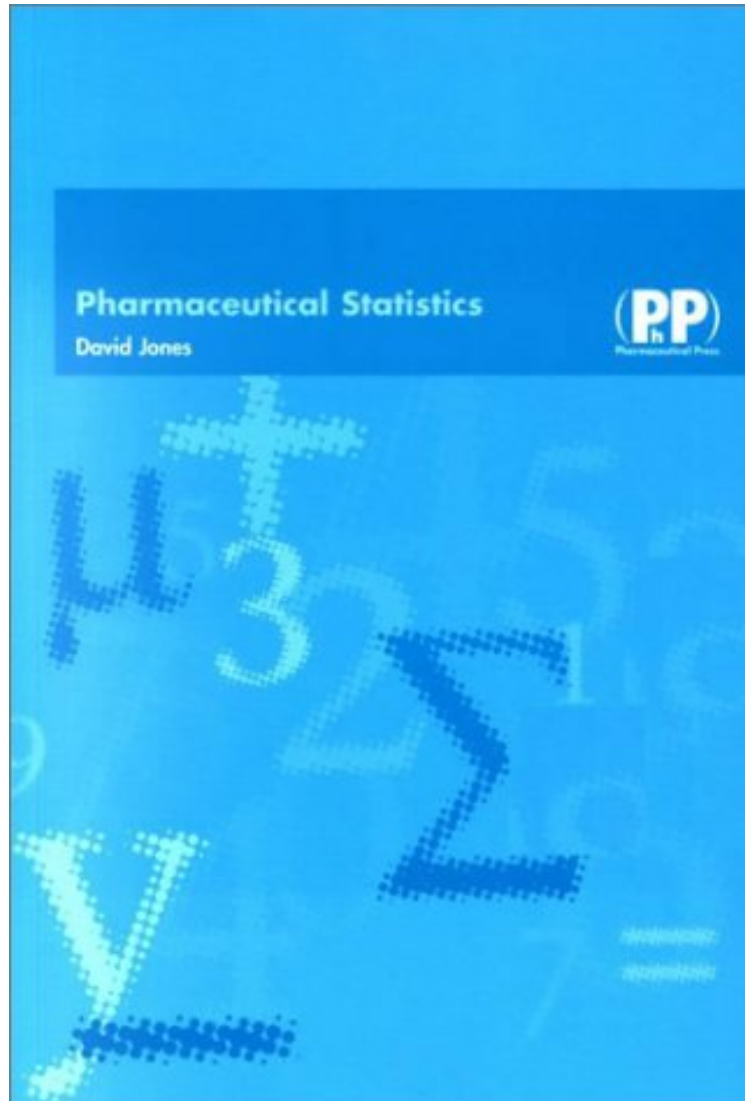


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Pharmaceutical Statistics

David Jones

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David Jones : Pharmaceutical Statistics before purchasing it in order to gage whether or not it would be worth my time, and all praised Pharmaceutical Statistics:

3 of 3 people found the following review helpful. While Jones might be the best, no single statistics book is adequate for all common formulas.By Tom BrodyPharmaceutical Statistics (2008) by David Jones is 586 pages long and printed on high quality semi-glossy paper. The book excels in that it tends to disclose the theory behind the equations, rather than just the equations alone, and in that it provides a representative number of examples for each equation. A particular virtue of David Jones' book is that, in providing an example, it expressly discloses each step or operation

