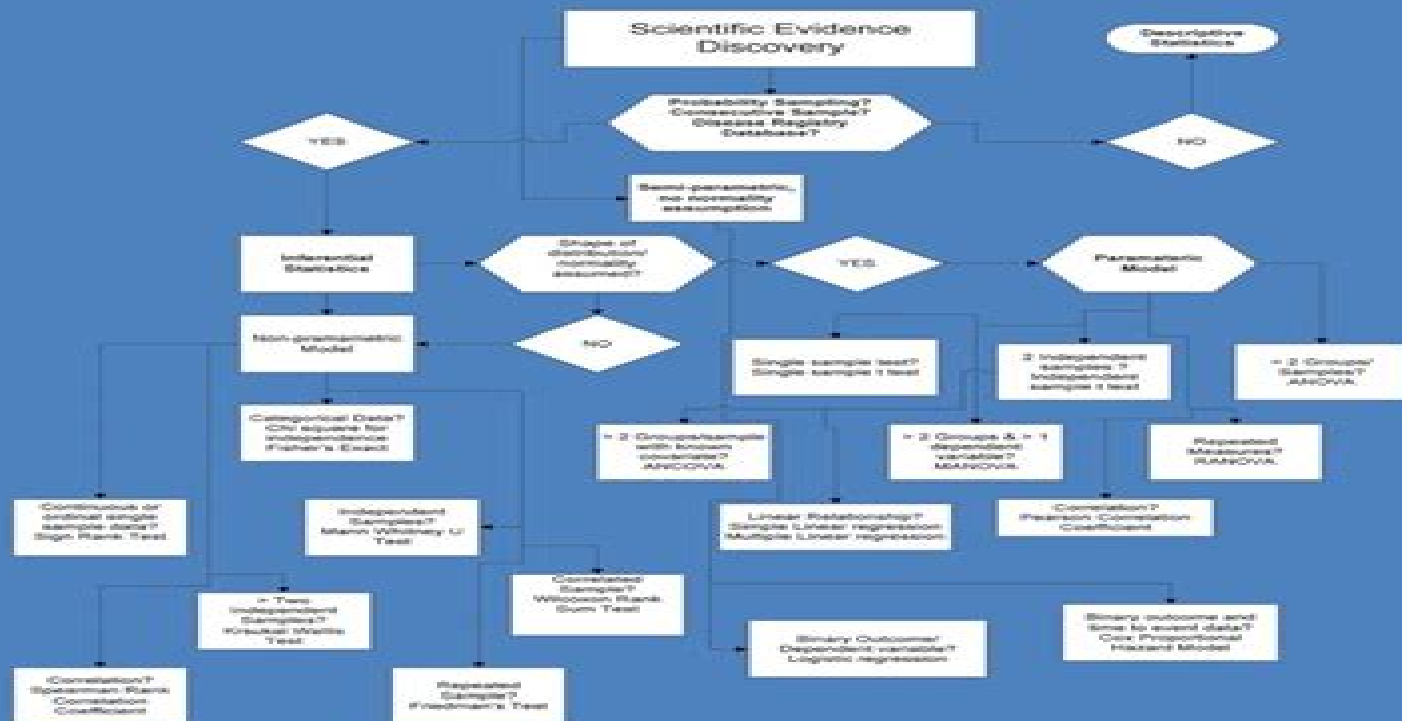


Concise Biostatistical Principles & Concepts

Guidelines for Clinical and Biomedical Researchers



Laurens Holmes, Jr.
and Franklin Opara

Concise Biostatistical Principles Concepts Guidelines For Clinical And Biomedical Researchers

Susan White



Concise Biostatistical Principles Concepts Guidelines For Clinical And Biomedical Researchers:

Concise Biostatistical Principles and Concepts Laurens Holmes, Jr, 2025-03-18 Concise Biostatistical Principles and Concepts 2nd Edition Clinical medicine or surgery continues to make advances through evidence that is judged to be objectively drawn from the care of individual patients The natural observation of individuals remains the basis for our researchable questions formulation and the subsequent hypothesis testing Evidence based medicine or surgery depends on how critical we are in evaluating evidence in order to inform our practice These evaluations no matter how objective are never absolute but probabilistic as we will never know with absolute certainty how to treat future patients who were not a part of our study Despite the obstacles facing us today in an attempt to provide an objective evaluation of our patients since all our decisions are based on a judgment of some evidence we have progressed from expert opinion to the body of evidence from randomized controlled clinical trials as well as cohort investigations prospective and retrospective The conduct of clinical trials though termed the gold standard which yields more reliable and valid evidence from the data relative to non experimental or observational designs depends on how well it is designed and conducted prior to outcomes data collection analysis results interpretation and dissemination The designs and the techniques used to draw statistical inferences are often beyond the average clinician's understanding A text that brings hypothesis formulation analysis and how to interpret the results of the findings is long overdue and highly anticipated Statistical modeling which is fundamentally a journey from sample to the application of findings is essential to evidence discovery The four past decades have experienced modern advances in statistical modeling and evidence discovery in biomedical clinical and population based research With these advances come the challenges in accurate model stipulation and application of models in scientific evidence discovery While the application of novel statistical techniques to our data is necessary and fundamental to research the selection of a sample and sampling method that reflects the representativeness of that sample to the targeted population is even more important Since one of the rationale behind research conduct is to generate new knowledge and apply it to improve life situations including the improvement of patient and population health sampling sample size and power estimations remain the basis for such inference With the essential relevance of sample and sampling technique to how we come to make sense of data the design of the study transcends statistical technique since no statistical tool no matter how sophisticated can correct the errors of sampling This text is written to highlight the importance of appropriate design prior to analysis by placing emphasis on subject selection and probability sample randomization process when applicable prior to the selection of the analytic tool In addition it stresses the importance of biological and clinical significance in the interpretation of study findings The basis for statistical inference implying the quantification of random error is a random sample When studies are conducted without random samples as often encountered in clinical and biomedical research it is meaningless to report the findings with p value However in the absence of a random sample the p value can be applied to designs that utilize consecutive samples and

disease registries since these samples reflect the population of interest and hence representative sample justifying inference and generalization Essential to the selection of test statistics is the understanding of the scale of the measurement of the variables especially the response outcome or dependent variable type of sample independent or correlated hypothesis and normality assumption In terms of the selection of statistical tests this text is based on the scale of measurement binary type of sample single independent and relationship linear For example if the scale of measurement of the outcome variable is binary repeated measure and normality is not assumed the repeated measure logistic regression model remains a feasible model for evidence discovery in using the independent variables to predict the repeated outcome This book presents a simplified approach to evidence discovery by recommending the graphic illustration of data and normality test for continuous ratio interval scale data prior to statistical test selection Unlike current text in biostatistics the approach taken to present these materials is very simple First this text uses applied statistics by illustrating what when where and why a test is appropriate Where a text violates the normality assumption readers are presented with a non parametric alternative The rationale for the test is explained with a limited mathematical formula and is intended in order to stress the applied nature of biostatistics Attempts have been made in this book to present the most commonly used statistical model in biomedical or clinical research We believe since no book is complete to have covered the basics that will facilitate the understanding of scientific evidence discovery We hope this book remains a useful guide which is our intention in bridging the gap between theoretical statistical models and reality in the statistical modeling of biomedical and clinical research data As researchers we all make mistakes and we believe we have learned from our mistakes during the past three decades hence the need to examine flaws and apply reality in the statistical modeling of biomedical and research data We hope this text results in increased reliability in the conduct analysis *Applied Biostatistical Principles and Concepts* Laurens Holmes,

