Cutting edge methodology

media thickness (CIMT) as primary endpoint subsequently analysed with linear mixed effects (LME) models.

Methods Analyses were based on a subset of 300 participants from the METEOR (Measuring Effects on Intima-Media Thickness: an Evaluation of Rosuvastatin) trial. CIMT measurements were performed at 12 carotid sites over seven examinations. The "true" difference in rate of change in CIMT between rosuvastatin and placebo was derived from a completed dataset. Scenarios with missing values were defined, both MCAR (Missing Completely At Random) and MAR (Missing at Random), with 10 to 60% missing values, related to, among others, age and treatment allocation. LME analyses were performed with and without preceding MI. The added value of MI was assessed by comparing the LME estimates with the true value in terms of bias and precision.

Results Bias in point estimates for LME analysis with and without preceding MI was similar in scenarios with \leq 40% missings. With 60% missing values, LME without MI was superior to LME with MI. Coverage of the 95% CIs was similar for LME with and without MI for all scenarios.

Conclusion Applying MI prior to LME analyses on longitudinal CIMT measurements does not increase precision or reduce bias in the estimated differences in rates of change in CIMT. Hence, MI has no added value in this context, and direct application of LME remains the preferred method in trials using CIMT as primary endpoint.

03-1.5

USING DATA LINKAGE TO EXPLORE USE OF GP SERVICES BY SMOKERS

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Introduction It is understood how confounding of mediator-outcome associations resulting in collider biases may cause error when estimating direct and indirect effects. Here we assess the impact of non-differential and independent measurement error of the exposure and mediator.

Methods We used as a motivating example the association of childhood socioeconomic position (exposure) with adult psychological distress (outcome), and possible mediation by adult socioeconomic position (mediator). We use quantitative bias analysis methods to quantify the impact of misclassification of exposure and mediator on three target parameters: the total effect of exposure on outcome; the direct effect (by conditioning on the mediator); and the indirect effect (identified by the percentage reduction in the excess OR upon adjusting for the mediator).

Results ORs before and after adjustment for mediators are both biased to the null by non-differential misclassification of the expo-

sure, but the percentage reduction in the excess OR is not affected by measurement error of the exposure. Conversely, measurement error of the mediator rapidly biases the percentage reduction the excess OR downwards.

Conclusions If the research objective is to quantify the proportion of the total association that is due to mediation (ie, indirect effect), then minimising (or adjusting for) non-differential misclassification bias of the mediator is much more important than that for the exposure (or outcome). Considering the relative importance of collider bias and measurement error when estimating direct and indirect effects, measurement error (of mediators in particular) will often be a (much) greater source of systematic error.

03-1.6

SYSTEMATIC REVIEW OF RECORD LINKAGE STUDIES OF MORTALITY IN EX-PRISONERS: WHY GOOD METHODS MATTER

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Introduction Worldwide more than 30 million people move through prisons each year. Record linkage studies have identified a markedly increased risk of death in ex-prisoners. In order to inform preventive interventions it is first necessary to understand who is most at risk, when and why. Unfortunately, limitations of existing studies have rendered synthesis and interpretation of this literature problematic.

Methods Systematic review of studies using record linkage to explore mortality in ex-prisoners. Based on analysis of >20 studies, we illustrate how methodological limitations and heterogeneity of design, analysis and reporting both hamper data synthesis and create potential for misinterpretation of findings. Using data from a recent Australian study involving 42015 ex-prisoners and 2329 observed deaths, we quantify the variation in findings associated with various approaches.

Results For example, given the very different age distributions of prisoners and the general population, the all-cause SMR among the cohort was 1.4 (95% CI 1.4 to 1.5) using direct methods and 3.1 (95% CI 3.0 to 3.2) using indirect methods. When the period of observation was constrained to 12 months from any release, the indirect SMR increased to 5.3 (95% CI 4.9 to 5.7). Similarly, when analyses were based on the first occasion of release during the period of observation the CMR was 9.3 (95% CI 8.4 to 10.3) per 1000 py, whereas based on the most recent release the CMR rose to 16.9 (95% CI 15.6 to 18.2) per 1000 py.

Conclusion We conclude with a series of recommendations for future studies, and provide a checklist for optimising study design, analysis and reporting.