions to change antibiotic prescription & evaluate HCAI outcomes (2005) & HTA (2003) review isolation practices in MRSA show limited evidence of some effect but inadequate reporting & major flaws in design & statistical analysis

- Lack of details eg on interventions & timings
- Failure to assess & adjust for confounders/biases
- Aggregation of outcomes (misses trends)
- Analysis fails to account for dependencies of infectious outcomes

- Quality of infection control research must improve to provide robust evidence for policy & practice

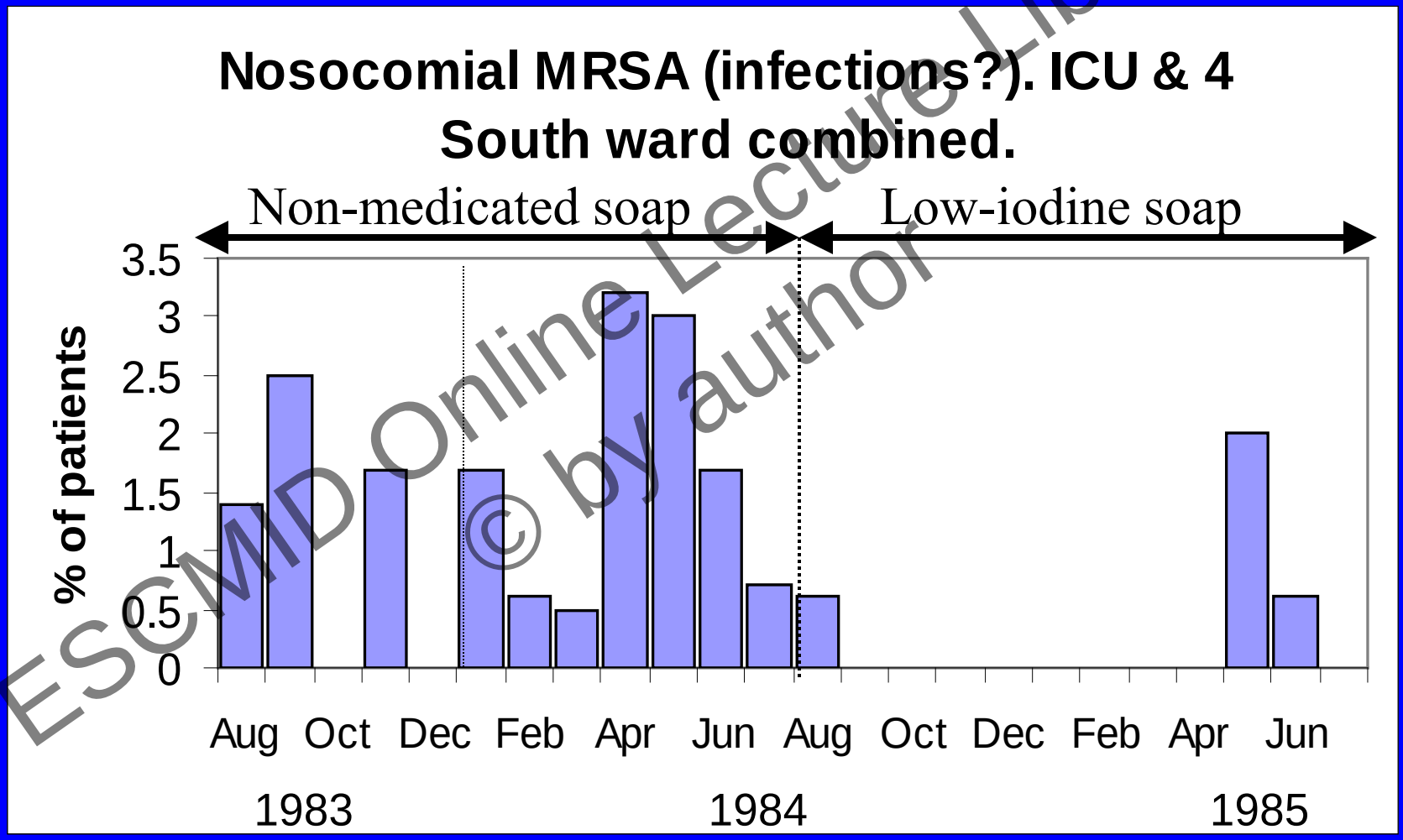
To summarise the problem…..

