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Wednesday, 21 September 2005

Memorandum

To: Center for Clinical Trials Students, Staff, and Faculty

Fr: Curtis Meinert

Re: Tables 101: Treatment comparisons

Tables contained in reports or manuscripts should be internally consistent in appearance and conventions used. Tables produced over the life of a trial for performance or treatment effects monitoring should be consistent over time as well.

An obvious requirement for consistency is the order of treatments, as displayed in columns across pages.

Even if the trial has just two treatment groups, the table master has decisions to make. Does the column for the control treatment precede or follow the column for the test treatment? Is there to be a "difference" or "p-value" column? Are tables to include a "Total" column and, if so, is that column the first or last column in tables?

Life gets more complicated in trials with more than one test treatment. With just two test treatments and a control treatment there is the possibility of seven columns if one opts for a"Total" column, test vs ctrl difference or p-value columns, and a column to show differences between the two test-treated groups.

Generally, it is reasonable to forego "Total" columns in treatment comparison tables because totaling across treatment groups is akin to "adding apples and oranges".

A key decision in treatment comparison tables has to do with labeling. Except, where treatment groups are masked, the labels should be mnemonic, for example as in ADAPT: **Cel** denoting celecoxib, **Nap** denoting naproxen, and **Plbo** denoting placebo. Use **Ctrl** when the comparison treatment is not a placebo.

The only option when treatment groups are masked is to use letter or number designations to denote treatment groups. Masked monitoring is dangerous and should not be practiced, but if one is forced into the practice, the treatment designations, once established, should remain as designated and the ordering of the treatment groups across columns should be invariant over the life of the trial. Hence, even though one may not know which column represents the Ctrl treatment in the layout, the column should always be in the same relative position within and across monitoring reports and should always carry the same code designation. Variation robs the monitoring body of the ability to compare across reports.

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Another place where consistency is at a premium is in regard to differencing. Trials are comparative so differences are of primary interest.

Treatment differences are obtained by subtracting the effect observed in one treatment group from that observed in another treatment group. The sign of the difference is a function of the order of subtraction.

For example, suppose the comparisons of interest are mortality and cancer free-survival times, that the observed death rates are 10/100 in the test-assigned group and 5/100 in the control-assigned group, and that the cancer-free survival times are 12 and 18 months, respectively. Then the mortality treatment effect is 5 or -5/100 and the corresponding cancer-free survival time treatment effect is -6 or 6 months, depending on the direction of subtraction. Typically, treatment effect is relative to the control-assigned group so the 5/100 mortality rate difference and -6 months cancer-free survival time difference corresponds to an excess of 5/100 mortality and a 6 month deficit in cancer-free survival time for the test-assigned treatment group.

One could, of course, change the direction of the substraction depending on whether the outcome is measuring an adverse or beneficial outcome. The advantage would be that negative differences are always against the test-assigned group. But that kind of switching leads to its own confusion and, therefore, is not recommended.

Another subtraction, common in trials, is difference of differences. For example, suppose one is interested in change in diastolic blood pressure (DBP) for a patient from baseline to the 6-month followup visit. If the baseline DBP was 92 mmHg and 83 mmHg at the 6 month visit, then the change is -9 mmHg. If the median baseline DBP for persons assigned to the test treatment was 89 mmHg and 84 mmHg at month 6, and if the corresponding values for persons assigned to the control treatment were 88 mmHg and 82 mmHg, respectively, than the 6 month treatment differences in median DBP is [(84 - 89) - (82 - 88)] mmHg = [-5 - (-6)] mmHg = 1 mmHg. Differences of differences are confusing and, hence, it is important for table makers to include a note on each such table to indicate how the differencing was done.

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