Statistical Analysis in Medical Research

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Over 60 physicians have recently attended a series of five-hour workshops on "Statistical Analysis of Data ". This reflects very high professional interest in ongoing medical research. It also demonstrates that many physicians are keen for further training in the many confusions surrounding appropriate data analysis in medical research.

Statistical analysis can be broken into two very broad steps: (1) the series of decisions and assumptions made by the researcher as to how the data should be analyzed; and (2) the actual process of performing the selected statistical test. It is the first step which is most critical since even the smallest computers now routinely, quickly and accurately handle the second step. But no computer processing itself can substitute for the decision-making processes that always distinguishes good well-designed medical research.

This decision-making process can be broken down into seven sequential steps:

1. **Decide whether you really need a statistical model or not in your research.** Many interesting researches do not involve statistical models at all, e.g. case studies, follow-up studies, new treatment procedures, etc. Only if you expect patient variability of response and/or there is expected uncertainty of outcome, is a statistical model indicated. Of course, these two conditions are true in much of medical research today. So if there is uncertainty and/or patient variability, use a statistical model.

2. **Decide the type (scale) of data you have** because there are vastly different statistics appropriate for each data scale. Nominal scale statistics are used when you simply have frequencies within categories, e.g. males vs. females, Bahrainis vs. non-Bahrainis, diabetics vs. non-diabetics, etc. Ordinal scale statistics are used when your numbers represent that one patient is better or worse, but not how much better or worse, e.g. patient perceptions of pain, rated overall response to a specific treatment, etc. Interval scale statistics are used only when numbers actually represent exact amounts, e.g. some people have twice as much ferrous oxide in their blood as others and this can be precisely measured.

3. **Decide what information you want and need.** Do you need measures of central tendency (mean, mode, median), variability (range, standard deviation), relationship (correlation), or difference (chi-squared, t-tests, etc.).

4. **Decide whether your measures represent a total population or just a sample of that population.** Defining a population forces you to understand exactly what people are represented by your data. Measuring everyone (a population) avoids the whole issue of sampling error and thus is always preferable although it is seldom practical.

5. **Decide whether you utilized a "control-group" or a "control-test" design.** There are, of course, entirely different statistical tests for each design. In the simplest case, control-group is where you have two identical groups: one group receives the treatment variable (experimental group); the other group does not (control group). In control-test designs, the same group of people are measured before and after administration of the treatment variable. In general, control-test designs are preferred in medical research simply because it avoids the assumption that two groups of patients were identical to start with.

6. **Decide whether you need "directional" or "non-directional" statistical interpretations.** As a general rule, use directional tests (you can

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predict the direction of the treatment outcome) where at least four previous studies have arrived at the same general conclusions or all of your colleagues could predict the direction of outcome fairly easily based solely on their clinical experience. Use non-directional interpretations (you cannot predict whether the treatment would increase or decrease whatever you are actually measuring as the outcome) where there are less than four published studies indicating the direction of outcome, published studies have contradictory results, or colleagues' clinical judgment is mixed or unclear.

7. **Decide how much risk you are willing to take of being wrong in your conclusions.** This depends on how much is known in the specific research area you are investigating as well as the implications of you arriving at false conclusions. As a general rule of thumb, use a .05 level of confidence ($p<.05$) if: you cannot predict the direction of outcome, colleague opinion is mixed or unclear, previous studies have contradictory results, and/or there are no or very few previous studies in the area being investigated. Use .01 level of confidence ($p<.01$) if: you can predict direction of outcome, colleagues' opinion indicates professional agreement in the area, at least three or four previous studies have arrived at similar conclusions, and there are no published contradictory results. Use a far lower level of risk ($p<.00001$ or even $p<.0000001$) if life or death issues are involved, e.g. the risk of giving a patient poliomyelitis through the process of immunizing them against the disease.

These seven decisions should be made in order indicated above *before* any research design is completed and certainly long *before* any data is collected. It is the only way the medical researcher really understands what he or she is doing statistically and why. It is also the only way the researcher can select the appropriate statistical technique(s).

Only after all of these decisions have been made does the researcher actually run the appropriate statistical test(s) and arrive at his or her conclusions. But even at this final stage of data analysis, several "double-check" procedures need to be implemented.

1. Make sure all data was accurately recorded to start with and that it has been "fed" into the computer programme accurately. (Ask for a printout of all data and check this against your handwritten original records).
2. Make sure the computer has in fact run the specific statistical test(s) you decided was appropriate. To make sure, run the test twice while the data is in the computer's memory.
3. Check the measure of central tendency and variability you told the computer programme to generate. Does it sound reasonable compared to your clinical impressions of the data? Most simple errors can often be detected by simply asking yourself what is a reasonable outcome for your data based on your own professional judgement.
4. Does your data outcome compare realistically with other data collected in this research area? If not, it is generally due to human or computer error – not startling scientific discovery.
5. Do not assume statistical analysis is a substitute for either professional judgement or medical experience – it is not. It is simply a process to reduce data down to the point where you can cope with masses of data and a way to organize data so you can then meaningfully make professional judgments utilizing your medical training and experience.

Statistical analysis is *never* a substitute for thinking deeply about the nature and processes of your research area. It is simply a tool to help you *start* this thinking process – not finish it.

Lastly, the simpler the statistical analysis, the better. It is easier for you and other professionals to understand; the underlying assumptions are also simpler and easier for you to support, and it is far less likely that serious procedural or calculation errors will be made.

Editor's Note

Recommended text and computer programmes.

1. Ferguson GA (1981). Statistical analysis in psychology and education (5th ed) New York: McGraw-Hill (USA). It has good easy-to-use tables

and easy access to formulae and is reasonably complete.

2. Key-Stat-PC. A comprehensive statistical package including over 30 common parametric and non-parametric tests. Has "built-in" tables for most statistical tests – it computes significance and level of confidence for you. Accepts large data sets. Manual and back up disk included. Adopted at over 200 colleges and universities. Very very easy to use and very understandable. To order:ask for IBM-PC version – specify whether you want it on 5.25" – or 3.5" – disk. Order from Oakleaf Systems, P.O. Box 472, Decorah, Iowa 52101, USA. This programme is not copyable. Also available for App II and MacIntosh computer systems.