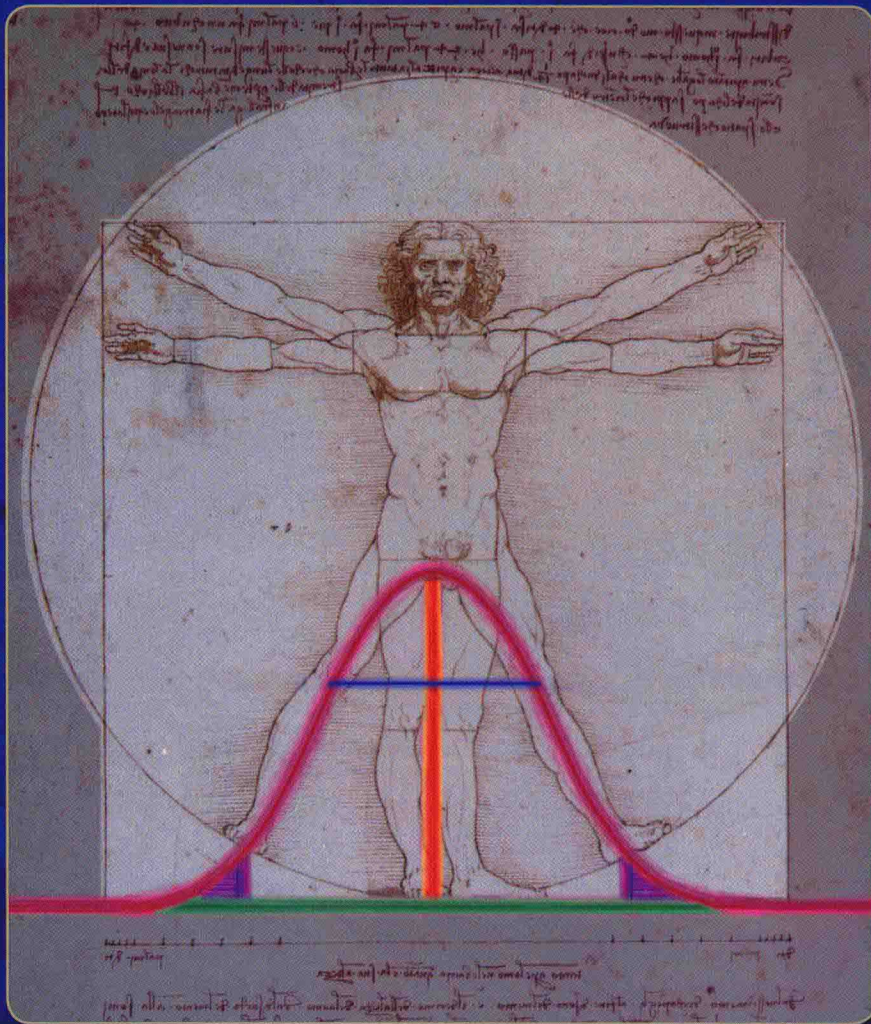


fourth edition

BIOSTATISTICS

THE BARE ESSENTIALS



Norman & Streiner

BIOSTATISTICS

The Bare Essentials

Fourth Edition

Geoffrey R. Norman, PhD

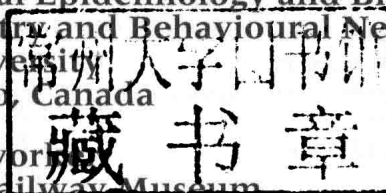
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BIOSTATISTICS

The Bare Essentials

Fourth Edition

Testimonials from Readers

"I'm actually enjoying a stats book! When you said someone was laughing so hard they dropped your textbook in the bath, I was skeptical, but now, I truly understand! I often comment that your text is very funny and people are surprised that I did not mean the phrase as an oxymoron. Thank you for taking this approach to teaching stats!"

Le-anh Ngo

"I hate stats, loath stats. But, I have just discovered *Biostatistics*, and just had to say thank you for making me laugh. I have never had things explained so simply and appropriately (this is my third go at stats, as an undergraduate, in my graduate dip, and now my PhD). Keep writing ... you are making a difference to some poor stats students.

Karen Munk

Yes, the marginalia is very popular with faculty and students alike; a colleague and I giggled hysterically over the humorous examples and marginalia (those passing her office thought we'd lost our marbles). My favorite is Chapter 13—the yuppie patients. Usually statistics books put me to sleep, but *Biostatistics* is the exception."

