Establishing Guidelines for Reporting Clinical Trials: An Extension of the CONSORT Statement for Trials Involving Livestock with Production, Health, and Food Safety Outcomes

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Introduction

Recently, several reviews of clinical trials in preharvest food safety and production animal medicine 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 checklist of 22 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. The CONSORT statement is endorsed by hundreds of medical journals and has resulted in improvements in trial reporting. Livestock clinical 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 common use of deliberate disease challenge models.

Materials and Methods

A consensus meeting was organized to develop an extension of the CONSORT statement that addressed randomized trials in livestock species with production, health, and food safety outcomes. To prepare for the meeting, a web-based survey was conducted to identify specific issues for discussion.

Results

Twenty-four experts attended the meeting. The experts were biostatisticians, epidemiologists, food safety researchers, and livestock production specialists. Many participants had expertise in multiple disciplines. Among the group, seven were journal editors or assistant/associate editors. To meet the needs of a CONSORT statement for trials in livestock species with production, health, and food safety, the consensus was that 13 items on the CONSORT checklist needed some modification as well as the inclusion of one additional item: item 1 (title and abstract), item 3 (participants), item 4 (interventions), item 5 (objectives), item 7 (sample size), item 8 (randomization sequence allocation), item 9 (allocation concealment), item 10 (randomization implementation), item 11 (blinding/masking), item 12 (statistical methods), item 13 (participant flow), item 15 (recruitment), and item 20 (interpretation). The additional item proposed was a new sub-item for item 4 (challenge trials). The consensus group also proposed terminology to describe study subjects to make the language more consistent with common usage in livestock production.

Significance

The development of a modified CONSORT statement for clinical trials in livestock species is underway, with expected implementation in late 2009. This presentation will outline the process and progress, and present the livestock CONSORT statement. The aim of the project is to improve the quality of information reported about intervention efficacy and enable veterinarians to make better clinical decisions.

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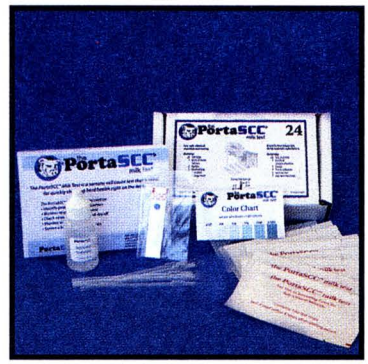

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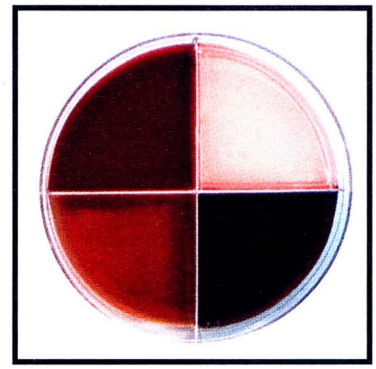

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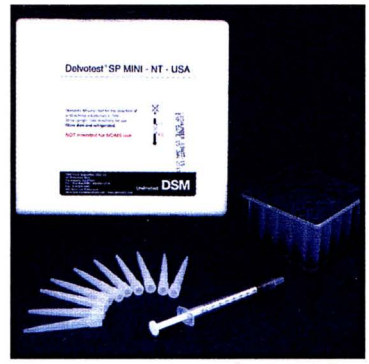

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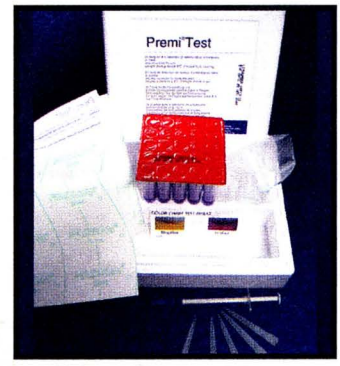

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