

*Statistical analysis of recurrent failure time data: Assessing vaccine efficacy for the prevention of acute otitis media by pneumococcal vaccination in children*

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Acute otitis media (AOM) is the most common bacterial infectious disease among children and *Streptococcus pneumoniae* is the most frequent pathogen of AOM in young children. Long term sequelae, antibiotic resistance of pneumococcal strains and health economic considerations are reasons for the need of effective vaccines. Numerous trials evaluating pneumococcal vaccine efficacy have been performed. The statistical methods for assessing and analyzing vaccine efficacy varies among trials. We will describe and assess those techniques applied in randomized controlled clinical trials included in a recent Cochrane Review. Particularly in early studies, when experience with analyzing vaccine efficacy was limited, the applied statistical method was either inefficient or even inappropriate. In recent years, most trials were evaluated by a generalization of the Cox proportional hazard method (Andersen-Gill). We compare this approach with poisson and negative binomial regression. The comparison is based on simulated data and is exemplified on a phase III vaccination trial.