Christine Marton

I thought *Biostatistics* looked interesting—and it definitely is! Without it, I don't know if I would ever have made sense of the subject. I'm in the midst of writing up my PhD thesis, and it's been an invaluable reference and—perhaps more miraculous—I never read a page without a chuckle. The great mix of humor and statistics are too often thought to be mutually exclusive. I'm recommending this book to all my fellow graduate students."

Joe Brown

"*Biostatistics: The Bare Essentials* would have been life-changing had it been published when I was in graduate school in at University of Chicago. It now must settle for being life-enhancing. Statistics doesn't have to be that god-awful boring! And it can be simply described as well. I thought Howard Wainer was clear, but you guys are even better."

Rebecca J. McCauley

I just wanted you to know that you and Dr. Streiner are the only people on the planet who can make me laugh when trying to figure out statistics."

Monica McHenry

A NOTE ON THE FRONT COVER

The cover depicts the famous "Study of Human Proportion in the Manner of Vitruvius" by Leonardo da Vinci, drawn about 1490, and done to death 500 years later in 2000. Those with a classical bent may wish to know the origin of the idea. According to Renaissance notions, the "Perfect Man" was based on geometric principles. The arms outstretched, the top of the head, and the tip of the feet defined a square, and the tips of the arms and legs outstretched in a fanlike position inscribed a circle centered on the navel.

What da Vinci failed to notice is that the legs fit precisely on a normal curve, with the mean between the two heels and the apex at the crotch, one standard deviation falling exactly on the two kneecaps, and the asymptotes at the corners of the inscribed square. The centers of the two feet, at the point where they intersect the arc of the circle, then determine the conventional criterion for statistical significance at \pm two standard deviations from the mean.

Leonardo da Vinci can be forgiven, however. Statistics hadn't been invented yet in 1492.

*To two people whose hard work, patience, diligence,
and, most important, unflagging good humor,
have made it possible:*

*Geoff R. Norman
and
David L. Streiner*

Too many people confuse being serious with being solemn.

John Cleese

One of the first symptoms of an approaching nervous breakdown is the belief that one's work is terribly important.

Bertrand Russell

Most researchers use statistics the way a drunkard uses a lamp-post—more for support than illumination.

Winifred Castle

PREFACE TO THE FOURTH EDITION

What more can we possibly say about statistics that we haven't said already? Haven't we exhausted the world of biostatistics? Well, we've possibly exhausted the people reading about that world, but not the contents of it. It seems as if the world of statistics is like the astronomers' picture of the universe—expanding without limit and, like black holes, devouring everything around it. What we've expanded into with this edition is a soupçon of epidemiology.

We were delighted with a very positive review of the 3rd edition of the book in *JAMA*, in which Dr. Naomi Vaisrub—a real statistician!—praised the book, but suggested that we cover some topics in epidemiology, and we took her up on it. There's an entirely new chapter, called *Measures of Impact*, in which we discuss measures of incidence and prevalence, risk, morbidity and fatality rates, and the number needed to treat. She also suggested that we deal with different types of distributions, so we used this as a rationale for delving into the Poisson distribution for doing regressions on count data. We have completely rewritten Chapter 6, "Elements of Statistical Inference," to deal with a chronic problem common to many statistical books: reconciling the two historical approaches to logic of inference—the computation of exact p -values due to Fisher and the decision-making approach of Neyman and Pearson. We may still not have it right, but we think it's better. You'll also find new sections on robust estimators of the mean, the problems of multiple hypothesis testing, bootstrapping and resampling, and we've beefed up the section on non-parametric stats.

On the basis of a suggestion from our good friend, Dr. Doug Ammons, we're also trying something new: giving suggestions for how results should be reported. We realize this can be a bit tricky, since various journals—especially in different disciplines—report statistics in diverse ways. But, we thought we'd give it a try for some of the tests and see how it goes. If we get positive feedback, there's always a fifth edition.

So, keep those cards, letters, and e-mails coming in. We're always delighted to hear from you (even when you tell us where we screwed up).

