there is a good example or explanation given in the documentation. It is a sound practice to test programs using textbook examples (if available) or small amounts of data which can be checked mathematically by hand.

A further caution to the statistician working with investigators in clinical trials: Merely handing the clinician a computer print-out of results of the analysis – whether small or, worse, very large – is not very helpful. "What does it mean?" Being inundated with a number of result options, foreign terms and abbreviations, or masses of paper will often cause researcher mis-interpretation and poor description of the statistical analysis in oral or written presentations. Depending on the clinician's statistical background and experience in dental clinical trials, the statistician should describe both orally and in writing what methods he used and why, and the meaning of any output options he wishes to discuss with the researcher.

Overall, the computer, whether small or large, is an invaluable tool in the design and analysis of dental clinical trials. The availability of a wide variety of statistical programs has increased the options for more refined analysis of the data. Easier collection and editing of data *via* interactive terminals, optical marked forms, and on-line tape recorders or PC's have decreased the time between examination and analysis.

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Use and Misuse of Computers in the Design and Analysis of Dental Clinical Trials: Discussion of Ms. Brunelle's Presentation

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I would first like to compliment Ms. Brunelle for a fine and thorough review of her topic. There are many "uses" for computers today in the clinical testing area, and a number of them have just been described by Ms. Brunelle. There will undoubtedly be more uses in the future. This is the easier part of this topic to discuss. The more difficult part of the topic to discuss is the "misuse" of the computer. I believe this could more accurately be re-defined, not as "the misuse of computers", but as "the misuse of statistics" which is facilitated by the use of computers.

First, I would like to mention some specific uses of computers which may not be so obvious to some. These uses do not involve statistical analyses but involve the use of the computer to help ensure double-blindness in studies and ways to take some of the time-consuming clerical work out of preparing for studies.

In the area of double-blindness, the computer can be used to generate random numbers with restrictions and allocate the numbers to specified treatment groups. For example, if 3000 subjects were to be recruited for three treatment groups, the numbers from 1 to 3000 could be allocated to groups with restrictions to 3's. In other words, the numbers 1, 2, and 3 would each be allocated to one of the treatment groups, with the same for the numbers 4, 5, and 6, and so forth. This random allocation can be stored in the computer for future reference, and the numbers themselves will become the subject identification numbers for the remainder of the study.

For assignment of subjects to treatment groups, the computer can be used to generate sheets of random permutations of the treatment groups with any number of factors, such as age, sex, DMFS scores, etc.

Using the stored master file of random allocation of numbers to treatment groups, the computer can be used to generate a file of tamper-proof, opaque, active disclosure envelopes. These envelopes are manufactured as three-part continuous computer forms and are similar to the W-2 forms with which we are all familiar. The computer then prints on them, showing the treatment identity for each subject. The first part is stripped away, leaving sealed envelopes that are tamper-proof. As subjects are randomly assigned to treatment groups, the subjects' names are then written on the envelope containing the subject number which has been randomly assigned. These envelopes are retained by the investigator for his use during the study in the event of an emergency, rather than having a master list with all the subjects' treatment identities.

As assignment progresses, rosters can be created with each subject's assigned number, name, and location (school, classroom). This roster can be entered into the computer and can be used to generate product labels that bear each subject's name and number, to make each subject unique and avoid the use of group codings which could accidentally be identified. These labels can be printed by the computer in any order, such as by school by classroom, to facilitate distribution of products to subjects by the investigator's staff.

A very time-consuming part of the investigator's preparations for field work is in getting forms ready to be used. The master roster stored in the computer can be used to pre-print continuous examination forms with the necessary subject identification information. Again, the computer can sort and print these forms in any order requested.

I would like at this point to speak a few minutes on several uses of the computers which have just been discussed by Ms. Brunelle. The first of these is the optical mark readers. Admittedly, my experience with these devices has not been recent, and the state of the art may have changed enough to make my experience obsolete, but nevertheless these are my observations.

For years we have used three-part carbonless paper (NCR) for examination forms. When the form is completed, it is separated, with one copy returned to the sponsor, one copy retained by the examiner, and one copy retained by the investigator. However, the NCR paper was not of quality suitable for processing through the optical readers. To obtain a suitable quality paper for processing through optical readers and keep the three-part form system required the use of carbon paper between forms. However, the carbon copies could not be processed by the optical readers, which then made it very difficult for the examiner and investigator to verify the results at the end of the study, because they had to do all their summaries by hand. The data processing error rate that we encountered was about 5% of the cards or lines of output generated.

With the direct entry keypunch form that we currently use, we have flexibility to change or add new codes. The document is recorded in ink with changes crossed out (never erased) and re-recorded. NCR paper is used so that the investigator, the examiner, and the sponsor may each receive a copy immediately after the completion of the record. The data are then edited and coded, and the DMFS scores are counted and entered onto the form. The data are directly entered and verified. The computer program that summarizes the data computes a DMFS score and compares it to a "read-in score". If they disagree, an error message is printed. In a typical study, the direct entry and verification error rate is less than 0.01%, and, since these are detected by the computer and then corrected, the final error rate, if not zero, is so small as to be inestimable.

With the use of highly flexible summary programs, such as we are currently using, examiners are free to use any coding system with which they feel comfortable, as long as they define their coding for us. Since examiners will grade caries at various acuity levels, it is a better statistical strategy to block on examiners rather than calibrate them and hope they will all remain the same.

The one case that I have recently seen that exemplifies the thought that computers facilitate the misuse of statistics was a publication of a caries trial where the data were analyzed by the use of χ^2. In this study, carious and non-carious surfaces were analyzed by χ^2, using each surface as the sampling unit instead of the subject. Significant differences were observed because of the very large "sample" that was available for analyses. The use of computers does make it much easier for such misuse of statistics.

I would like to thank you for the opportunity to present and share with you some methods that we have developed to make conducting clinical studies a little easier and to help ensure they will be conducted double-blindly.