that is used to solve the problem. In contrast, some statistics books just present the equations with no examples at all, or with only one example. In buying this book, I was specifically interested in understanding standard deviations, the Z statistic, the t statistic, p values, confidence intervals, alpha values, hazard ratios, Wilcoxon rank sum test, critical values, sample size and power calculations, hazard ratios, logrank statistics, and survival curves (Kaplan-Meier curves). In setting out to understand these equations, I also bought and read: (1) Dawson and Trapp (2004) Basic Clinical Biostatistics (Lange Series); (2) Durham and Turner (2008) Introduction to Statistics in Pharmaceutical Clinical Trials; (3) Kirkwood and Sterne (2003) Medical Statistics; and (4) Motulsky (1995) Intuitive Biostatistics. In my opinion, Motulsky leaves the reader in a free-fall. On occasion, Motulsky provides some insight or guidance on using the various equations. But I would not recommend that any novice interested in statistics look first to Motulsky. (5) Bart J. Harvey (2009) Statistics for Medical Writers and Editors. This short book is the best for understanding Standard Deviations. Harvey also has very good introductory material. The book's test questions might seem elementary, but they do establish some subtle but basic concepts. Harvey does not get much beyond SDs, and there is almost nothing about the t test or about p values. (6) Rosner. Fundamentals of Statistics. Providing that you have all three of these books -- Jones, Kirkwood, and Lange, it is possible to learn statistics for clinical trials. Jones is good in that it has more examples for solving. But Kirkwood is stronger on formulas for clinical trials. KAPLAN-MEIER PLOTS. Jones fails to disclose Kaplan-Meier curves. For this topic, I refer the reader to the excellent discussion in Dawson Turner. Kirkwood (pages 272-286) also discloses survival curves. But Lange (pages 221-244) is by far the best for this topic. Z STATISTIC CALCULATION SCHEMES. First, plug in the population mean, SD of population, and sample mean, into the equation for Z, and arrive at a value for Z. (pages 102-105). Now, with a value for Z in hand, plug this value of Z into Appendix One (left-most column). When Z is plugged into Appendix One, you arrive at a value for probability (located in an inner column). This probability will be the likelihood of acquiring a value for that particular sample mean. The probability may be high, e.g., 0.80, or it might be low, e.g., 0.01. To repeat, the result is a probability value. The author then discloses the reverse calculation scheme (pages 107-121). First, choose a probability value, for example, $\alpha = 0.10$. Then, go to Appendix One until you get to a value in a column (an interior column). Then, look leftwards, and let your eyes find a home in the left-most column. At this point, you will find a value for Z. For example, $Z = 1.28$. Then, plug all the available information into the formula $Z = (X - \mu) / \sigma$. The result will be a value for X, where X is a value for the sample mean that is taken to be a "critical value" or a "cut-off value." To repeat, the result is a "critical value." What is confusing is that Jones fails to tell the reader that what is happening on pages 102-105 is a procedure going forwards, and that what is going on in pages 107-121 is the same procedure going backwards. That's all there is to it. What is also confusing is that Jones fails to tell us what to do about Z values that are negative. Appendix One of another book, Durham and Turner, is able to accommodate Z values that are positive, and also Z values that are negative. Even more confusing is that Table One of Jones has a massive error in it (page 556), which takes the form of a dramatic discontinuity in the numbers in the table. CALCULATING Z. Jones is confusing on pages 87-94, 102-118, when he informs us that: $Z = [(sample\ mean) - (population\ mean)] / (SD\ of\ population)$. This is confusing because another book, Rosner (page 244), informs us that: $Z = [(sample\ mean) - (population\ mean)] / [(SD\ of\ sample) / (square\ root\ of\ \#\ of\ samples)]$. Fortunately, we have Lange to turn to (pages 85-88 of Lange). Lange tells us that the first formula for Z is used when we are interested in individual observations, but that the second formula for Z is used when we are interested in the mean (and not in individual observations). FORMULA for CONFIDENCE INTERVAL FOR SMALL SAMPLES. Pages 151-154 of Jones is equivalent to pages 53-55 of Kirkwood, for this simple formula. But Kirkwood's presentation of general information on Confidence Intervals (pages 50-53 of Kirkwood) is far superior to any presentation in Jones on this particular topic. Hence, I would recommend readers consult both Jones and Kirkwood for this formula. WILCOXON SIGNED-RANK TEST. The Wilcoxon signed-rank test involves a simple transformation that any middle school student can perform, where the result is a T value (this is something separate from the t statistic). Following this simple transformation, the reader plugs the T value into a specialized formula for the Z statistic (pages 307-312 Jones). Jones is careful to provide some theory for the Wilcoxon signed rank test--the theory is that the Wilcoxon signed rank test needs to be used whenever the MEAN is a lot different from the MEDIAN (page 304 Jones) and that the Wilcoxon signed rank test is only used where one subject (given drug A) is compared with the same subject (given drug B or placebo). For the Wilcoxon signed rank, I find that Jones is better than Lange. In Lange, the text provides an excellent description of how to do the Wilcoxon test, but the answer provided by Lange (-2.42), at least in my hands, should actually be another number (-1.947). Another problem with Lange is that Lange's parameters (mean SD) shown on page 146 of Lange do not match up with the parameters given in Table 6.5 (page 146). Thus, for the Wilcoxon signed rank test I find Jones to be better than Lange. SAMPLE SIZE AND POWER CALCULATIONS. Jones discloses sample size and power calculations on pages 172-179. The Jones narrative seems to come to a dead end on page 175, where delta is revealed as equaling 2.5 mL. But according to my calculations, delta should be 1.2 mL ($50 - 48.8 = 1.2$ mL). Lange (page 127) seems to lead to a dead end (since Lange fails to explain where the number -0.84 comes from). Kirkwood (pages 417-418) is the best of the books for sample size calculations, as Kirkwood provides a straightforward formula. CONFUSING AND INCONSISTENT TERMINOLOGY IN STATISTICS BOOKS. In David Jones' book, the "the t statistic" is called

"the t statistic." (page 153). But in Kirkwood, it is nowhere called "the t statistic," and instead it is called by three different terms: "t prime" (page 55), "percentage point of the t distribution with (n-1) degrees of freedom" (page 55), and "the t distribution" (page 55). In yet another book, Lange calls the "t statistic" not by "t statistic," but by the name, "critical value for the t distribution" (page 101 of Lange). Motulsky calls the "t statistic" "t asterisk" (page 41, Motulsky). A way out of this confusion, at least in part, is the fact that there are really TWO DIFFERENT NUMBERS. The first is that the "t statistic" is something calculated from the formula: $t = (\text{mean1} - \text{mean2}) / (\text{SD} / \text{square root of } n)$. The second is that "critical value of the t statistic" is acquired by plugging two numbers (degrees of freedom, and predetermined probability value) into a table, and here no mathematics is used at all. To repeat, for the second of these TWO DIFFERENT NUMBERS, you do use any formula and no calculations are used.