DLS

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GRN

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PREFACE TO THE THIRD EDITION

Well, we're back, yet again. In the preface to the second edition, we wrote that the half-life of statistical knowledge is comparable to the life span of an elephant. Now, maybe it's just a sign of our incipient decrepitude, but it seems that the pace of developments in statistics has been increasing of late. Techniques that were just a glimmer in our eye when we worked on the previous edition seven years ago, such as hierarchical linear modeling, are now found in nearly all psychology journals and are starting to creep into biomedical ones. Also, when we first wrote this book, we thought it would be used by people as a sort of underground resource, to be read behind the backs of their instructors, that would help explain the "real," "grown-up" statistics books. We've been pleasantly surprised and delighted by the number of e-mails we get from people that indicate that this is the only stats book they have on their shelves, or at least the only one they bother to look at.

So, the effect of these two forces has led to this third edition. In response to the first issue, we've taken topics such as growth curve analysis, which had been a section in the chapter on measuring change, and given it its own chapter, under the more up-to-date heading of hierarchical linear modeling. As for making this more of a textbook, two additions are obvious: one new chapter on testing for equivalence and non-inferiority, and another on how to get started using the computer statistics program SPSS, because most of the chapters end with a section on using SPSS to run the tests. Other changes are less obvious, because they're buried within the chapters. For example, with an increasing number of journals, it's not sufficient to run a test of significance; they now require authors to supplement statistical tests with confidence intervals and some indication of effect size, so we've added these whenever possible. We've added a lot more to the chapters on regression and ANOVA (analysis of variance), and, in short, turned an excellent book into a fantastic one.

One thing hasn't changed (we hope), and that's our belief that having the word *statistics* in the same sentence as *funny*, *irreverent*, and *possibly obscene* doesn't constitute an oxymoron. We still regard as our highest compliment the fact that one student had to buy another copy of the book, because, while reading her first copy in the bathtub (don't ask), she laughed so hard that she dropped it. So, learn and laugh along the way.

DLS
GRN

PREFACE TO THE SECOND EDITION

We have been extremely pleased by the positive comments we have received about the first edition of *Biostatistics: The Bare Essentials*.¹ It is very gratifying to get e-mail messages out of the blue telling us that, for the first time, people really understand what statistics are all about and are having fun learning it—almost as gratifying as getting royalty checks in the snail-mail. We debated for a long time whether we should write a second edition. Our hesitation was due to two considerations. First, if the half-life of medical knowledge is about 5 years, then it must be longer than the life-time of an elephant for statistical knowledge. After all, we are still using the correlation coefficient that was proposed by Galton (and he died in 1911), and the work done by Ronald Fisher in the early 1900s continues to provide the basic core of statistics. Second, there were other things we wanted to do with our lives, such as eating, sleeping, and seeing our families.

So, what made us decide to do a second edition? For one thing, statistics *have* changed. Path analysis and structural equation modeling have been around for about a quarter of a century, but with the recent introduction of programs that do these easily on a desktop computer, their use has proliferated over the past few years. It is almost impossible to read any journal in fields such as psychology without seeing at least one example in each issue. The same is true for other computer-intensive techniques, such as logistic regression and multivariate analysis of variance; so, we have added chapters on all of these subjects. Now, after nearly a half century of debate, we are starting to reach some consensus about the best way to measure change, and this deserves its own chapter.

Writing a second edition has also allowed us to correct the mistakes that we and others have discovered over the years. However, writing new chapters has also offered us the opportunity to make new ones, so keep your eyes open and the e-mails coming. In closing, we would like to thank three people who have been especially diligent in pointing out our mistakes and in reading drafts of some of the new chapters: Bill Marks from Villanova University, Kathleen Wyrwich from St. Louis University, and Jose Luis Saiz from Universidad de la Frontera.

¹And even more pleased by the reaction to the back cover. In response to many inquiries about it, yes, Geoff really does have four arms.

