Understanding adverse perinatal outcome: sequential analytical models for the 21st century.

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Perinatal morbidity occurs infrequently in modern obstetric practice. Research projects planned on the basis of these infrequent outcomes therefore require large sample sizes to achieve adequate power. In addition, high quality prospective research is very resource-intensive. Planning to study a fixed number of subjects can result in failure to complete the research project if recruitment is slower than expected and vital personnel are available only on fixed contracts.

Sequential analysis optimizes the information content of results as they are obtained, sometimes allowing a project to terminate earlier than would have occurred with the equivalent fixed sample size. This may occur due to a larger than expected effect size resulting in earlier than expected achievement of statistical significance; or due to an inadequate effect size making it impossible to reach statistical significance within a reasonable time-frame.

The triangular test is an advanced format for sequential analysis, providing a single model for continuous, ordinal, preference or even survival data, which eliminates the need for 1:1 matching of pairs of subjects, allowing analysis of unequal sized trial and control groups.

Examples of the use of these tests compared to conventional sequential formats for continuous or preferential data will be demonstrated, as well as some new examples using ordinal and survival data.