DISORGANIZATION. A fault with all of the above statistics books is their gross disorganization (though Harvey's book is too small to be disorganized). The reader would have an easier time if the authors would devote one page to disclosing that statistics requires making ones way through this decision tree. There are four yes/no questions in this decision tree. These four yes/no questions are independent of each other: (1) Are you interested in CI, or are you interested in hypothesis testing? (2) Is your sample from a large group, e.g., 60 data points or more (then you should use Z statistic) or is your sample a small group, e.g., under 60 data points (then you use t statistic). (3) Are you comparing one sample mean with a population mean? Or does your comparison involve a "paired measurement," that is, data from a STUDY DRUG GROUP and data from CONTROL GROUP, where you compare [sample mean#1 minus sample mean#2] with [population mean#1 minus population mean#2]? (4) Does your experimental setup involved a 1-tailed experiment, or does your experimental setup involve a 2-tailed experiment? Then, there are three additional decisions to make in the decision tree:

FIRST DECISION. If you are working with the t statistic, you can use it to acquire a P value (page 66, Kirkwood) or you can use it for comparing with the "critical value of the t statistic, for use in hypothesis testing (page 63, Kirkwood; page 140-141, Lange). To repeat, once you have a value for the "t statistic," you can use this value for two different purposes: (1) PLUG IT INTO A TABLE TO GET A P VALUE; or (2) COMPARE IT WITH THE CRITICAL VALUE OF THE t STATISTIC TO DO HYPOTHESIS TESTING.

SECOND DECISION. If you are working with the Z statistic, you can use it to acquire a P value (page 92, Jones), or you can use it to do hypothesis testing (pages 157-159 of Jones, page 244 of Rosner, page 141 of Lange). To repeat, once you have a value for the "Z statistic," you can use this value for two different purposes: (1) PLUG IT INTO A TABLE TO GET A P VALUE; or (2) COMPARE IT WITH THE CRITICAL VALUE OF THE NORMAL DISTRIBUTION TO DO HYPOTHESIS TESTING.

THIRD DECISION. If you are working with the Z statistic, you need to decide between two formulas. $Z = [X-u]/[SD]$ (FIRST FORMULA); and $Z = [X-u] / [(SD)/(square root of n)]$ (SECOND FORMULA). The question is, when do you use the FIRST FORMULA and when do you use the SECOND FORMULA? Kirkwood fails to address this question. But Jones in combination with Lange provides excellent guidance as to when to use the FIRST FORMULA and when to use the SECOND FORMULA. For use of the FIRST FORMULA, see Jones pages 87-89 and Lange page 87. For use of the SECOND FORMULA, see Jones pages 156-159, and Lange pages 85-86. In a nutshell, the FIRST FORMULA is used for comparing data from a mean with a hypothetical value of interest to you (a value that you dreamed up out of thin air). The SECOND FORMULA is used when numbers are available for a Population Mean (and Population SD), and where numbers are available for a Sample Mean, and where your goal is to find probability of a hypothetic sample mean will have a value that is higher than (or lower than) the value of the sample mean. Jones does a better job at distinguishing between the two formulas than does Lange. Jones comes to the rescue!

The above collection of decisions in the decision tree is inherent in all of the statistics books, but the books fail to make explicit (or in an organized manner) the fact that these decisions are waiting for you in the text. In my opinion, there is no excuse for this sort of obscurity that so characterizes statistics books. It does not have to be this way. The formulas used for clinical statistics have been around for over 100 years. The mathematics used in these books is on the level of a college freshman. Why is it that the presentation of statistics in all of these books is so disorganized, disjointed, and sporadic? These formulas are not rocket science. There is no excuse for generally uneven quality of the available statistics books.

0 of 0 people found the following review helpful.
 Good! By jan_07
 Came in a timely fashion and in the same condition that it was stated to be in. Just stinks that my professor decided not to use the book once it got here!

Written specifically for pharmacy students, this book explains basic statistics. It contains chapters on basic concepts such as types of data, graphical representation of data, distribution and standard deviation. More advanced statistical techniques, such as ANOVA, are also discussed.

From the Back Cover
 Statistics is fundamental in the study of pharmaceutical and related sciences. Knowledge of statistics is required to interpret data generated from all types of physical and biological investigations. For example, statistical analysis is applied to the comparison of pharmacological activities of therapeutic agents, the evaluation of the physicochemical properties of dosage forms, and the validation of analytical methods, to name a few. This new book on basic statistics has been specifically written for pharmacy students. It contains chapters on basic concepts

such as types of data, graphical representation of data, distribution and standard deviation. More advanced, frequently used, statistical techniques such as ANOVA and the chi-squared test are also discussed using pharmaceutical examples. A series of questions and answers are also given for self-study. Pharmaceutical Statistics is essential reading for all pharmacy students and will also be of interest to those working in the pharmaceutical industry. David Jones is Professor of Biomaterials Science at the School of Pharmacy, Queen's University of Belfast, UK.