GRN
DLS

PREFACE TO THE FIRST EDITION

Are congratulations in order? Have you finally overcome those years of denial about your ignorance of statistics, those many embarrassing incidents at scientific meetings, those offhand comments at drug company receptions when someone dropped tidbits like “analysis of covariance” into the conversation and you had to admit your bewilderment? Are you prepared to recognize your condition and deal with your problem? Face it, you are a **photonumerophobic**!¹

Now that you have come out of the closet (clinic), we are here to help. To begin, it would be useful for you to understand that all statisticians are not created equal, and as a result all statistics books are not equal.² An analogy with home renovation might help. Three basic types of folks are involved in home renovation. First there are architects, who design houses that no one except dermatologists can afford—they worry about concepts, esthetics, and design at the theory level. Next there are carpenters who *do* home renovations, are highly specialized and skilled,³ and have a special language consisting of terms such as plates, sills, rafters, sheathing, R28, and the like that describe goings on at the practical level.⁴

Finally, there are the do-it-yourselfers (DIYers), who have the temerity to sally forth in blissful ignorance and make their own additions. Now, the fact of the matter is that it isn't all that difficult to put a nail into a 2 × 4, or to do anything else related to foundations, walls, ceilings, plumbing, and wiring. But a frustration for accomplished DIYers is that the books on do-it-yourselfing are written either by the architects, or by carpenters, but not by really good DIYers, and they all miss the mark. So, you either get pieces about the esthetic considerations involved in a \$200,000 bathroom renovation, or a DIY book that starts and stops with “How to change a fuse.”

Unfortunately, the same conventions hold in statistics. There are the architects of statistics—card-carrying PhDs who contribute to the theory of statistics and publish journal articles in *Biometrika* or little monographs to be read only by other members of this closed community. Then there are the carpenters—the most common species. They usually have a PhD in statistics, but they don't actually contribute to the discipline base of statistics—they just *do* statistics. They don't usually publish articles in statistics journals, beyond the cookbook recipes. Then there are the DIYers—folks like us who have arrived

at statistics by the back door through disciplines such as psychology or education. With the advent of modern statistical packages and PCs, nearly anyone can be a do-it-yourself statistician—even you. Note that we are assuming in this book, unlike many other statistics books, that you will *not* actually *do* statistics. No one except students in statistics courses has done an analysis of variance for 20 years. If God had meant people to do statistics, He wouldn't have invented computers.

This description reveals two problems with the present state of affairs. First, doing statistics really is easier now than doing plumbing, but unfortunately errors are much better hidden—there is no statistical equivalent of a leaky pipe. Also, there is no building inspector or building code in statistics, although journal editors wish there were.

Secondly, most Do-It-Yourself stats books are written by tradesmen (oops, that should “tradespersons”). They are a possessive lot and likely feel a little guilty that they, too, don't publish in *Biometrika*.⁵ So, they commit two fundamental errors. First, they cannot resist dazzling you with the mysteries of the game and subliminally impressing you with the incredible intelligence that they must have had to master the field. This is achieved by sprinkling technical lingo throughout the book, doing lots and lots of derivations and algebra to make it look like science, and, above all, writing in a stilted, formal, and ultimately unreadably boring prose, as if this is a prerequisite for credibility. That is one type of statistics book—until recently, in the majority.

There is a second strategy, however. Recognizing that no one in possession of his or her senses would actually lay out hard-earned cash to buy such a book,⁶ a number of carpenters have begun to publish little thin books, with lively prose and with a sincere hope of demystifying the field and making good royalties. The only problem is that they usually presume that the really contemporary stuff of statistics is much too complicated for the average DIYer to comprehend. As a result, these books begin, and end, with statistical methods that were popular around the turn of the last century. An argument used to justify such books goes like, “We have carefully surveyed the biomedical literature, and contemporary and powerful methods like factor analysis are used only rarely, so we are just teaching methods

¹Photonumerophobia: fear that one's fear of numbers will come to light (thanks to Dave Sackett).

²Most statisticians who write statistics books don't understand this distinction, which is why most statistics books are so boring.

³Always the optimists, aren't we?

⁴Damn fools. If they had the good sense to put Graeco-Latin names on these things they could have tripled their salaries. Admit it, you can charge more for making a diagnosis of acute nasopharyngitis than for snotty nose.

⁵Norman can sympathize. He has a PhD in physics, which he never used. He was recently introduced at a meeting as a “fallen physicist,” a term which Streiner calls a redundancy.