Cooper B et al BMJ 2004, HTA 20003, Davey et al Cochrane 2005;Ramsay et al JAC 2003

- Studies conclude interventions cause Δ MRSA or antibiotic use or *Clostridium difficile*

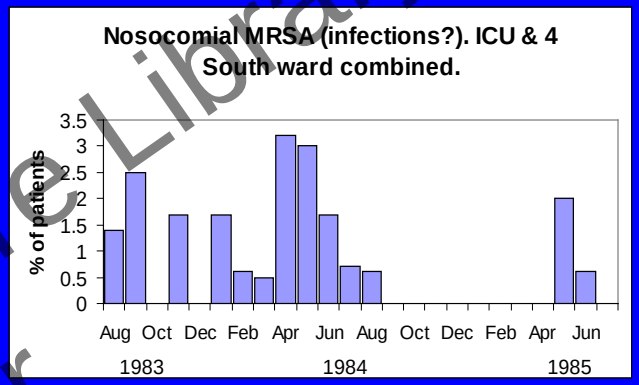
- Validity of conclusions threatened by **confounders & biases**, unaccounted for in studies, which provide plausible alternative explanations of outcome and by **inappropriate statistics** e.g. aggregation of data (misses time trends) & assumption that infection outcomes are independent (Chi-Sq; OR)

The sort of problems: regression to mean, statistical analysis



Onesko KM, Infection Control 1987

Question 5



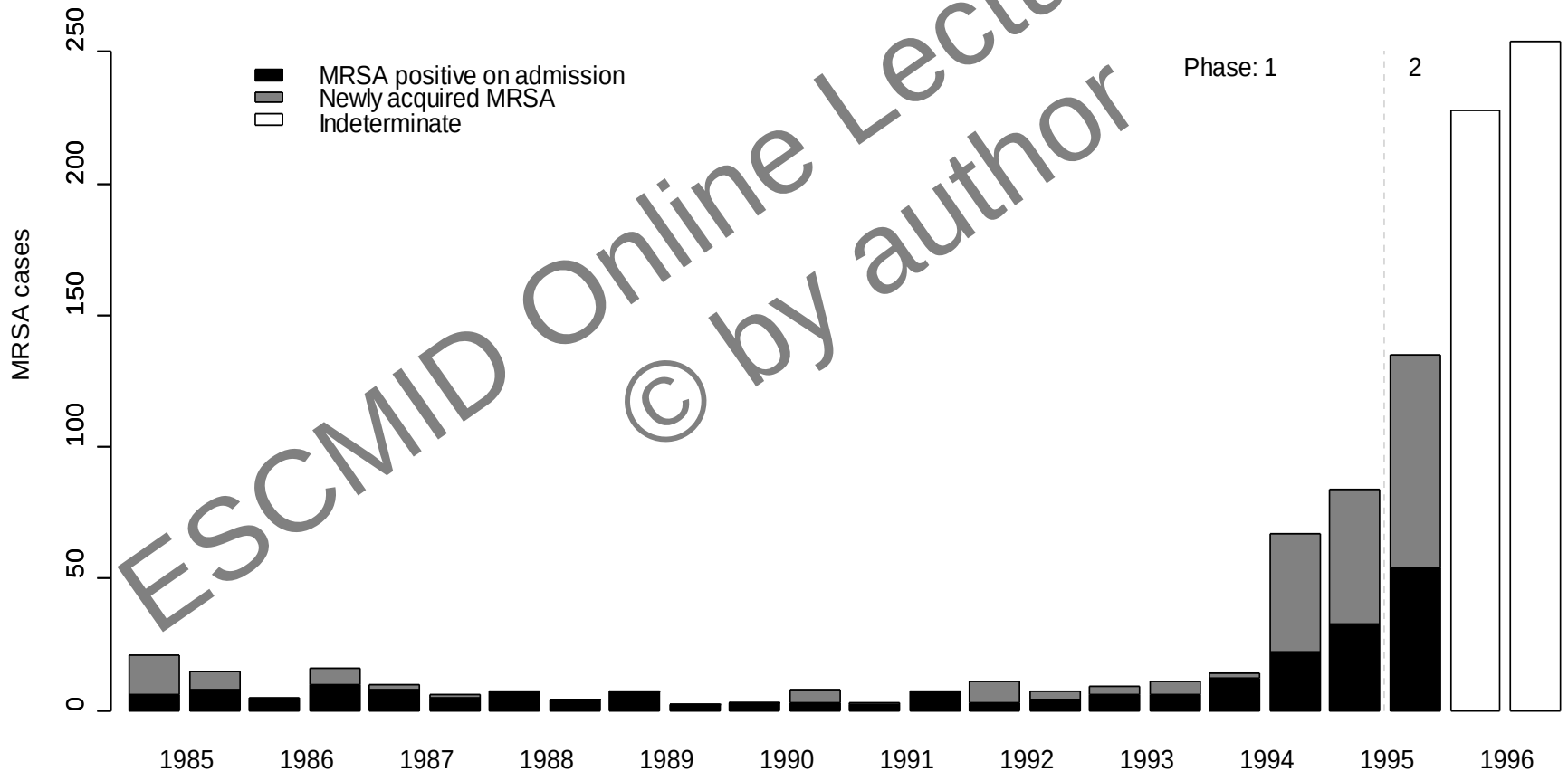
In this Onesko et al study

