SOME PRACTICAL PROBLEMS IN CLINICAL TRIALS

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1. Introduction

In 1971, the Mayo Clinic received a large grant to carry out clinical research on cancer. Twenty new projects were approved for support. Ordinarily these would be considered to be twenty independent projects and they would each have been provided with statistical services separately by our Medical Statistics Section. Something has been added, however, which provides a new set of problems. There exists now a new organization called a Clinical Cancer Center. It has been our problem (those of us in Medical Statistics) to try to define what a clinical cancer center is and to provide its statistical heart. At this writing we are still trying to develop a workable, unified record system tied in with appropriate computerization. So far the Center helps prepare protocols, designs the research records, handles randomization, edits data promptly, and prepares the data for analysis. Our intent is to examine results frequently, to provide summary reports frequently and, in general, to keep an aggressive watch over the course of the research. (There are a number of our statistical acquaintances around the country who have been through the same thing that we are going through now. They have our respect and admiration. Incidentally, we used to scoff at this sort of work as being pedestrian and dull. We scoff no more.)

In preparation for this grant, a massive effort was made at the Mayo Clinic to come up with suggestions of research projects that could be done with our large clinical practice. (It should be remembered that the Mayo Clinic has an enormous cancer patient load. About 6,000 new ones appear there each year.) As a result of this effort some 100 projects were proposed for support by a grant. These were whittled down by a committee to around 40 projects which were written up in formal NIH style and submitted to the National Cancer Institute. Site visits are never pleasant things if you are the one being visited. In this instance we were confronted by a distinguished panel of cancer experts. The visitors were both highly competent and highly critical. They examined our requests thoroughly. About half of our projects were turned down by the site visitors for one reason or another. Their report said, in part, the following.

"With respect to the scientific merit and design of the proposed studies, practically all suffered from primarily one weakness, namely, an improper experimental design from a biostatistical standpoint. Because of this, protocols were