Standards for reporting clinical trials: The CONSORT statement for clinical trials in livestock. Application to food safety.

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Recently reviews of interventions studies in pre-harvest food safety have identified issues with lack of reporting of key methodological quality features and items necessary for interpretation and replication of trial findings. In human medicine, similar issues with the reporting of clinical trials were identified 10-15 years ago. This led to the publication of the CONsolidated Standards Of Reporting Trials (CONSORT) statement, which consists of a 22-item checklist of items that should be reported when publishing a clinical trial, a flow diagram to describe participant movement at all stages of a trial, and an explanation and elaboration document (1, 2). The CONSORT statement is endorsed by hundreds of medical journals and has resulted in improvements in trial reporting. Food safety intervention trials incorporate issues not covered by CONSORT, including the distinction between animal owners and study subjects, the frequent allocation of treatments to groups, the conduct in both research and commercial settings, and the use of challenge models. The process for extending the CONSORT statement to other applications is well documented. The steps include a survey to solicit expert opinion on modifications, a consensus meeting to discuss proposed modifications, followed by a draft publication containing modifications and changes proposed at the consensus meeting, a comment period for consensus meeting members and finally publication of the modified statement and accompanying explanation and elaboration document. In the presentation we will present the modified CONSORT statement for intervention studies in livestock species and its application to food safety.