

FINAL REPORT:“ A Workshop to Develop Reporting Guidelines for Interventions Studies in Food Safety and Production Animal Science: Modifying the CONSORT Statement.

The objective of this project was to modify the CONSORT (Consolidated Standards of Reporting Trials) statement to reflect the unique aspects of reporting livestock trials with health, production or food safety outcomes. A two-day consensus meeting was held on November 18-19, 2008 in Chicago, Ill, United States of America, to achieve the objective. Prior to the meeting, a Web-based survey was conducted to identify issues for discussion. The 24 attendees were biostatisticians, epidemiologists, food-safety researchers, livestock production specialists, journal editors, assistant editors, and associate editors. Prior to the meeting, the attendees completed a Web-based survey indicating which CONSORT statement items may need to be modified to address unique issues for livestock trials. The consensus meeting resulted in the production of the REFLECT (Reporting Guidelines for Randomized Control Trials) statement for livestock and food safety (LFS) and 22-item checklist. Fourteen items were modified from the CONSORT checklist, and an additional sub-item was proposed to address challenge trials. The REFLECT statement proposes new terminology, more consistent with common usage in livestock production, to describe study subjects. Evidence was not always available to support modification to or inclusion of an item. The use of the REFLECT statement, which addresses issues unique to livestock trials, should improve the quality of reporting and design for trials reporting production, health, and food-safety outcomes.

Deliverables:

We have published the REFLECT statement : Reporting Guidelines for Randomized Controlled Trials in Livestock and Food Safety. The publication was accepted by 5 journals (Preventive Veterinary Medicine, Journal of Veterinary Internal Medicine, Journal of Food Protection, Zoonoses and Public Health and Journal of Swine Health and Production) and the accompanying Explanation and Elaboration document was published in 2 journals (Journal of Food Protection, Zoonoses and Public Health).

We retained copyright of the REFLECT statement and they REFLECT statement is available on line at www.reflect-statement.org. Translations of the checklist on the website include Spanish and French.

We would like to encourage that AMIF request that authors format the final report of randomized controlled trials using the approach described in the REFLECT statement as this will standardize the approach to reporting and increase the value of reports received.

We are pleased that within 3 months of publication of the REFLECT statement we currently have 8 journals that endorse using REFLECT are

1. Australian Veterinary Journal
2. Journal of the American Veterinary Medical Association

3. American Journal Veterinary Research
4. Journal of Food Protection
5. Journal of Veterinary Internal Medicine
6. Journal of Swine Health and Production
7. Preventive Veterinary Medicine
8. Zoonoses and Public Health

Next Steps:

The next step in the process is to contact journals and funding bodies for endorsement of the REFLECT statement. Endorsement means that journals or funding bodies strongly recommend that their authors use the REFLECT statement in the preparation of publications or reports. We have already begun the process of contacting several journals about endorsement. We have also been in direct contact with Vaccine, The Veterinary Record, and Meat Science, and Food-borne Pathogens and Disease and are continuing those discussions.

My collaborator (Jan Sargeant) and I have been invited to present the REFLECT statement at the annual meeting of Veterinary Journal Editors. At that meeting we expect to increase the number of journals that recommend using REFLECT to report RCTs.

