

is not in fact confined to a few clinics and that this particular criticism should not be taken to detract from the interpretation of the UGDP findings."

4. The contention that randomization was not successful was studied in detail by the committee which identified "a puzzling anomaly concerning the distribution of the two sexes to the four treatment groups within clinics." The committee reviewed the randomization procedure in detail and examined the log books containing records of the allocation of each patient. The committee's report reads: "We were not able to find an assignable cause for the surprising allocation of the sexes to treatments but have no reason to think that the study has been compromised by a breakdown in the randomization of patients to the treatment groups. Because of the imbalance of sexes in the treatment groups in some clinics, however, allowance for this has been made in our analysis." The committee went on to analyze the data by several different statistical approaches, including those used originally by the UGDP investigation. The committee concluded: "Our findings* * * take into account the differences between centers and the differences in length of treatment, as well as the baseline variables. They support the view of Cornfield [ref. 18] that there is no evidence that the baseline differences arising from the randomization contributed in any important way to the finding of adverse effect from tolbutamide."