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Appendix 2

This appendix was part of the submitted manuscript and has been peer reviewed.
It is posted as supplied by the authors.

Appendix to: Scott IA, Wakefield JB. Deciding when quality and safety improvement interventions warrant widespread adoption. *Med J Aust* 2013; 198: 408-410. doi: 10.5694/mja12.10858.

On-line appendix 2. Critical appraisal of studies of quality and safety improvement interventions

A. Examples of biased estimates of QSII effects due to flawed outcome measures

- Non-standardised outcome measures may also generate spurious associations. In a before-after study of medical emergency teams (MET) which reported a 22% decrease in hospital mortality, the definition of 'cardiac arrest' changed from pulseless, clear-cut arrests in the pre-intervention phase to any event that triggered a MET call in the post-intervention phase[3] – a change clearly biasing the study towards a favourable effect of MET on mortality rate.

- Studies dependent on subjective end-points (such as deciding if adverse events are care-related) should employ multiple reviewers and report the level of agreement between them. For example, in a study of medication reconciliation, three clinicians independently reviewed each outcome – unintended discrepancy between discharge and admission prescriptions with potential to cause harm – and found they agreed only 26% more often than would have been expected by chance.[22]

B. Observational study designs which help to minimise bias

- Prospective data gathering which avoids recall or hindsight bias.
- Random, consecutive or purposive sampling of target populations, as opposed to convenience samples, which minimises selection bias.
- Analytic methods which minimise confounding bias:
    - regression-based adjustment to control for variation between intervention and control periods in patient baseline risk of adverse outcomes (risk-adjustment methods), or likelihood of receiving particular types of care according to clinician preference (propensity scores)
    - risk-adjusted statistical process control methods for assessing QSII effects on rare events.
- Analyses of all populations in whom the QSII was implemented, including those where it was less than fully implemented as planned.
- Data collection and analyses performed independently by investigators not directly involved in the 'hands-on' implementation of the intervention