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Colonisation endpoints in vaccine trials – design questions for *Streptococcus pneumoniae*

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There is growing interest in use of nasopharyngeal colonisation as an alternative to common (disease) endpoints in vaccine trials. There are several benefits and potential drawbacks in this choice. On one hand, because of the specific measurement and larger numbers of cases, the sample size may be much smaller with colonisation endpoints. On the other hand, while being a prerequisite of disease, colonisation typically does not lead to any of the clinical outcomes against which the vaccine is considered. In this talk, I will approach the question of colonisation endpoints from the statistical and epidemiological viewpoints in the context of vaccine trials for *Streptococcus pneumoniae*. I will review current knowledge of the direct biological protective effect of pneumococcal vaccination in an individual, define VE-col (vaccine efficacy against colonisation) for all vaccine serotypes as well as for specific serotypes, and propose new feasible designs for estimation of VE-col. Special emphasis is given to interpretation of VE-col estimates and reduction of bias in their estimation in face a number of interacting serotypes. While herd immunity and other indirect effects of pneumococcal vaccination may ultimately determine the success of a vaccination programme and, indeed, colonisation endpoints in vaccine trials may help to improve projections about the success of vaccination, the indirect effects may distort measurement of the direct protection afforded by the vaccine. In the final part of the talk I will discuss potential means to control for indirect effects in individually randomised trials.