Jr.,2017-11-22 The past three decades have witnessed modern advances in statistical modeling and evidence discovery in biomedical clinical and population based research With these advances come the challenges in accurate model stipulation and application of models in scientific evidence discovery *Applied Biostatistical Principles and Concepts* provides practical knowledge using biological and biochemical specimen samples in order to understand health and disease processes at cellular clinical and population levels Concepts and techniques provided will help researchers design and conduct studies then translate data from bench to clinics in attempt to improve the health of patients and populations This book is suitable for both clinicians and health or biological sciences students It presents the reality in statistical modelling of health research data in a concise manner that will address the issue of big data type I error tolerance and probability value effect size and confidence interval for precision effect measure modification and interaction as well as confounders thus allowing for more valid inferences and yielding results that are more reliable valid and accurate Concise Epidemiologic Principles and Concepts Laurens Holmes Jr.,Franklin Opara,2013-09-11 This textbook describes the basics of research in medical clinical

and biomedical settings as well as the concepts and application of epidemiologic designs in research conduct Design transcends statistical techniques and no matter how sophisticated a statistical modeling errors of design sampling cannot be corrected The authors of this textbook have presented a complex field in a very simplified and reader friendly manner with the intent that such presentation will facilitate the understanding of design process and epidemiologic thinking in clinical and biomedical research Covers these relevant topics in epidemiology Case Cohort Design Prospective Case Control Quantitative Evidence Synthesis QES Instant Cohort Design Case Crossover Design Effect Modification Interaction Epidemiologic Tree Molecular Epidemiology Health Disparities Epidemiologic Challenge Big Data mHealth Social Media 3 Ts Team Science Transdisciplinary Research Translational Research Bias Random error Confounding Systems Science Evidence Discovery Research is presented as an exercise around measurement with measurement error inevitable in its conducthence the inherent uncertainties of all findings in clinical and biomedical research Concise Epidemiologic Principles and Concepts covers research conceptualization namely research objectives questions hypothesis design implementation data collection analysis results and interpretation While the primary focus of epidemiology is to assess the relationship between exposure risk or predisposing factor and outcome disease or health related event causal association is presented in a simplified manner including the role of quantitative evidence synthesis meta analysis in causal inference Epidemiology has evolved over the past three decades resulting in several fields being developed This text presents in brief the perspectives and future of epidemiology in the era of the molecular basis of medicine With molecular epidemiology we are better equipped with tools to identify molecular biologic indicators of risk as well as biologic alterations in the early stages of disease

Concise Biostatistical Principles and Concepts, 2nd Edition Laurens Holmes, Jr, 2025-03-18 Concise Biostatistical Principles and Concepts Statistical Reality in Evidence Discovery Clinical medicine or surgery continues to make advances through evidence that is judged to be objectively drawn from the care of individual patients The natural observation of individuals remains the basis for our researchable questions formulation and the subsequent hypothesis testing Evidence based medicine or surgery depends on how critical we are in evaluating evidence in order to inform our practice These evaluations no matter how objective are never absolute but probabilistic as we will never know with absolute certainty how to treat future patients who were not a part of our study Despite the obstacles facing us today in an attempt to provide an objective evaluation of our patients since all our decisions are based on a judgment of some evidence we have progressed from expert opinion to the body of evidence from randomized controlled clinical trials as well as cohort investigations prospective and retrospective The conduct of clinical trials though termed the gold standard which yields more reliable and valid evidence from the data relative to non experimental or observational designs depends on how well it is designed and conducted prior to outcomes data collection analysis results interpretation and dissemination The designs and the techniques used to draw statistical inferences are often beyond the average clinician s understanding A text that brings hypothesis formulation analysis and how

to interpret the results of the findings is long overdue and highly anticipated Statistical modeling which is fundamentally a journey from sample to the application of findings is essential to evidence discovery The four past decades have experienced modern advances in statistical modeling and evidence discovery in biomedical clinical and population based research With these advances come the challenges in accurate model stipulation and application of models in scientific evidence discovery While the application of novel statistical techniques to our data is necessary and fundamental to research the selection of a sample and sampling method that reflects the representativeness of that sample to the targeted population is even more important Since one of the rationale behind research conduct is to generate new knowledge and apply it to improve life situations including the improvement of patient and population health sampling sample size and power estimations remain the basis for such inference With the essential relevance of sample and sampling technique to how we come to make sense of data the design of the study transcends statistical technique since no statistical tool no matter how sophisticated can correct the errors of sampling This text is written to highlight the importance of appropriate design prior to analysis by placing emphasis on subject selection and probability sample randomization process when applicable prior to the selection of the analytic tool In addition it stresses the importance of biological and clinical significance in the interpretation of study findings The basis for statistical inference implying the quantification of random error is a random sample When studies are conducted without random samples as often encountered in clinical and biomedical research it is meaningless to report the findings with p value However in the absence of a random sample the p value can be applied to designs that utilize consecutive samples and disease registries since these samples reflect the population of interest and hence representative sample justifying inference and generalization Essential to the selection of test statistics is the understanding of the scale of the measurement of the variables especially the response outcome or dependent variable type of sample independent or correlated hypothesis and normality assumption In terms of the selection of statistical tests this text is based on the scale of measurement binary type of sample single independent and relationship linear For example if the scale of measurement of the outcome variable is binary repeated measure and normality is not assumed the repeated measure logistic regression model remains a feasible model for evidence discovery in using the independent variables to predict the repeated outcome This book presents a simplified approach to evidence discovery by recommending the graphic illustration of data and normality test for continuous ratio interval scale data prior to statistical test selection Unlike current text in biostatistics the approach taken to present these materials is very simple First this text uses applied statistics by illustrating what when where and why a test is appropriate Where a text violates the normality assumption readers are presented with a non parametric alternative The rationale for the test is explained with a limited mathematical formula and is intended in order to stress the applied nature of biostatistics Attempts have been made in this book to present the most commonly used statistical model in biomedical or clinical research We believe since no book is complete to have covered the basics that will facilitate