1. There is convincing evidence that the intervention worked.
2. There are at least two issues with the data
3. There is just one issue with the data

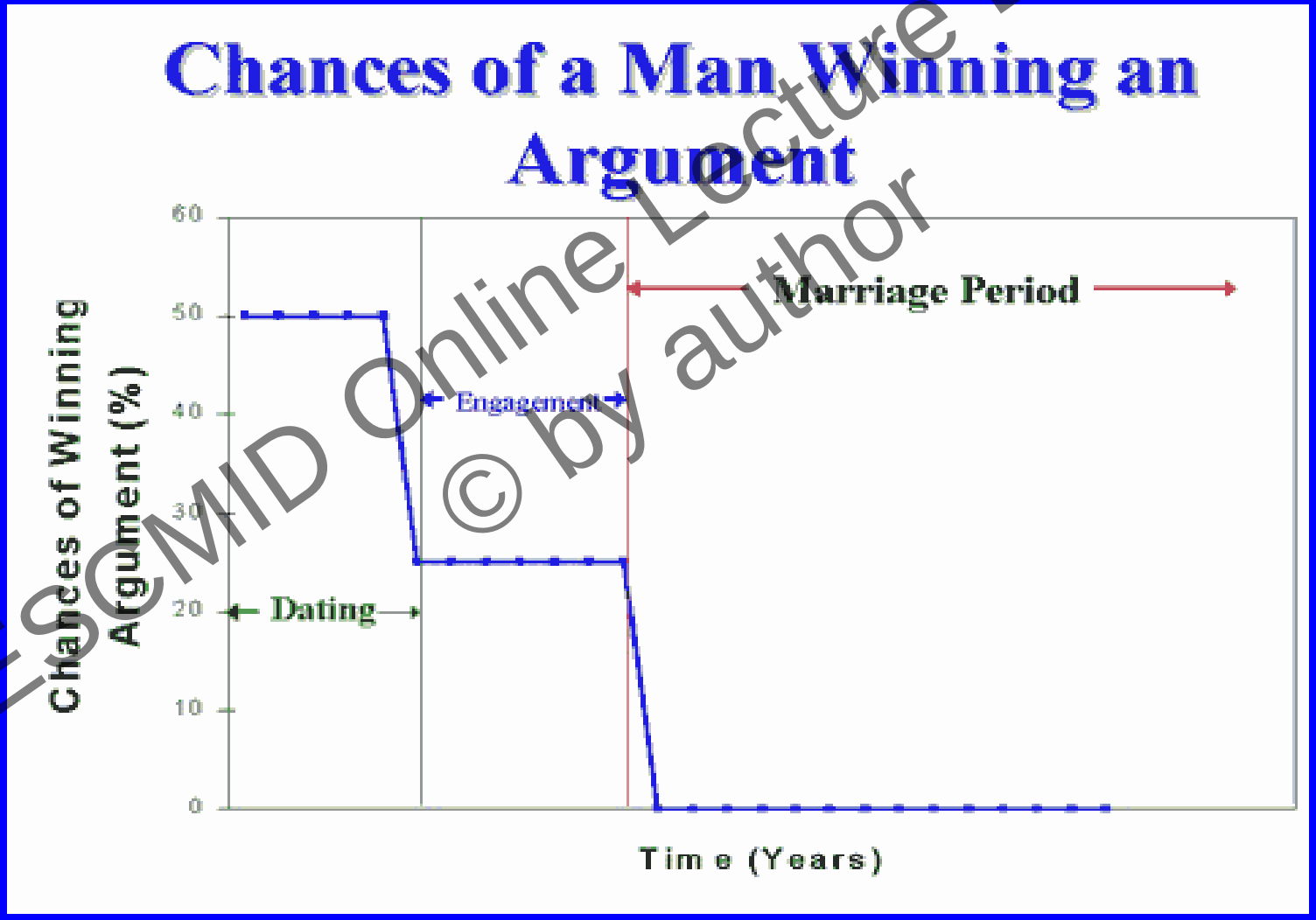
Which is the correct answer?

