Summary of discussions

1. Factorial designs: Buy-one-get-one-free or a mirage?

The group discussed a range of issues relating to factorial design the main conclusions were that they are not nearly as common in practice as text books would have you believe and probably not as useful.

Problems arise in the independence of the interventions when there is a ceiling effect (i.e. when (or both) one intervention work particularly well, as any potential effect of the other intervention become invisible'.

The group did decide though that the design may be useful in some situations where the interventions would be considered biologically independent.

2. Adaptive designs

The group discussed how only one trial using an adaptive design had been published to date, although there were several published protocols, suggesting that more studies were underway.

A major drawback that was highlighted was the complexity of presenting this design to a funder; hence they were more common in industry, where the funder and the researcher were often one and the same. A particular example of a study type where they would be useful is thought to be assessing the correct dose of a drug.

Another issue related to funding was the choice of the number of arms in the study: how many should be pursued and how is that decision made. The way in which this is carried out, and the resulting number of arms has a potentially large impact on costs. Linked to this is the issue of the volume of up-front work required to conduct such a study properly.

3. Stepped-wedge designs: Are they worth it?

The group had divided opinions on the value of stepped-wedge designs. The reason behind this disagreement seemed largely to stem from the different types of studies that they had experience of conducting.

It was greed that, as with many cluster trials where the recruiting HCP is aware of whether or not they are in the intervention arm, there may be bias in recruiting patient between the before and after intervention periods. However, this was only deemed to be a disadvantage if the person recruiting the patient was the same person treating them.

The question was raised as to whether a stepped-wedge trial could become unethical if it became obvious part way through that the intervention was either considerably better or worse than the control. This would also depend on the time scales of the study, with longer studies being more prone to this problem.

There was also the issue, especially with long follow-up periods of contamination if a control patient were to re-consult whilst still in follow-up, but after their practice had been randomised. This may affect the decision as to how soon each practice can be ‘stepped-up’ to the intervention.

The over-riding feeling with respect to all designs was that the choice of design should depend on the individual study and the circumstances in which it is being run. Whilst innovative designs are able to solve some problems, they also present new hurdles to overcome.