Publications

1. **O'Connor, A.M.**, Sargeant, J.M., Gardner, I.A., Dickson, J.S., Torrence, M.E., Dewey, C.E., Dohoo, I.R., Evans, R.B., Gray, J.T., Greiner, M., Keefe, G., Lefebvre, S.L., Morley, P.S., Ramirez, A., Sisco, W., Smith, D.R., Snedeker, K., Sofos, J.N., Ward, M.P., Wills, R. 2010. The REFLECT Statement: Methods and Processes of Creating Reporting Guidelines for Randomized Controlled Trials for Livestock and Food Safety. *J Food Prot.* 73(1):132-139.
2. **O'Connor, A.M.**, Sargeant, J.M., Gardner, I.A., Dickson, J.S., Torrence, M.E., Dewey, C.E., Dohoo, I.R., Evans, R.B., Gray, J.T., Greiner, M., Keefe, G., Lefebvre, S.L., Morley, P.S., Ramirez, A., Sisco, W., Smith, D.R., Snedeker, K., Sofos, J.N., Ward, M.P., Wills, R. 2010. The REFLECT Statement: Methods and Processes of Creating Reporting Guidelines for Randomized Controlled Trials for Livestock and Food Safety. *J Vet Intern Med.* 24(1):57-64
3. **O'Connor, A.M.**, Sargeant, J.M., Gardner, I.A., Dickson, J.S., Torrence, M.E., Dewey, C.E., Dohoo, I.R., Evans, R.B., Gray, J.T., Greiner, M., Keefe, G., Lefebvre, S.L., Morley, P.S., Ramirez, A., Sisco, W., Smith, D.R., Snedeker, K., Sofos, J.N., Ward, M.P., Wills, R. 2010. The REFLECT Statement: Methods and Processes of Creating Reporting Guidelines for Randomized Controlled Trials for Livestock and Food Safety. *Prev Vet Med.* 93(1):11-18. [Link to PDF](#)
4. **O'Connor, A.M.**, Sargeant, J.M., Gardner, I.A., Dickson, J.S., Torrence, M.E., Dewey, C.E., Dohoo, I.R., Evans, R.B., Gray, J.T., Greiner, M., Keefe, G., Lefebvre, S.L., Morley, P.S., Ramirez, A., Sisco, W., Smith, D.R., Snedeker, K., Sofos, J.N., Ward, M.P., Wills, R. 2010. The REFLECT Statement: Methods and Processes

- of Creating Reporting Guidelines for Randomized Controlled Trials for Livestock and Food Safety. *J Swine Health Prod.* 18(1):18–26. [Link to PDF](#)
5. **O'Connor, A.M.**, Sargeant, J.M., Gardner, I.A., Dickson, J.S., Torrence, M.E., Dewey, C.E., Dohoo, I.R., Evans, R.B., Gray, J.T., Greiner, M., Keefe, G., Lefebvre, S.L., Morley, P.S., Ramirez, A., Sisco, W., Smith, D.R., Snedeker, K., Sofos, J.N., Ward, M.P., Wills, R. 2010. The REFLECT Statement: Methods and Processes of Creating Reporting Guidelines for Randomized Controlled Trials for Livestock and Food Safety. *Zoonoses and Public Health* Jan 12 E Pub
 6. Sargeant, J. M., **O'Connor, A. M.**, Gardner, I A., Dickson, J. S., Torrence, M. E. 2010. The REFLECT Statement: Reporting Guidelines for Randomized Controlled Trials in Livestock and Food Safety: Explanation and Elaboration. *Zoonoses Public Health.* Jan 12 Epub.
 7. Sargeant, J. M., **O'Connor, A. M.**, Gardner, I A., Dickson, J. S., Torrence, M. E. 2010. The REFLECT Statement: Reporting Guidelines for Randomized Controlled Trials in Livestock and Food Safety: Explanation and Elaboration. *J Food Prot.* 73(3):579-603.

Presentations:

1. **O'Connor, A.M.** 2009. Modifying the CONSORT statement for livestock intervention trials. College of science week scientific meeting. Gold coast, Queensland, July 1-3.
2. **O'Connor A.M.**, Sargeant, J., Gardner, I., Dickson, J., Bennett, P., Torrence, M.E. 2009. Standards for reporting clinical trials: The REFLECT statement for clinical trials in veterinary medicine. 12th International symposium on veterinary epidemiology and economics, Durban, South Africa, August 10-14.
3. **O'Connor, A.M.** 2009. Establishing Guidelines for Reporting Clinical Trials: An Extension of the CONSORT Statement for Trials Involving Livestock with Production, Health, and Food Safety Outcomes. American Association for Bovine Practitioners, Omaha Convention Omaha, NE, Sept 8-12.
4. **O'Connor, A.M.** 2009. Standards for reporting clinical trials: The CONSORT statement for clinical trials in livestock. Application to food safety. Annual Meeting of the American College of Epidemiology, Washington D.C.-Silver Spring, September 12-15.
5. O'Connor A.M., Sargeant J.M., Gardner I., Dickson J., Torrence, M.E. 2009. Standards for reporting clinical trials: The CONSORT statement for clinical trials in livestock. Application to food safety. Safe Pork Symposium, Québec City, Canada Safe Pork Symposium, Québec City, Quebec, Canada.