⁶Unless, of course, it was assigned reading in a course taught by another statistical carpenter.

that appear commonly." The circular nature of this argument somehow escapes them.⁷

We have news for you. Contemporary statistics are not all that complicated; in fact, now that computers are around to do all the dirty work, it's much less painful than in yesteryear. Certainly compared to physiology or physics, it's pain free. But an author has to approach it with a genuine desire to try very hard to explain it. Let us just return to the DIY analogy one last time. There are really two types of activities that accomplished DIYers get involved in. For some chores on the house, they want to be sufficiently informed that they can hire a professional and feel confident that they will recognize when it is done well or poorly. That is, they know they can't do it all on their own, but they know enough to be able to tell shoddy workmanship when they see it. Other tasks they may decide to complete themselves. Again, for the biomedical researcher confronted with statistics, both avenues are open. On the one hand, it is a prerequisite, in examining the analyses conducted by others, to be able to understand when it was done well or poorly, even though one may choose to not do it oneself. On the other hand, with the flexibility and ease of many contemporary statistics packages, just about anyone can now get involved in the doing of statistics.

Our first book, *PDQ Statistics* (Norman and Streiner, 1986), was written to satisfy consumers of statistics. We found that it was possible to explain most of contemporary statistics at the conceptual level, with little recourse to algebra and proofs. However, it does take somewhat more knowledge and skill to do something—plumbing, wiring, or statistics—than it does to recognize when others are doing it well or poorly. That, then, is the intent of this book. If you never intend to do statistics, save a few bucks and buy *PDQ*. However, if you are actually involved in research, or if you have had your appetite whetted by *PDQ* or some other introductory book, pay the salesperson for this book and carry on.

Some comments about the format of the book. A perusal of the contents reveals that it is laid out much as any other traditional stats book. We contemplated doing it in problem-based fashion, both because we come from a problem-based medical school and also because it would sound contemporary and sell more books (we never said we were in it for altruism). But this would constitute, in our view, a debasement of the meaning of problem based learning (PBL). This book is a resource, not a curriculum. By all means, we urge the reader to consult it when there is a statistical problem around, thereby doing PBL. But PBL does not dictate the format of the resources—all medical students, wherever they are, still engorge Harrison and the Merck Manual. We felt that we could better explain the conceptual underpinnings by following the traditional sequence.

Some differences go beyond style. Most chapters begin with an example to set the stage. Usually the

examples were dreamt up in our fertile imaginations and are, we hope, entertaining. Occasionally we reverted to real-world data, simply because sometimes the real world is at least as bizarre as anything imagination could invent. Although many reviews of statistics books praise the users of real examples and castigate others, we are unapologetic in our decision for several reasons: (1) the book is aimed at all types of health professionals, and we didn't want to waste your time and ours explaining the intricacies of podiatry for others; (2) the real world is a messy place, and it is difficult, or well nigh impossible, to locate real examples that illustrate the pedagogic points simply;⁸ and (3) we happen to believe, and can cite good psychological evidence to back it up, that memorable (read "bizarre") examples are a potent ally in learning and remembering concepts.

There are far more equations here than in *PDQ*, although we have still tried to keep these to a minimum. Our excuse is simply that this is the language of statistics; if we try to avoid it altogether, we end up with such convoluted prose that the message gets lost in the medium. But we continue to try very hard to explain the underlying concept, instead of simply dropping a formula in your lap.

There are a few other distinctive features. We have retained the idea of C.R.A.P. Detectors⁹ from *PDQ* as a way to help you see the errors of other's (and your own) ways. We have included computer notes at the end of most chapters¹⁰ to help you with one of the more common and powerful statistical programs—SPSS (Statistical Program for the Social Sciences). Finally, we acknowledge that many clinical investigators use most of their skills to get grants so that they can hire someone else to do statistics. Also, it is impossible to squeeze money out of most federal, state, or provincial agencies without an impressive sample size calculation.¹¹ That means, of course, that the only analysis many biomedical researchers do is the sample size calculations in their grant proposals. Recognizing this harsh reality, every chapter has a section devoted to sample size calculations (when these are available) so you will be as good as the next person at befuddling the grant reviewers.

On the issue of format, you will already have noticed that the book has an excessively wide outside margin. This is not a publisher's error or an attempt to salvage the pulp and paper industry. Instead, it accomplishes two things: (1) we can use the margin for rubrics,¹² expanding on things of slightly peripheral interest, or inflicting our base humor on the reader; and (2) you can use it to make your own notes if you don't like ours.

