

Journal of the American Medical Association. Testimony before this subcommittee on January 31, 1975, by the members of the Biometric Society who had conducted the review, had provided a preview of their conclusions.

The Biometric Society Committee assessed the scientific quality of the UGDP study, particularly the design, conduct, and analysis of the trial, and evaluated other controlled trials involving oral hypoglycemic agents. The committee discussed in detail the published criticisms of the UGDP study and found that "most of the criticisms unpersuasive."

Specifically, the committee concluded that:

1. The criticism that patient selection had been inappropriate was "largely irrelevant" to the validity of the evidence for the toxicity of the oral agents.
2. The criticism that total mortality in the tolbutamide group was not significantly different from that in the placebo group had some weight and "the toxic effect of the oral hypoglycemics cannot be affirmed with the certainty that would be present if total mortality were significantly different."
3. Excess mortality in tolbutamide-treated patients was not confined to a few clinics, as critics had claimed.