Confounders; strains, trends

Farrington et al QJM



Interrupted time series



AIM OF ORION Statement

CONSORT equivalent for infection control studies

- Improve standards research & publication
- Transparency of reporting
- Readers relate studies to their situation.
- Facilitate synthesis of evidence
- Framework for reviewers & editors to assess papers
- Criteria research grant assessment panels

- Designed especially for Interrupted Time Series (with or without controls groups) and outbreak reports.

Key issues addressed by ORION

Transparency: Why was the study done? (hypothesis)
What sort of study? (design)
Exactly what was done, to whom, when?

Analysis: Disaggregated data
Account for dependencies
Confounders

Inference: How do findings relate to hypothesis?
What else influenced the findings?
Do findings generalise ?

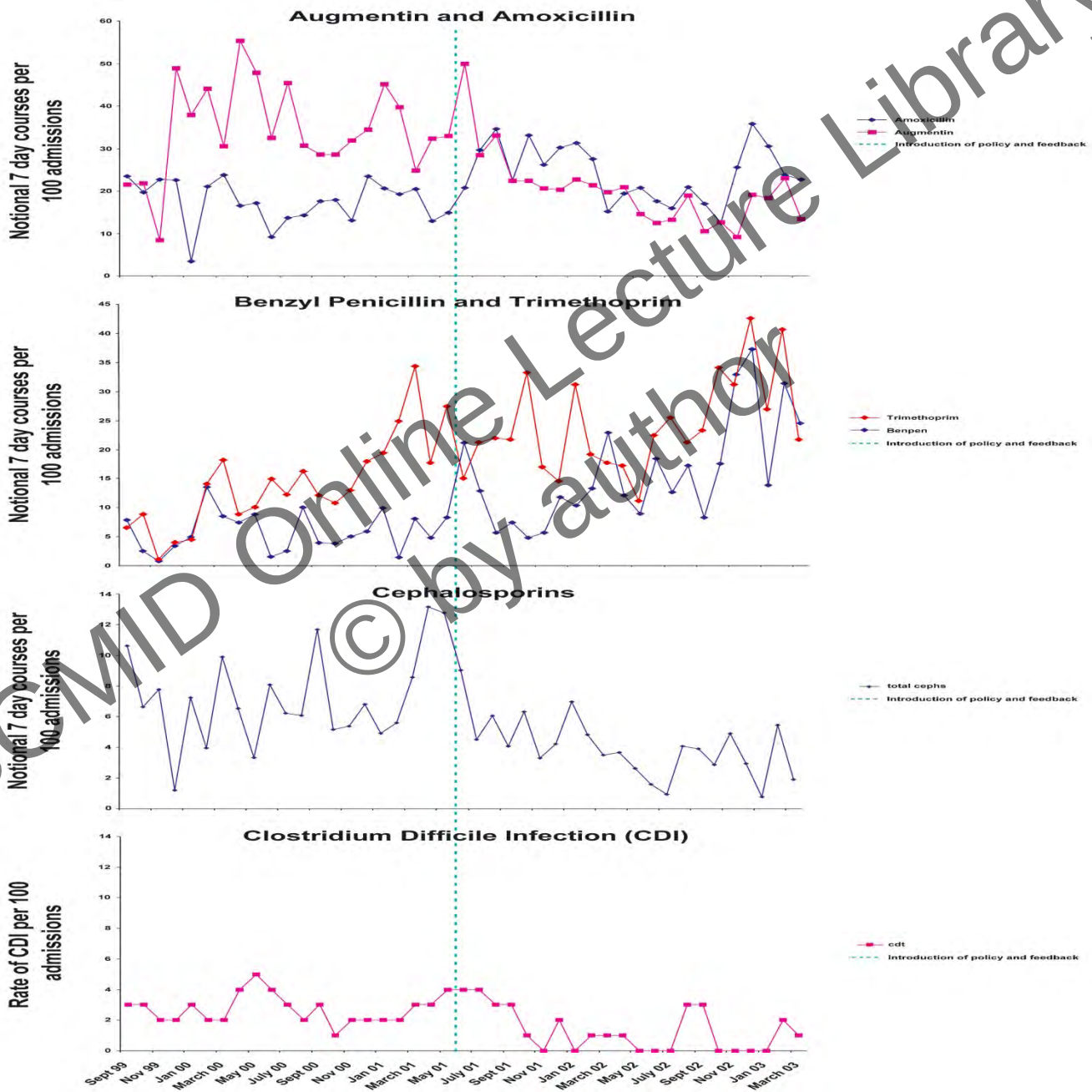
Components of ORION

Stone et al Lancet ID 2007;JAC 2007;www.idrn.org/orion.php

- adapted CONSORT statement to the wide variety settings interventions, designs & statistical issues infection control studies & outbreak reports
- Consultation with professional societies
- Independent academic review in two journals

- 22 item checklist
  - Title
  - Abstract
  - Introduction
  - Methods
  - Results
  - Discussion
- Summary table
  - Population
  - Clinical setting
  - Precise nature & timing of all interventions
- Graphical summary results

ORION exemplar paper…… .*Fowler S et al JAC 2007*



CONSORT journal & conference abstract checklist

Hopewell et al PLOS Med 2008

- CONSORT for ABSTRACTS : for submission & review of conference & journal abstracts of RCTs (same flaws as full articles)
- ORION and then STROBE suit
- STROBE
- Used for SHEA Conference 2011 & ECCMID 2012 & 2013

AIMS ABSTRACT CHECKLISTS

1. Help investigators write a high quality conference/journal abstract

2. Provide referees with a framework to help referee a conference abstract

3. Help HCWs and researchers select the best papers/conference presentations for continuing professional development..

   what article to read?

   what conference oral/poster session to go to?

SUBMISSION & REVIEWER'S ORION ABSTRACT CHECKLIST FOR INTERVENTION STUDIES & OUTBREAK REPORTS (see handouts)

Title	1.Clear statement that this is an intervention study or outbreak report.
Background	2.Rationale for study with clear hypothesis for intervention studies or objective for outbreak reports
Methods-	3.Clear statement of intervention study design[1] or case and outbreak definition for outbreak report.
	4.Brief description of participants, setting and of intervention or outbreak control measures (with start & stop dates)
	5. Clearly defined outcomes & denominators at regular time intervals[2], not as totals for each phase *(can be put in results instead)*
	6. Statistical analysis accounts for any dependencies in the data (can be in results instead) *(analysis may not be appropriate for OR)*

ABSTRACT CHECKLIST (cont)

Methods (cont)	7. Which potential confounders or biases were considered, recorded or adjusted for[3] *(can be in results instead)*
	8. Where relevant: details of culture, typing, environmental sampling, & risk factors for acquisition, root cause analysis or organisational risk assessment.
Results-	9. For main outcomes: estimated effect size & its precision (usually 95% CI) (A graphical summary is often appropriate eg for most time series-conference programme v main figure paper).
Conclusions	10. For intervention studies: consider in relation to original hypothesis, accounting for potential confounders & biases. For outbreak reports: consider clinical significance of observations & hypothesis to explain them.

STROBE (see hand outs)

http://www.strobe-statement.org/

- STrengthening the Reporting of OBservational studies in Epidemiology
- Cohort, Case control (+/-matched) & Cross sectional studies
- Abstract checklist with same aims as CONSORT and ORION abstract checklists

Similarities ORION, CONSORT and STROBE

- Design study clearly stated (title)
- Objective/Hypothesis explicit
- Eligibility criteria/case definition/ascertainment for setting and participants
- Clearly defined primary outcome
- Statistical issues addressed- ----
  -dependencies (ORION)
  --disaggregation data (ORION)
  --confounding (STROBE)
- Estimate size effect & precision

The Feedback Intervention Trial (FIT)—Improving Hand-Hygiene Compliance in UK Healthcare Workers: A Stepped Wedge Cluster Randomised Controlled Trial

*Fuller et al PLoS ONE 2012 (*PLoS ONE 7(10): e41617. doi:10.1371/journal.pone.0041617

- ABSTRACT: **Introduction:** Achieving a sustained improvement in hand-hygiene compliance is the WHO's first global patient safety challenge. There is no RCT evidence showing how to do this. Systematic reviews suggest feedback is most effective and call for long term well designed RCTs, applying behavioural theory to intervention design to optimise effectiveness.

- **Methods:** 3 year stepped wedge cluster RCT of a feedback intervention testing hypothesis that intervention more effective than routine practice in 16 UK Hospitals (16 Intensive Therapy Units [ITU]; 44 Acute Care of the Elderly [ACE] wards) routinely implementing a national cleanyourhands campaign). Intervention-based on Goal & Control theories. Repeating 4 week cycle (20 mins/week) of observation, feedback and personalised action planning, recorded on forms. Computer-generated stepwise entry of all hospitals to intervention. Hospitals aware only of own allocation.

  Primary outcome: direct blinded hand hygiene compliance (%).

Results: All 16 trusts (60 wards) randomised, 33 wards implemented intervention (11 ITU, 22 ACE). Mixed effects regression analysis (all wards) accounting for confounders, temporal trends, ward type and fidelity to intervention (forms/month used).

Intention to Treat Analysis: Estimated odds ratio (OR) for hand hygiene compliance rose post randomisation (1.44; 95% CI 1.18, 1.76;p,0.001) in ITUs but not ACE wards, equivalent to 7–9% absolute increase in compliance.

Per-Protocol Analysis for Implementing Wards: OR for compliance rose for both ACE (1.67 [1.28–2.22]; p,0.001) & ITUs (2.09 [1.55–2.81];p,0.001) equating to absolute increases of 10–13% and 13–18% respectively. Fidelity to intervention closely related to compliance on ITUs (OR 1.12 [1.04, 1.20];p = 0.003 per completed form) but not ACE wards.

Conclusion: Despite difficulties in implementation, intention-to-treat, per-protocol and fidelity to intervention, analyses showed an intervention coupling feedback to personalised action planning produced moderate but significant sustained improvements in hand-hygiene compliance, in wards implementing a national hand-hygiene campaign. Further implementation studies are needed to maximise the intervention's effect in different settings.

Trial Registration: Controlled-Trials.com ISRCTN65246961

Funding: Patient Safety Research Programme (PS/029), Trustees of the Royal Free & GOJO industries (educational grant).

FIT and CONSORT abstract checklist

- Title-
  study identified as RCT
- Trial Design-
  described as stepped wedge cluster

- Methods:
  Participants-
  setting clear ? eligibility criteria
- Interventions-
  described
- Objective-
  clearly stated hypothesis

- Outcome-
  clearly defined primary outcome
- Randomisation-
  computer generated stepwise
- Blinding-
  observers and participants
- Results-
  Numbers randomised-
  all trusts (16)
- Trial status-
  complete?
- Numbers analysed in each group-
  is it clear?