the understanding of scientific evidence discovery We hope this book remains a useful guide which is our intention in bridging the gap between theoretical statistical models and reality in the statistical modeling of biomedical and clinical research data As researchers we all make mistakes and we believe we have learned from our mistakes during the past three decades hence the need to examine flaws and apply reality in the statistical modeling of biomedical and research data We hope this text results in increased reliability in the conduct analysis Concise Epidemiologic Principles and Concepts - Second Edition Laurens Holmes, Jr, 2025-03-19 Concise Epidemiologic Principles Concepts Study Design Conduct and Application We often conceive epidemiology in either simplistic or complex terms and neither of these is accurate To illustrate this the complexities in epidemiology could be achieved by considering a study to determine the correlation between serum lipid profile as total cholesterol HDL LDL triglyceride and total body fatness or obesity measured by BMI in children Two laboratories measured serum lipid profiles and one observed a correlation with BMI while the other did not Which is the reliable finding To address this question one needs to examine the context of blood drawing since fasting blood level may provide a better indicator of serum lipid Epidemiologic studies could be easily derailed given the inability to identify and address possible confounding Therefore understanding the principles and concepts used in epidemiologic studies designed and conducted to answer clinical research questions facilitates accurate and reliable findings in these areas Another similar example in a health fair setting involves geography and health termed health o graphy The risk of dying in one zip code A was 59.5 per 100 000 and in the other zip code B was 35.4 per 100 000 There is a common sense and non epidemiologic tendency to conclude that there is an increased risk of dying in zip code A To arrive at such inference one must first find out the age distribution of these two zip codes since advancing age is associated with increased mortality Indeed zip code A is comparable to the United States population while zip code B is the Mexican population These two examples are indicative of the need to understand epidemiologic concepts such as confounding by age or effect measure modification prior to undertaking clinical research This textbook describes the basics of research in medical and clinical settings as well as the concepts and application of epidemiologic designs in research Design transcends statistical techniques and no matter how sophisticated statistical modeling errors of design sampling cannot be corrected The author of this textbook has presented a complex field in a very simplified and reader friendly manner with the intent that such a presentation will facilitate the understanding of the design process and epidemiologic thinking in clinical research Additionally this book provides a very basic explanation of how to examine the data collected for research conduct for the possibility of confounders and how to address such confounders thus disentangling such effects for reliable and valid inference Research is presented as an exercise around measurement with measurement error inevitable in its conduct hence the inherent uncertainties of all findings in clinical and medical research Concise Epidemiologic Principles and Concepts Second Edition for Clinicians covers research conceptualization namely research objectives questions hypothesis design implementation data collection analysis

results and interpretation While the primary focus of epidemiology is to assess the relationship between exposure risk or predisposing factor and outcome disease or health related event the causal association is presented in a simplified manner including the role of quantitative evidence synthesis QES in causal inference Epidemiology has evolved over the past three decades resulting in several fields being developed This text presents in brief the perspectives and future of epidemiology in the era of the molecular basis of medicine 3Ts and systems science as well as Epigenomic Epidemiology Epidemiologic evidence is more reliable if conceptualized and conducted within the context of translational transdisciplinary and team science With molecular epidemiology we are better equipped with tools to identify molecular biologic indicators of risk as well as biologic alterations in the early stages of disease and with 3 Ts and systems science we are more capable of providing accurate and reliable inference on causality and outcomes research Further the author argues that unless sampling error and confounding are identified and addressed clinical research findings will remain largely inconsistent implying an inconsequential epidemiologic approach Appropriate knowledge of research conceptualization design and statistical inference is essential for conducting clinical and biomedical research This knowledge is acquired through the understanding of epidemiologic observational non experimental and experimental designs and the choice of the appropriate test statistic for statistical inference However regardless of how sophisticated the statistical technique employed for statistical inference is study conceptualization and design are the building blocks of valid scientific evidence Since clinical research is performed to improve patients care it remains relevant to assess not only the statistical significance but the clinical and biologic importance of the findings for clinical decision making in the care of an individual patient Therefore the aim of this book is to provide clinicians biomedical researchers graduate students in research methodology students of public health and all those involved in clinical biomedical research with a simplified but concise overview of the principles and practice of epidemiology In addition the author stresses common flaws in the conduct analysis and interpretation of epidemiologic studies Valid and reliable scientific research is that which considers the following elements in arriving at the truth from the data namely biological relevance clinical importance and statistical stability and precision statistical inference based on the p value and the 90 95 and 99 percent confidence interval The interpretation of results of new research must rely on factual association or effect and the alternative explanation namely systematic error random error precision confounding and effect measure modifier Therefore unless these perspectives are disentangled the results from any given research cannot be considered reliable However even with this disentanglement all study findings remain inconclusive with some degree of uncertainty This book presents a comprehensive guide on how to conduct clinical and medical research mainly research question formulation study implementation hypothesis testing using appropriate test statistics to analyze the data and results interpretation In so doing it attempts to illustrate the basic concepts used in study conceptualization epidemiologic design and appropriate test statistics for statistical inference from the data Therefore though statistical inference is emphasized throughout the

presentation in this text equal emphasis is placed on clinical relevance or importance and biological relevance in the interpretation of the study results Specifically this book describes in basic terms and concepts how to conduct clinical and medical research using epidemiologic designs The author presents epidemiology as the main profession in the trans disciplinary approach to the understanding of complex ecologic models of disease and health Clinicians even those without preliminary or infantile knowledge of epidemiologic designs could benefit immensely from what when where who and how studies are conceptualized data collected as planned with the scale of measurement of the outcome and independent variables data edited cleaned and processed prior to analysis appropriate analysis based on statistical assumptions and rationale results tabulation for scientific appraisal results interpretation and inference Unlike most epidemiologic texts this is the first book that attempts to simplify complex epidemiologic methods for users of epidemiologic research namely clinicians and allied health researchers Additionally it is rare to find a book with integrates of basic research methodology into epidemiologic designs Finally research innovation and the current challenges of epidemiology are presented in this book to reflect the currency of the materials and the approach as well as the responses to the challenges of epidemiology today namely epigenomic epidemiology in environmental and gene interaction disease determinants A study could be statistically significant but biologically and clinically irrelevant since the statistical stability of a study does not rule out bias and confounding The p value is deemphasized while the use of effect size or magnitude and confidence intervals in the interpretation of results for application in clinical decision making is recommended The use of p value could lead to an erroneous interpretation of the effectiveness of treatment For example studies with large sample sizes and very little or insignificant effects of no clinical importance may be statistically significant while studies with small samples though a large magnitude of effects are labeled negative result i Such results are due to low statistical power and increasing variability hence the inability to pass the arbitrary litmus test of the 5 percent significance level Epidemiology Conceptualized Epidemiologic investigation and practice are as old as the history of modern medicine It dates back to Hippocrates circa 2 400 years ago In recommending the appropriate practice of medicine Hippocrates appealed to the physicians ability to understand the role of environmental factors in predisposition to disease and health in the community During the Middle Ages and the Renaissance epidemiologic principles continued to influence the practice of medicine as demonstrated in *De Morbis Artificum* 1713 by Ramazzini and the works on scrotal cancer in relation to chimney sweeps by Percival Pott in 1775 With the works of John Snow a British physician 1854 on cholera mortality in London the era of scientific epidemiology began By examining the distribution pattern of mortality and cholera in London Snow postulated that cholera was caused by contaminated water Epidemiology Today Epigenomic Epidemiology There are several definitions of epidemiology but a practical definition is necessary for the understanding of this science and art Epidemiology is the basic science of public health The objective of this profession is to assess the distribution and determinants of disease disabilities injuries natural

