

are needed, and, in particular, control groups are essential. Consequently we reviewed only such trials as were controlled. It then became clear that the major study to consider, other than the U.G.D.P., was the study in Bedford, England, organised by Dr. H. Keen and Dr. R. J. Jarrett. It should be said at once, however, that the Bedford study, based on 125 patients in each of two treatment groups was not comparable in size or in detail to the U.G.D.P. in which approximately 200 patients were followed on each of five treatments.

The work of the committee appointed by the Biometric Society fell into four sections:

1. Visits were made to the U.G.D.P. co-ordinating Center and to two of the co-operating clinical centers to study methods used in the trial.
2. The methods and findings of the U.G.D.P. study were discussed with several authors who had written about them, and the Bedford study was discussed with Dr. Keen and Dr. Jarrett.
3. The published criticisms of the U.G.D.P. were reviewed in detail. Comparable criticisms of the Bedford study do not exist, though several of the major criticisms made about the U.G.D.P. would apply a fortiori to the Bedford study.
4. New analyses were made of the data from the U.G.D.P. and Bedford studies, the data being kindly made available by the directors concerned.

Critics have pointed out that in the U.G.D.P. study the total mortality was not significantly higher in the tolbutamide group than in the placebo group, even though there was a significant difference in the case of deaths from cardiovascular causes. We consider that this criticism has some weight but is not convincing. Criticisms that have been commonly made but which, in our view, are not correct are: