



Center for Clinical Trials

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Department of International Health*

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Wednesday, 14 September 2005

Memorandum

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

Fr: Curtis Meinert

Re: Tables 101: Cross checking

To err is human. If you want proof just try making a piece of furniture.

But not all errors are created equal. Some are inconsequential, some are embarrassing, and some are disastrous. In clinical trials some can even be career ending, for example, as could be the case in publishing a paper with the treatment groups mislabeled leading investigators to conclude that test treatment is inferior to the control treatment when, in reality, it was superior to the control treatment.

The wonderful thing about the electronic age is that it makes it possible to make big errors with little mistakes. For example, it takes just one errant line in a driver program to mis-label treatment groups in every treatment comparison table.

The most important variable in trials is treatment assignment. There should be as many checks on whether the labeling is correct in trials as in operating rooms before taking the knife to a leg for knee replacement. (Parenthetically, one of the reasons for my strong and unrelenting criticism of masked monitoring and firewalls in coordinating centers is because those practices limit the ability to check for this kind of error. They are akin to requiring the surgeon to rely on others to identify the leg to be operated upon.)

We have grown accustomed to taking truth as coming from computers, as evidenced by "That is what the computer said" or assertions that "Computers don't lie". But programs have bugs - some never detected and some only when "conditions are right". The destruction of NASA's Mariner 1, seconds off the launch pad in July of 1962 was due to a transcription error in a FORTRAN program controlling the launch. (The transcriber failed to copy a superscript bar over a mathematical expression. Without the smoothing function represented by the bar, normal variations in velocity were treated as serious causing spurious course corrections resulting in the vehicle going off course and destruction by the range safety officer.) Some of the high profiles bugs resulting in disasters can be reviewed at Wikipedia.Org on the web.

Some things need to be checked the old-fashion way - with paper and pencil and by two people working independently of one another. Among those are counts of assignments and events by treatment group. The counts had better be the same or "Houston, we have a problem".

But the harsh reality is that errors, once embedded into a program, table, or manuscript, have a non-zero probability of surviving undetected. You want proof take something you have written and introduce errors and then see how many are found by someone else. Hence, the first priority has to go to systems and procedures aimed at keeping errors out in the first place.

Counts by clinic are important in monitoring performance. Labeling errors, while generally of lesser consequence than errors in counts by treatment group, are bad because of the eroding effect they have at clinics on materials produced by the coordinating center and because of the consternation they produce in clinic ranks. However, the reality is that counting errors by clinic, even if not found in the coordinating center, will likely be discovered when the tables are distributed to clinics. Clinic personnel will do their own counting and will be quick to note discrepancies. This cross checking ability does not exist for counts by treatment groups. Largely, the only place such errors can be detected is by checks performed in the coordinating center.

Counts and totals should agree across tables. You can expect members of TEMCs and reviewers of manuscripts to query cross-table discrepancies, no matter how small.

Ideally, the working version of tables should include "hot" total lines or columns, even if those lines or columns are not displayed in the finished tables – "hot" to allow the table maker to update totals using the math features of word processors every time numbers are changed in tables. A way to hide lines or columns in WP 9 is via the "hidden text" feature or by use of a paired "color style" to display text or to make it "disappear" depending upon whether the document being assembled is in draft or finished form.

(Sun 8:28am) 17 Jul 05

Tables.101XCheck.WPD

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