disasters tsunamis hurricanes tornados and earthquakes and health related events at the population level Epidemiologic investigation or research focuses on a specific population The basic issue is to assess the groups of people at higher risk women children men pregnant women teenagers whites African Americans Hispanics Asians poor affluent gay lesbians married single older individuals etc Epidemiology also examines how the frequency of the disease or the event of interest changes over time In addition epidemiology examines the variation of the disease of interest from place to place Simply descriptive epidemiology attempts to address the distribution of disease with respect to who when and where For example cancer epidemiologists attempt to describe the occurrence of prostate cancer by observing the differences in populations by age socioeconomic status occupation geographic locale race ethnicity etc Epidemiology also attempts to address the association between the disease and exposure For example why are some men at high risk for prostate cancer Does race ethnicity increase the risk for prostate cancer Simply is the association causal or spurious This process involves the effort to determine whether a factor exposure is associated with the disease outcome In the example of prostate cancer such exposure includes a high fat diet race ethnicity advancing age pesticides family history of prostate cancer and so on Whether or not the association is factual or a result of chance remains the focus of epidemiologic research The questions to be raised are as follows Is prostate cancer associated with pesticides Does pesticide cause prostate cancer Epidemiology often goes beyond disease exposure association or relationship to establish a causal association In this process of causal inference it depends on certain criteria one of which is the strength or magnitude of association leading to the recommendation of preventive measures However complete knowledge of the causal mechanism is not necessary prior to preventive measures for disease control Further findings from epidemiologic research facilitate the prioritization of health issues and the development and implementation of intervention programs for disease control and health promotion Epidemiology today reflects the application of gene and environment interaction in disease causation morbidity prognosis survival and mortality in subpopulation health outcomes The knowledge and understanding of subpopulation differentials in DNA methylation of specific genes and histone modification allows for the application of abnormal transcriptomes impaired gene expression protein synthesis dysfunctionality and abnormal cellular functionality This book is conceptually organized into three sections Section I deals with research methods section II epidemiologic designs as well as causal inference and perspectives in epidemiology while section III delves into perspectives epidemiologic challenges and special topics in epidemiology namely epidemiologic tree challenges emerging fields the consequentialist perspective of epidemiology and epidemiologic role in health and healthcare policy formulation as well as epigenomic epidemiology and epigenomic determinants of health EDH Throughout this book attempts are made to describe the research methods and non experimental as well as experimental designs Section I comprises research methods with an attempt to describe the following Research objectives and purposes Research questions Hypothesis statements null and alternative Rationales for research clinical reasoning and diagnostic tests

as well as Study conceptualization and conduct research question data collection data management hypothesis testing data analysis

Modern Epidemiologic Principles and Concepts Laurens Holmes, Jr, 2025-03-06

Modern Epidemiologic Principles and Concepts Study Conceptualization Design Conduct and Application We often conceive epidemiology in either simplistic or complex terms and neither of these is accurate To illustrate this the complexities in epidemiology could be achieved by considering a study to determine the correlation between serum lipid profile as total cholesterol HDL LDL triglyceride and total body fatness or obesity measured by BMI in children Two laboratories measured serum lipid profiles and one observed a correlation with BMI while the other did not Which is the reliable finding To address this question one needs to examine the context of blood drawing since fasting blood level may provide a better indicator of serum lipid Epidemiologic studies could be easily derailed given the inability to identify and address possible confounding Therefore understanding the principles and concepts used in epidemiologic studies designed and conducted to answer clinical research questions facilitates accurate and reliable findings in these areas Another similar example in a health fair setting involves geography and health termed health ography The risk of dying in one zip code A was 59.5 per 100,000 and in the other zip code B was 35.4 per 100,000 There is a common sense and non epidemiologic tendency to conclude that there is an increased risk of dying in zip code A To arrive at such inference one must first find out the age distribution of these two zip codes since advancing age is associated with increased mortality Indeed zip code A is comparable to the United States population while zip code B is the Mexican population These two examples are indicative of the need to understand epidemiologic concepts such as confounding by age or effect measure modification prior to undertaking clinical research This textbook describes the basics of research in medical and clinical settings as well as the concepts and application of epidemiologic designs in research Design transcends statistical techniques and no matter how sophisticated statistical modeling errors of design sampling cannot be corrected The author of this textbook has presented a complex field in a very simplified and reader friendly manner with the intent that such a presentation will facilitate the understanding of the design process and epidemiologic thinking in clinical research Additionally this book provides a very basic explanation of how to examine the data collected for research conduct for the possibility of confounders and how to address such confounders thus disentangling such effects for reliable and valid inference Research is presented as an exercise around measurement with measurement error inevitable in its conduct hence the inherent uncertainties of all findings in clinical and medical research

Modern Epidemiologic Principles and Concepts for Clinicians covers research conceptualization namely research objectives questions hypothesis design implementation data collection analysis results and interpretation While the primary focus of epidemiology is to assess the relationship between exposure risk or predisposing factor and outcome disease or health related event the causal association is presented in a simplified manner including the role of quantitative evidence synthesis QES in causal inference