Finally, on the issue of style. You might have already noticed that we have cultivated a somewhat irreverent tone, which we will proceed to apply as we see fit to all folks who have the misfortune to appear in these pages—statisticians, physicians, administrators, nurses, physiotherapists, psychologists, and social workers. We recognize that we run a certain

⁷This is an argument for maintaining the status quo despite much discussion of the inadequacy of reporting statistics in the biomedical literature. It's analogous to saying that we have studied primary care clinics and we found that most visits (about 80%) are related to acute respiratory infections, hypertension, depression, and chronic pulmonary disease, so that is all we will teach our medical students.

⁸Every time we get on an airplane, we are grateful that the pilots practiced landing the 747 with both starboard engines blown on a simulator so (a) they would know what to do if it happened, and (b) they wouldn't have to practice on us.

⁹Lest we be accused of profane language, this stands for "Convoluted Reasoning and Anti-intellectual Pomposity Detectors." Ernest Hemingway likely thought so too—he coined the phrase.

¹⁰See the note at the end of this preface.

¹¹Most sample size calculations are based on exact analysis of impossibly wild guesses, resulting in an illusion of precision. As Alfred North Whitehead said, "Some of the greatest disasters of mankind were inflicted by the narrowness of men with a sound methodology."

¹²No doubt you wonder what a **rubric** is. Literally, it is the note written in red in the margin of the Book of Common Prayer telling the preacher what to do next. That's why these are red.

¹³We don't like the term either, but it's shorter than spelling out all the allies.

¹⁴We forget whether it was Lenny Bruce or Mort Sahl who ended every routine with the line, "Is there anyone in the audience whom I haven't insulted yet?" In either case, he was our inspiration.

¹⁵And thereby resulting in some people castigating us for not including the best statistical package (i.e., the one they have on their machine). Such are the perils of authorship.

¹⁶Not that we recommend, "Hi there. Do you know SPSS?" as an ice-breaker at a singles bar. Chapter 8 to the contrary notwithstanding, sex and stats make poor bedfellows.

risk of offending the "allied"¹³ health professionals, who have historically felt somewhat downtrodden, with good reason, by folks with MD after their name. However, we felt the risk was greater if we omitted them altogether. Fear no evil, all ye downtrodden—our intent is not racist, sexist, or otherwise prejudiced. We will attempt, as much as possible, to insult all professions equally.¹⁴

Notes on the Computer Notes

We are of the firm belief that our mothers didn't raise us to waste our time doing calculations by hand; that's why we have computers and computerized statistical packages. However, learning the arcane code words demanded by many of these programs can be as intimidating as learning statistics itself. So, in our never-ending quest to be as helpful as possible, we've supplied the commands necessary to make one of these programs bow to your wishes.

A few years ago, it would have been a simple job to choose which programs to include; because there were only three or four that could be run on desktop computers, we could have included all of them and be seen as comprehensive and erudite. Now, though, it seems as if a new, "better," package is introduced every month, forcing us to make some choices.¹⁵ When we wrote the first edition, there were a bunch of popular and powerful programs which stood out from the rest — SPSS, BMDP, SAS, and Minitab. So, we obligingly included some hints on how to run three of the four. Well, things have changed considerably in the past decade or so. SPSS (Statistical Package for the Social Sciences) has done to statistical software what Microsoft did to operating systems — it swallowed them whole for breakfast. While you

can still buy SAS and Minitab, SPSS bought out BMDP had then let it wither on the vine. "Real" statisticians still use SAS, but you'll need a separate bookcase just to house all of its manuals. The reality is that wherever you look in the social and medical sciences, folks are running SPSS. It's never been the best at everything, but it's good at many things, and it's pretty well created a monopoly. Since no manual or Help directory can ever compete with a knowledgeable friend, and friends knowledgeable in SPSS are far more common than friends of the other ilks¹⁶, it makes no sense for us to buck a trend. Accordingly, this time around we've only included instructions for the Windows version of SPSS (Version 9 point something or other).

Good luck (and don't call us if your machine blows up).

Acknowledgments

Many of our students have waded through early drafts of this book, giving us valuable advice about where we were going astray. Unfortunately, they are too numerous to mention (and we have forgotten most of their names). However, special thanks are due to Dr. Marilyn Craven, who patiently (and sometimes painfully) helped us with our logic and English. So, any mistakes you find should be blamed on them; we humbly accept any praise as due to our own efforts.

On a serious note (which we hope will be the last), we would like to express our thanks to Brian C. Decker, who dreamt up the idea of this book and who encouraged us from the beginning.

GRN
DLS

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