# MEDICAL STATISTICS MATH38072

# Course Work Assignment

**Deadline:** Monday 30th November 16:00

**Hand in point:** Undergraduate Reception, Turing Building.

**Penalty for late submission:** If this coursework is handed in late, 20% of the marks awarded to the student for the coursework will be deducted for each weekday it is late. Thus work submitted more than four days late will get no marks. If the *Mitigating Circumstances Panel* determines that mitigating circumstances are acceptable, the deducted marks will be restored.

**Format:** Your submission may be either hand written or word processed.

**Please note that by making a submission you are declaring the work to be all your own.**

Read through the attached clinical trial report “Does a single application of topical chloramphenicol to high risk sutured wounds reduce incidence of wound infection after minor surgery? Prospective randomised placebo controlled double blind trial” by Clare F Heal, Petra G Buettner, Robert Cruickshank, David Graham, Sheldon Browning, Jayne Pendergast, Herwig Drobetz, Robert Gluer, Carl Lisec.

The article can be found at **<http://www.bmj.com/content/bmj/338/bmj.a2812>**.

Please note that there are other versions of this paper on the BMJ web site and there are also reader’s responses to the article.

This paper uses the term *relative risk*. In this context *relative risk* equals the *rate ratio* as defined in the course notes.

Answer **ALL** Five questions.

1. Commenting on the low rate of infection the authors suggest that a much larger study would be needed had the infection rate been lower. Assuming an infection rate of 5% for the placebo, determine the *total number of patients* that would need to be randomised to have 80% power to detect a rate ratio (RR) for *placebo* compared *chloramphenicol* treatment equal to 2, using a two-side 5% significance level z-test of proportions assuming that 5% of patients may not return for their follow-up assessment. [3 marks]
2. The authors state “Large differences existed between the intervention and the control groups at baseline (table 2). In the intervention group, 71.7% of patients were diagnosed with non-melanoma skin cancer or solar keratosis compared with 65.1% in the control group.” Briefly explain how the design of the trial could have been improved to prevent imbalance for a prognostic factor such as that referred to here. [2 marks]
3. Using the delta method (see notes) derive a formula for the standard error of the log of the Rate Ratio (RR), that is loge[RR]. [5 marks]
4. Table 3 of the paper summarize the results for the outcome measure “*erythema >1 cm*”. Using the result from Q4 and data from table 3, determine a 95% confidence interval of the rate ratio of *chloramphenicol* treatment compared to *placebo* for the outcome measure “*erythema >1 cm*”.
5. Briefly comment on the results of the analysis in (i) [3 marks]
6. By considering (a) the objective of the trial and (b) the different types of bias that may occur in clinical trials, in your own words discuss the strengths and weaknesses of this trial. (Suggested length about 250 words). [7 marks]

[Total 20 marks]

[End of Assessment]