Epidemiology has evolved over the past three decades resulting in several fields being developed This text presents in brief

the perspectives and future of epidemiology in the era of the molecular basis of medicine big data 3Ts and systems science Epidemiologic evidence is more reliable if conceptualized and conducted within the context of translational transdisciplinary and team science With molecular epidemiology we are better equipped with tools to identify molecular biologic indicators of risk as well as biologic alterations in the early stages of disease and with 3 Ts and systems science we are more capable of providing accurate and reliable inference on causality and outcomes research Further the author argues that unless sampling error and confounding are identified and addressed clinical research findings will remain largely inconsistent implying an inconsequential epidemiologic approach Appropriate knowledge of research conceptualization design and statistical inference is essential for conducting clinical and biomedical research This knowledge is acquired through the understanding of epidemiologic observational non experimental and experimental designs and the choice of the appropriate test statistic for statistical inference However regardless of how sophisticated the statistical technique employed for statistical inference is study conceptualization and design are the building blocks of valid scientific evidence Since clinical research is performed to improve patients care it remains relevant to assess not only the statistical significance but the clinical and biologic importance of the findings for clinical decision making in the care of an individual patient Therefore the aim of this book is to provide clinicians biomedical researchers graduate students in research methodology students of public health and all those involved in clinical biomedical research with a simplified but concise overview of the principles and practice of epidemiology In addition the author stresses common flaws in the conduct analysis and interpretation of epidemiologic studies Valid and reliable scientific research is that which considers the following elements in arriving at the truth from the data namely biological relevance clinical importance and statistical stability and precision statistical inference based on the p value and the 90 95 and 99 percent confidence interval The interpretation of results of new research must rely on factual association or effect and the alternative explanation namely systematic error random error precision confounding and effect measure modifier Therefore unless these perspectives are disentangled the results from any given research cannot be considered reliable However even with this disentanglement all study findings remain inconclusive with some degree of uncertainty This book presents a comprehensive guide on how to conduct clinical and medical research mainly research question formulation study implementation hypothesis testing using appropriate test statistics to analyze the data and results interpretation In so doing it attempts to illustrate the basic concepts used in study conceptualization epidemiologic design and appropriate test statistics for statistical inference from the data Therefore though statistical inference is emphasized throughout the presentation in this text equal emphasis is placed on clinical relevance or importance and biological relevance in the interpretation of the study results Specifically this book describes in basic terms and concepts how to conduct clinical and medical research using epidemiologic designs The author presents epidemiology as the main profession in the trans disciplinary approach to the understanding of complex ecologic models of disease and health Clinicians even those without

preliminary or infantile knowledge of epidemiologic designs could benefit immensely from what when where who and how studies are conceptualized data collected as planned with the scale of measurement of the outcome and independent variables data edited cleaned and processed prior to analysis appropriate analysis based on statistical assumptions and rationale results tabulation for scientific appraisal results interpretation and inference Unlike most epidemiologic texts this is the first book that attempts to simplify complex epidemiologic methods for users of epidemiologic research namely clinicians and allied health researchers Additionally it is rare to find a book with integrates of basic research methodology into epidemiologic designs Finally research innovation and the current challenges of epidemiology are presented in this book to reflect the currency of the materials and the approach as well as the responses to the challenges of epidemiology today namely big data accountability and policy A study could be statistically significant but biologically and clinically irrelevant since the statistical stability of a study does not rule out bias and confounding The p value is deemphasized while the use of effect size or magnitude and confidence intervals in the interpretation of results for application in clinical decision making is recommended The use of p value could lead to an erroneous interpretation of the effectiveness of treatment For example studies with large sample sizes and very little or insignificant effects of no clinical importance may be statistically significant while studies with small samples though a large magnitude of effects are labeled negative result Such results are due to low statistical power and increasing variability hence the inability to pass the arbitrary litmus test of the 5 percent significance level

Epidemiology Conceptualized Epidemiologic investigation and practice are as old as the history of modern medicine It dates back to Hippocrates circa 2 400 years ago In recommending the appropriate practice of medicine Hippocrates appealed to the physicians ability to understand the role of environmental factors in predisposition to disease and health in the community During the Middle Ages and the Renaissance epidemiologic principles continued to influence the practice of medicine as demonstrated in *De Morbis Artificum* 1713 by Ramazzini and the works on scrotal cancer in relation to chimney sweeps by Percival Pott in 1775 With the works of John Snow a British physician 1854 on cholera mortality in London the era of scientific epidemiology began By examining the distribution pattern of mortality and cholera in London Snow postulated that cholera was caused by contaminated water

Epidemiology Today Epigenomic Epidemiology There are several definitions of epidemiology but a practical definition is necessary for the understanding of this science and art Epidemiology is the basic science of public health The objective of this profession is to assess the distribution and determinants of disease disabilities injuries natural disasters tsunamis hurricanes tornados and earthquakes and health related events at the population level Epidemiologic investigation or research focuses on a specific population The basic issue is to assess the groups of people at higher risk women children men pregnant women teenagers whites African Americans Hispanics Asians poor affluent gay lesbians married single older individuals etc Epidemiology also examines how the frequency of the disease or the event of interest changes over time In addition epidemiology examines the variation of the disease of interest from place to place

Simply descriptive epidemiology attempts to address the distribution of disease with respect to who when and where. For example, cancer epidemiologists attempt to describe the occurrence of prostate cancer by observing the differences in populations by age, socioeconomic status, occupation, geographic locale, race, ethnicity, etc. Epidemiology also attempts to address the association between the disease and exposure. For example, why are some men at high risk for prostate cancer? Does race/ethnicity increase the risk for prostate cancer? Simply is the association causal or spurious? This process involves the effort to determine whether a factor/exposure is associated with the disease outcome. In the example of prostate cancer, such exposure includes a high fat diet, race/ethnicity, advancing age, pesticides, family history of prostate cancer, and so on. Whether or not the association is factual or a result of chance remains the focus of epidemiologic research. The questions to be raised are as follows: Is prostate cancer associated with pesticides? Does pesticide cause prostate cancer? Epidemiology often goes beyond disease/exposure association or relationship to establish a causal association. In this process of causal inference, it depends on certain criteria, one of which is the strength or magnitude of association leading to the recommendation of preventive measures. However, complete knowledge of the causal mechanism is not necessary prior to preventive measures for disease control. Further findings from epidemiologic research facilitate the prioritization of health issues and the development and implementation of intervention programs for disease control and health promotion. Epidemiology today reflects the application of gene and environment interaction in disease causation, morbidity, prognosis, survival, and mortality in subpopulation health outcomes. The knowledge and understanding of subpopulation differentials in DNA methylation of specific genes and histone modification allows for the application of abnormal transcriptomes, impaired gene expression, protein synthesis dysfunctionality, and abnormal cellular functionality.