FIT and CONSORT (cont)

- Outcome-
  estimated effect size & precision

- Harms-
  not relevant

- Conclusions-
  General interpretation of results

- Trial Registration-
  Stated
- Funding-
  stated by journal at end of abstract

Thank you and over to Barry for some ORION practice

Comments & suggestions to

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STROBE ABSTRACT CHECKLIST (1)

Title **Authors listed**	Indicate the study's design with a commonly used term in the title (e.g cohort, case-control, cross sectional) : Authors listed and contact no.
Objectives	Specific objectives or hypothesis
Methods: **Setting**	Description of setting, follow-up dates or dates at which the outcome events occurred or at which the outcomes were present, as well as any points or ranges on other time scales for the outcomes (e.g., prevalence at age 18, 1998-2007).
Participants	*Cohort study*—Give the most important eligibility criteria, and the most important sources and methods of selection of participants. Describe briefly the methods of follow-up *Case-control study*—Give the major eligibility criteria, and the major sources and methods of case ascertainment and control selection *Cross-sectional study*—Give the eligibility criteria, and the major sources and methods of selection of participants *Cohort study*—For matched studies, give matching and number of exposed and unexposed*Case-control study*—For matched studies, give matching criteria and the number of controls per case

STROBE ABSTRACT CHECKLIST (2)

Variables	Clearly define primary outcome for this report.
Statistical methods	Describe statistical methods, including those used to control for confounding
Results:	Report Number of participants at the beginning and end of the study
Main results	Report estimates of associations. If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
	Report appropriate measures of variability and uncertainty (e.g., odds ratios with confidence intervals
Conclusions	General interpretation of study results

National One Week Audit of MRSA Admission Screening: current practice, MRSA prevalence and screening yield in 144 English hospital trusts.
Fuller et al

METHODS

Surveys were sent to infection control teams in all 167 English NHS acute hospital trusts for completion between 9 &15th May 2011. Data requested: (1) number of patients admitted & screened that week (2) MRSA screening practice & patient management (3) number of MRSA +ve patients on a given day (4) clinical details & presence of 6 checklist risk factors for MRSA carriage (in all newly identified MRSA +ve and a random sample of 5-10 MRSA –ve patients screened that week).

RESULTS

Response : 144/167 (86.2%) trusts responded. Risk factor information received for 760 new MRSA+ves & 951 MRSA-ves. Proportion patients screened: 61% (emergency admissions), 81% (electives), 47% (day-cases) Proportion of MRSA screens positive on admission: 2.1% (emergencies), 0.9% (elective), 0.7% (day-case). Only half of these were newly identified cases. Number needed to screen to identify one new positive: 102 (emergencies) 180 (elective) 186 (day-case). Screening practice & management: Mean time to MRSA+ve result 2.87 days (sd 1.33). 33% patients discharged before result available, 67% isolated after result known & 80% decolonised.

MRSA prevalence: 3.3% of inpatients had MRSA on audit day, 10% currently treated for MRSA infection. Risk factors: 60.3% of new +ves & 51% of negatives were checklist positive for one or more risk-factor. In an average trust, screening only checklist +ve patients would reduce screens from 858 to 478/week, identifying 82% of positives. Screening only High risk specialties would reduce screens to 94/week,identifying only 10% of +ves.

National One Week Audit of MRSA Admission Screening: current practice, MRSA prevalence and screening yield in 144 English hospital trusts.
Fuller et al

CONCLUSIONS

Uptake of admission screening was low (especially for emergency and day-case admissions) as was the yield of MRSA+ve patients. The use of checklist activated screening would reduce the number of MRSA admission screens by 50% but identify 82% of all +ves. Screening high risk specialties only would reduce screens by c90% but identify only 10% of +ves. Health Economic modelling will use this data to determine the most cost effective screening policy.

NOW Study STROBE

- Title/Authors α
  Prevalence survey :
  "Cohort" in STROBE!
- Objectives: clearly stated α
- Methods: Description of setting, follow-up dates or dates at which the outcome events occurred/ present α
- Setting α
- Participants α
  Data described too
- Dates α
- Variables α
- Statistical methods β
  NA for aims: will be progressed for stratifications.

- Results
- Estimates of associations.
  NA: No CIs provided β
- Relative risk into absolute risk for a meaningful time period
  NA
- Report appropriate measures of variability and uncertainty (e.g., odds ratios with confidence intervals β
- Conclusions : General interpretation of study results α