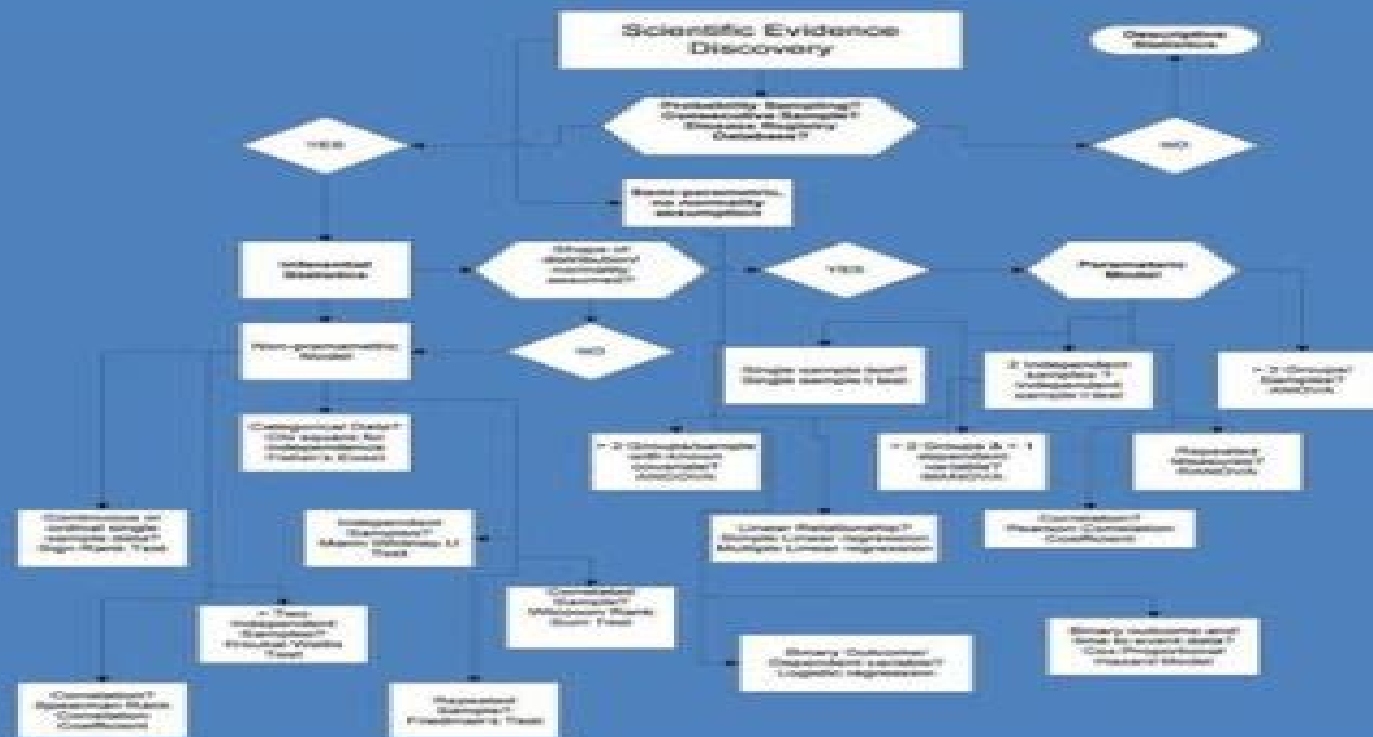


Concise Biostatistical Principles & Concepts

Guidelines for Clinical and Biomedical Researchers



Laurens Holmes, Jr.
and Franklin Opara

Concise Biostatistical Principles Concepts Guidelines For Clinical And Biomedical Researchers

Carol K. Redmond, Theodore Colton



Concise Biostatistical Principles Concepts Guidelines For Clinical And Biomedical Researchers:

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 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 rationales 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 a 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
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 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 biostatics 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

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 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 author's 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

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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

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

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