Clinical and Translational Science
David Robertson, Gordon H. Williams, 2009-03-02

Clinical or translational science is the field of study devoted to investigating human health and disease interventions and outcomes for the purposes of developing new treatment approaches, devices, and modalities to improve health. New molecular tools and diagnostic technologies based on clinical and translational research have led to a better understanding of human disease and the application of new therapeutics for enhanced health. Clinical and Translational Science is designed as the most authoritative and modern resource for the broad range of investigators in various medical specialties taking on the challenge of clinical research. Prepared with an international perspective, this resource begins with experimental design and investigative tools to set the scene for readers. It then moves on to human genetics and pharmacology with a focus on statistics, epidemiology, genomic information, drug discovery and development, and clinical trials. Finally, it turns to legal, social, and ethical issues of clinical research, concluding with a discussion of future prospects to provide readers with a comprehensive view of this developing area of science. Clinical research is one of the fastest growing fields in private practice and academic medicine, with practical biological, physiological, cellular, and therapeutic applications. Contributions from international leaders provide insight into background and future understanding.

for clinical and translational science Provides the structure for complete instruction and guidance on the subject from fundamental principles approaches and infrastructure to human genetics human pharmacology research in special populations the societal context of human research and the future of human research **Clinical Trials** Steven Piantadosi, 2017-10-06 Presents elements of clinical trial methods that are essential in planning designing conducting analyzing and interpreting clinical trials with the goal of improving the evidence derived from these important studies This Third Edition builds on the text's reputation as a straightforward detailed and authoritative presentation of quantitative methods for clinical trials Readers will encounter the principles of design for various types of clinical trials and are then skillfully guided through the complete process of planning the experiment assembling a study cohort assessing data and reporting results Throughout the process the author alerts readers to problems that may arise during the course of the trial and provides common sense solutions All stages of therapeutic development are discussed in detail and the methods are not restricted to a single clinical application area The authors bases current revisions and updates on his own experience classroom instruction and feedback from teachers and medical and statistical professionals involved in clinical trials The Third Edition greatly expands its coverage ranging from statistical principles to new and provocative topics including alternative medicine and ethics middle development comparative studies and adaptive designs At the same time it offers more pragmatic advice for issues such as selecting outcomes sample size analysis reporting and handling allegations of misconduct Readers familiar with the First and Second Editions will discover revamped exercise sets an updated and extensive reference section new material on endpoints and the developmental pipeline among others and revisions of numerous sections In addition this book Features accessible and broad coverage of statistical design methods the crucial building blocks of clinical trials and medical research now complete with new chapters on overall development middle development comparative studies and adaptive designs Teaches readers to design clinical trials that produce valid qualitative results backed by rigorous statistical methods Contains an introduction and summary in each chapter to reinforce key points Includes discussion questions to stimulate critical thinking and help readers understand how they can apply their newfound knowledge Provides extensive references to direct readers to the most recent literature and there are numerous new or revised exercises throughout the book Clinical Trials A Methodologic Perspective Third Edition is a textbook accessible to advanced undergraduate students in the quantitative sciences graduate students in public health and the life sciences physicians training in clinical research methods and biostatisticians and epidemiologists This book is accompanied by downloadable files available below under the DOWNLOADS tab These files include MATHEMATICA program A set of downloadable files that tracks the chapters containing code pertaining to each SAS PROGRAMS and DATA FILES used in the book The following software programs included in the downloadables were developed by the author Steven Piantadosi M D Ph D RANDOMIZATION This program generates treatment assignments for a clinical trial using blocked stratified

randomization CRM Implements the continual reassessment methods for dose finding clinical trials OPTIMAL Calculates two stage optimal phase II designs using the Simon method POWER This is a power and sample size program for clinical trials Executables for installing these programs can also be found at <https://riscweb.csmc.edu/biostats> Steven Piantadosi MD PhD is the Phase One Foundation Distinguished Chair and Director of the Samuel Oschin Cancer Institute and Professor of Medicine at Cedars Sinai Medical Center in Los Angeles California Dr Piantadosi is one of the world's leading experts in the design and analysis of clinical trials for cancer research He has taught clinical trials methods extensively in formal courses and short venues He has advised numerous academic programs and collaborations nationally regarding clinical trial design and conduct and has served on external advisory boards for the National Institutes of Health and other prominent cancer programs and centers The author of more than 260 peer reviewed scientific articles Dr Piantadosi has published extensively on research results clinical applications and trial methodology While his papers have contributed to many areas of oncology he has also collaborated on diverse studies outside oncology including lung disease and degenerative neurological disease

Biostatistics in Clinical Trials Carol K. Redmond, Theodore Colton, 2001-04-25 The second volume in the Wiley reference series in Biostatistics Featuring articles from the prestigious Encyclopedia of Biostatistics many of which have been fully revised and updated to include recent developments Biostatistics in Clinical Trials also includes up to 25% newly commissioned material reflecting the latest thinking in Bayesian methods Benefit risk assessment Cost effectiveness Ethics Fraud With exceptional contributions from leading experts in academia government and industry Biostatistics in Clinical Trials has been designed to complement existing texts by providing extensive up to date coverage and introducing the reader to the research literature Offering comprehensive coverage of all aspects of clinical trials Biostatistics in Clinical Trials Includes concise definitions and introductions to numerous concepts found in current literature Discusses the software and textbooks available Uses extensive cross references helping to facilitate further research and enabling the reader to locate definitions and related concepts Biostatistics in Clinical Trials offers both academics and practitioners from various disciplines and settings such as universities the pharmaceutical industry and clinical research organisations up to date information as well as references to assist professionals involved in the design and conduct of clinical trials *Modern Biostatistical Principles and Concepts* Laurens Holmes, Jr, 2025-03-14 Modern Biostatistical Principles Conduct Clinical Medicine and Public Population Health Assessment Clinical medicine or surgery continues to make advances through evidence that is judged to be objectively drawn from the care of individual patients The natural observation of individuals remains the basis for our researchable questions formulation and the subsequent hypothesis testing Evidence based medicine or surgery depends on how critical we are in evaluating evidence in order to inform our practice These evaluations no matter how objective are never absolute but probabilistic as we will never know with absolute certainty how to treat future patients who were not a part of our study Despite the obstacles facing us today in an attempt to provide an objective

