

BLOOD MANAGEMENT IN CARDIAC SURGERY: WHERE ARE WE AT?

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Background. Evidence-based recommendations for specific blood management practices in cardiac surgery are based on evidence hierarchies. However it is increasingly evident that much research evidence is either hidden or distorted. Systematic reviews are not sufficiently nimble to keep up with evolving practice, and will be misleading if based on biased or incomplete data. I estimated the extent of evidence distortion and disappearance for research pertinent to cardiac surgery and blood management.

Methods: I extracted information on patient populations, outcomes, and trial design for relevant completed clinical trials registered between 2007 and 2017 in five registries (e.g. *ClinicalTrials.gov*, EUCTR, WHO-ICTRP), and corresponding PubMed entries. Quality was assessed by trial type (interventional, observational), trial size and duration, and use of bias minimisation methods (randomisation, blinding). Distortion risk was assessed by retrospective trial registration, failure to post study results, and outcome 'switching' between registry entries and publications. Data were summarised by descriptive summary statistics.

Results: Preliminary results from 250 trials suggest that more than 50% of trials were registered after completion, < 15 % studies posted study results to the registry site (compared to overall compliance of ~30-50%) or the primary literature (35%), < 10% reported blood use or transfusion management as a primary outcome, and outcome switching occurred in 15% of publications. Over 75% failed to report results 3 to 10 y after trial completion.

Conclusions. When investigators are not compliant with best-practice guidelines for research reporting and data go missing in action, evidence extraction and assessment procedures are unable to produce high-quality, timely, actionable, and reliable support for fully integrated evidence-based PBM programmes.