

Statistical ward rounds—9

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Very good reports—why not perfect?

"Every departure from the design of an experiment lowers its efficiency to some extent; too many departures may wholly nullify it. The individual may think 'it won't matter if I do this (or don't do that) just once'; he forgets that many other individuals may have the same idea." This remark by the English medical statistician, Bradford Hill,² reflected his experiences in the Medical Research Council's pioneering work in multicenter studies during the 1940's. He was thinking of such departures from schedule as a radiograph taken at the wrong time and an erythrocyte sedimentation rate entirely omitted; but the remark has a much wider application than that. I often recall it when I am copying onto a patient's data summary card the observations recorded at a recent clinic visit in a cooperative study and I find obvious defects—errors, omissions, obscurities, and questionable statements.

I am not referring here to the work of inexperienced physicians or of those who consider such studies a "chore." During recent years I have had the good fortune to work with investigators who are seriously interested in the studies and are anxious to maintain a high standard. I am continually impressed by the amount of time and effort that they put into the observations and reports, month after month, and by their interest in, and knowledge of,

the patients, as is revealed by the notes that they add to the report forms.

Of the thousands of items of information reported on the patients during a trial the visibly defective items constitute only a very minute fraction. Therefore I sometimes wonder why we should try to reduce this fraction—why we should not treat it as an irreducible minimum. I wonder also whether it is quite fair for someone sitting in a central office to point out defects in records that are produced under the distracting conditions of a clinic. Such a demonstration seems to imply that if people in the central office could make the records they would do much better. On the contrary, every kind of defect that I have found in clinic reports (including illegible handwriting) I have produced myself in a quiet office, protected from interruption. I have, therefore, a fellow feeling for the recorders and admiration for their over-all success; but when I recall individual examples of defects I realize that I must not allow fellow feeling and admiration to overpower me.

The first step in trying to reduce the frequency of defects should, I think, follow the line of Hill's remark. An individual investigator or study secretary who receives from a central office a request for a bit of missing information does not visualize the total picture. A few days spent in the central office would reveal it best; but a glance at a few examples may help.

Omissions

Other diseases. In a drug trial in disease X the report form for the initial data contains the following question:

Any diseases, other than X, known to

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