evaluation of our patients since all our decisions are based on a judgment of some evidence we have progressed from expert opinion to the body of evidence from randomized controlled clinical trials as well as cohort investigations prospective and retrospective The conduct of clinical trials though termed the gold standard which yields more reliable and valid evidence from the data relative to non experimental or observational designs depends on how well it is designed and conducted prior to outcomes data collection analysis results interpretation and dissemination The designs and the techniques used to draw statistical inferences are often beyond the average clinician's understanding A text that brings hypothesis formulation analysis and how to interpret the results of the findings is long overdue and highly anticipated Statistical modeling which is fundamentally a journey from sample to the application of findings is essential to evidence discovery This text Modern Biostatistics for Clinical Biomedical and Population Based Researchers has filled this gap not only in the way complex modeling is explained but the simplification of statistical techniques in a way that had never been explained before This text has been prepared intentionally at the rudimentary level to benefit clinicians without sophisticated mathematical backgrounds or previous advanced knowledge of biostatistics as applied statistics in health and medicine Also biomedical researchers who may want to conduct clinical research as well as consumers of research products may benefit from the sampling techniques their relevance to scientific evidence discovery as well a simplified approach to statistical modeling of clinical and biomedical research data It is with this expectation and enthusiasm that we recommend this text to clinicians in all fields of clinical and biomedical research One's experience with biomedical research and how the findings in this arm are translated to the clinical environment signals the need for the application of biological and clinical relevance of findings prior to statistical inference The examples provided by the author to simplify research methods are familiar to orthopedic surgeons as well as clinicians in other specialties of medicine and surgery Whereas statistical inference is essential in our application of the research findings to clinical decision making regarding the care of our patients statistical inference without clinical relevance or importance can be very misleading and meaningless The authors have attempted to deemphasize the p value in the interpretation of clinical and biomedical research findings by stressing the importance of confidence intervals which allow for the quantification of evidence For example a large study due to a large sample size that minimizes variability may show a statistically significant difference while in reality the difference is too insignificant to warrant any clinical importance In contrast a small study as frequently seen in most clinical trials or surgical research may have a large effect size of clinical relevance but not statistically significant at $p < 0.05$ Thus without considering the magnitude of the effect size with the confidence interval we tend to regard these studies as negative findings which is erroneous since the absence of evidence simply on the basis of an arbitrary significance level of 5% does not necessarily mean evidence of absence 1 In effect clinical research results cannot be adequately interpreted without first considering the biological and clinical significance of the data before the statistical stability of the findings p value and 95% Confidence Interval since the p value as observed by the

authors merely reflects the size of the study and not the measure of evidence In recommending this text it is one's inclination that this book will benefit clinicians research fellows clinical fellows postdoctoral students in biomedical and clinical settings nurses clinical research coordinators physical therapists and all those involved in clinical research design conduct and analysis of research data for statistical and clinical relevance Convincingly knowledge gained from this text will lead to our improvement of patient care through well conceptualized research Therefore with the knowledge that no book is complete no matter its content or volume especially a book of this nature which is prepared to guide clinicians on sampling statistical modeling of data and interpretation of findings this book will benefit clinicians who are interested in applying appropriate statistical technique to scientific evidence discovery Finally we are optimistic that this book will bridge the gap in knowledge and practice of clinical and biomedical research especially for clinicians in busy practice who are passionate about making a difference in their patient's care through scientific research initiatives **Encyclopedia of Public Health** Sally

Kuykendall, 2018-06-08 Providing context to today's public health practices and broad coverage of topics this book demonstrates how cross disciplinary studies are critical to addressing current health issues The concepts of public health and the methods we use to care for and promote the health of people in communities groups and our nation as a whole are of interest to all health professionals Comprising contributions from historians scholars researchers sociologists and other public health professionals the Encyclopedia of Public Health Principles People and Programs offers a firsthand in depth view of public health as it applies to everyday life and practice The encyclopedia contains a wealth of information on critical theories people and movements and shows how various disciplines can work together to create healthy communities and practices for many people As a secondary objective the book encourages future generations to actively participate in public health This reference covers the defining moments in the development of public health from ancient times to the modern day and offers entries with historical information and examinations of current controversies as they relate to recurring social conflicts The entries provide a breadth and depth of content that is accessible to a wide readership Readers will understand the benefits of physical activity and good nutrition as well as the psychology behind the choices that we make and how early life and social experiences can influence behaviors even decades after the event The wide variety of topics covered includes the life expectancy of Americans at birth the Tuskegee syphilis study and marijuana use and will give readers an informed perspective on past public health successes and likely directions for the future Paediatric Cardiology Robert H.

Anderson, Edward J. Baker, Andrew Redington, Michael L. Rigby, Daniel Penny, Gil Wernovsky, 2009-09-25 As patients live longer and need to be treated over the long term and the management of pediatric cardiology problems and congenital heart disease moves more into the mainstream turn to Pediatric Cardiology for current clinical guidance Trust Dr Robert Anderson godfather of cardiac morphology to bring you coverage of potential cardiovascular anomalies all potential diseases related to anomalies or developmental problems and methods for management and treatment New contributors from all over the world

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Encyclopedia of Clinical Pharmacy Joseph T. DiPiro, 2012-11-04 The Encyclopedia of Clinical Pharmacy is a valuable resource for today's clinical pharmacist and pharmacotherapist Over 200 researchers and practitioners provide ready access to more than 5 000 primary literature citations and hard to find research on Gene therapy Health service delivery models Best practices documents Pharmaceutical software development Legal controversies ethical issues and court rulings Drug dosing and electronic prescription Post marketing surveillance Generic equivalency Quality management procedures Educational and training programs Compiling expertise and recommendations from the American College of Clinical Pharmacy and the American Society of Health System Pharmacists the Encyclopedia unravels the increasing complexity of pharmacotherapy the problems of medication related morbidity and mortality and the impact that clinically empowered pharmacists have on assuring safe and effective pharmaceutical care for patients

Principles of Research Design and Drug Literature Evaluation Rajender R. Aparasu, John P. Bentley, 2014-03-07 Principles of Research Design and Drug Literature Evaluation is a unique resource that provides a balanced approach covering critical elements of clinical research biostatistical principles and scientific literature evaluation techniques for evidence based medicine This accessible text provides comprehensive course content that meets and exceeds the curriculum standards set by the Accreditation Council for Pharmacy Education ACPE Written by expert authors specializing in pharmacy practice and research this valuable text will provide pharmacy students and practitioners with a thorough understanding of the principles and practices of drug literature evaluation with a strong grounding in research and biostatistical principles Principles of Research Design and Drug Literature Evaluation is an ideal foundation for professional pharmacy students and a key resource for pharmacy residents research fellows practitioners and clinical researchers FEATURES Chapter Pedagogy Learning Objectives Review Questions References and Online Resources Instructor Resources PowerPoint Presentations Test Bank and an Answer Key Student Resources a Navigate Companion Website including Crossword Puzzles Interactive Flash

Cards Interactive Glossary Matching Questions and Web Links From the Foreword This book was designed to provide and encourage practitioner s development and use of critical drug information evaluation skills through a deeper understanding of the foundational principles of study design and statistical methods Because guidance on how a study s limited findings should not be used is rare practitioners must understand and evaluate for themselves the veracity and implications of the inherently limited primary literature findings they use as sources of drug information to make evidence based decisions together with their patients The editors organized the book into three supporting sections to meet their pedagogical goals and address practitioners needs in translating research into practice Thanks to the editors authors and content of this book you can now be more prepared than ever before for translating research into practice L Douglas Ried PhD FAPhA Editor in Chief Emeritus Journal of the American Pharmacists Association Professor and Associate Dean for Academic Affairs College of Pharmacy University of Texas at Tyler Tyler Texas

