University of York
Department of Health Sciences
Applied Biostatistics
Exercise: Significance tests

Question 1

In a double-blind, randomized controlled trial, children with mild croup were allocated to receive a single dose of an oral steroid (dexamethasone) or placebo (Geelhoed *et al.*, 1996). The results were reported as follows:

Outcome measures for children with mild croup treated with steroid or placebo. Except where stated otherwise, values are means (standard deviation)

	Steroid	Placebo	Significance
Number followed up	48	48	
Number who re-attended with croup	0	8	P<0.01
Number admitted with croup	0	1	NS
Number who re-attended for other reasons	18	18	NS
Duration of croup symptoms (days)	1.7 (1.8)	2 (1.6)	NS
Duration of viral symptoms (days)	6.5 (4.4)	6.7 (4.2)	NS
NS = Not significant			

(a) What is meant by 'P<0.01'?

(b) How could 'NS' be more usefully reported?

(c) How could 'P<0.01' be more usefully reported?

(d) What feature of this analysis makes the P values difficult to interpret.?

Question 2

A clinical trial was carried out to compare two prescribing strategies for childhood acute otitis media (glue ear): immediate antibiotics or delayed antibiotics (antibiotic prescription to be collected at parents' discretion after 72 hours if child still not improving). 315 children aged between 6 months and 10 years presenting with acute otitis media were allocated to one or other strategy. The outcome measures were time until symptoms ceased, absence from school or nursery, and paracetamol consumption. Parents were asked to keep diaries of the child's symptoms and return to normal activities (Little *et al.*, 2001).

Children prescribed antibiotics immediately had shorter mean length of illness (1.1 days, P<0.01), fewer nights disturbed (0.72, P<0.01), and slightly less paracetamol consumption (0.52 spoons/day, P<0.01). The number of school days missed was mean (range) 1.97 (0-8) in the immediate group and 2.15 (0-13) in the delayed group, P=0.56. Parents of 36/150 of the children given delayed prescriptions used antibiotics, and 77% were very satisfied. Fewer children in the delayed group had diarrhoea (14/150 (9%) v 25/135 (19%), P=0.02).

(a) For the number of days off school, which term best describes the shape of the distribution which is suggested by the data given?

(b) Which term best describes the strength of evidence that the delayed antibiotics increases the mean length of the illness?

(c) Which term best describes the strength of evidence that the delayed antibiotics increases the time off school?

(d) Which term best describes the strength of evidence that the delayed antibiotics decreases the risk of diarrhoea?

References

Geelhoed GC, Turner J, Macdonald WBG. (1996) Efficacy of a small single dose of oral dexamethasone for outpatient croup: a double blind placebo controlled clinical trial. *British Medical Journal* **313**, 140-142.

Little P, Gould C, Williamson I, Moore M, Warner G, Dunleavey J. (2001) Pragmatic randomised controlled trial of two prescribing strategies for childhood acute otitis media. *British Medical Journal* **322**, 336-342.

Questions taken from Martin Bland and Janet Peacock: *Statistical Questions in Evidence-based Medicine*, Oxford University Press, Oxford, 2000.