Bayesian Analysis with R for Drug Development Harry Yang, Steven Novick, 2019-06-26 Drug development is an iterative process The recent publications of regulatory guidelines further entail a lifecycle approach Blending data from disparate sources the Bayesian approach provides a flexible framework for drug development Despite its advantages the uptake of Bayesian methodologies is lagging behind in the field of pharmaceutical development Written specifically for pharmaceutical practitioners Bayesian Analysis with R for Drug Development Concepts Algorithms and Case Studies describes a wide range of Bayesian applications to problems throughout pre clinical clinical and Chemistry Manufacturing and Control CMC development Authored by two seasoned statisticians in the pharmaceutical industry the book provides detailed Bayesian solutions to a broad array of pharmaceutical problems Features Provides a single source of information on Bayesian statistics for drug development Covers a wide spectrum of pre clinical clinical and CMC topics Demonstrates proper Bayesian applications using real life examples Includes easy to follow R code with Bayesian Markov Chain Monte Carlo performed in both JAGS and Stan Bayesian software platforms Offers sufficient background for each problem and detailed description of solutions suitable for practitioners with limited Bayesian knowledge Harry Yang Ph D is Senior Director and Head of Statistical Sciences at AstraZeneca He has 24 years of experience across all aspects of drug research and development and extensive global regulatory experiences He has published 6 statistical books 15 book chapters and over 90 peer reviewed papers on diverse scientific and statistical subjects including 15 joint statistical works with Dr Novick He is a frequent invited speaker at national and international conferences He also developed statistical courses and conducted training at the FDA and USP as well as Peking University Steven Novick Ph D is Director of Statistical Sciences at AstraZeneca He has extensively contributed statistical methods to the biopharmaceutical literature Novick is a skilled Bayesian computer programmer and is frequently invited to speak at conferences having developed and taught courses in several areas including drug combination analysis and Bayesian methods in clinical areas Novick served on IPAC RS and has chaired several national statistical conferences

Trustworthy AI in Medical Imaging Marco Lorenzi, Maria A

Zuluaga,2024-11-25 Trustworthy AI in Medical Imaging brings together scientific researchers medical experts and industry partners working in the field of trustworthiness bridging the gap between AI research and concrete medical applications and making it a learning resource for undergraduates masters students and researchers in AI for medical imaging applications The book will help readers acquire the basic notions of AI trustworthiness and understand its concrete application in medical imaging identify pain points and solutions to enhance trustworthiness in medical imaging applications understand current limitations and perspectives of trustworthy AI in medical imaging and identify novel research directions Although the problem of trustworthiness in AI is actively researched in different disciplines the adoption and implementation of trustworthy AI principles in real world scenarios is still at its infancy This is particularly true in medical imaging where guidelines and standards for trustworthiness are critical for the successful deployment in clinical practice After setting out the technical and clinical challenges of AI trustworthiness the book gives a concise overview of the basic concepts before presenting state of the art methods for solving these challenges Introduces the key concepts of trustworthiness in AI Presents state of the art methodologies for trustworthy AI in medical imaging Outlines major initiatives focusing on real world deployment of trustworthy principles in medical imaging applications Presents outstanding questions still to be solved and discusses future research directions

Abeloff's Clinical Oncology E-Book Martin D. Abeloff,James O. Armitage,John E. Niederhuber,Michael B. Kastan,W. Gillies McKenna,2008-06-30 Carrying on the tradition established by its founding editor the late Dr Martin Abeloff the 4th Edition of this respected reference synthesizes all of the latest oncology knowledge in one practical clinically focused easy to use volume It incorporates basic science pathology diagnosis management outcomes rehabilitation and prevention all in one convenient resource equipping you to overcome your toughest clinical challenges What s more you can access the complete contents of this Expert Consult title online and tap into its unparalleled guidance wherever and whenever you need it most Equips you to select the most appropriate tests and imaging studies for diagnosing and staging each type of cancer and manage your patients most effectively using all of the latest techniques and approaches Explores all of the latest scientific discoveries implications for cancer diagnosis and management Employs a multidisciplinary approach with contributions from pathologists radiation oncologists medical oncologists and surgical oncologists for well rounded perspectives on the problems you face Offers a user friendly layout with a consistent chapter format summary boxes a full color design and more than 1 445 illustrations 1 200 in full color to make reference easy and efficient Offers access to the book s complete contents online fully searchable from anyplace with an Internet connection Presents discussions on cutting edge new topics including nanotechnology functional imaging signal transduction inhibitors hormone modulators complications of transplantation and much more Includes an expanded color art program that highlights key points illustrates relevant science and clinical problems and enhances your understanding of complex concepts

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Gerald van Belle,Lloyd D. Fisher,Patrick J. Heagerty,Thomas Lumley,2004-10-06 A respected introduction to biostatistics

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Biostatistics and Epidemiology Sylvia Wassertheil-Smoller, Jordan Smoller, 2024-08-08 This book teaches foundations of epidemiological design and statistical methods as well as including topics applicable to new areas of research Since the publication of the first edition Biostatistics and Epidemiology has attracted loyal readers from various specialty areas in the biomedical community The Fifth Edition includes coverage of fixed and random effects and mixed effects models Poisson regression constructing confidence intervals for U shaped relationships analysis of rare variants Mendelian randomization and aspects of machine learning and big data analytics Biostatistics and Epidemiology was written to be accessible for readers without backgrounds in mathematics It provides clear explanations of underlying principles as well as practical guidelines of how to do it and how to interpret it Key features include a philosophical and logical explanation at the beginning of the book subsections that can stand alone or serve as reference cross referencing recommended reading and appendices covering sample calculations for various statistics in the text Basic & Clinical Biostatistics: Fifth Edition Susan White, 2019-10-22 Learn to evaluate and apply statistics in medicine medical research and all health related fields A Doody s Core Title for 2023 Basic Clinical Biostatistics provides medical students researchers and practitioners with the knowledge needed to develop sound judgment about data applicable to clinical care This fifth edition has been updated throughout to deliver a comprehensive timely introduction to biostatistics and epidemiology as applied to medicine clinical practice and research Particular emphasis is on study design and interpretation of results of research The book features Presenting Problems drawn from studies published in the medical literature end of chapter exercises and a reorganization of content to reflect the way investigators ask research questions To facilitate learning each chapter contain a set of key concepts underscoring the important ideas discussed Features Key components include a chapter on survey research and expanded discussion of logistic regression the Cox model and other multivariate statistical methods Extensive examples illustrate statistical methods and design issues Updated examples using R an open source statistical software package

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