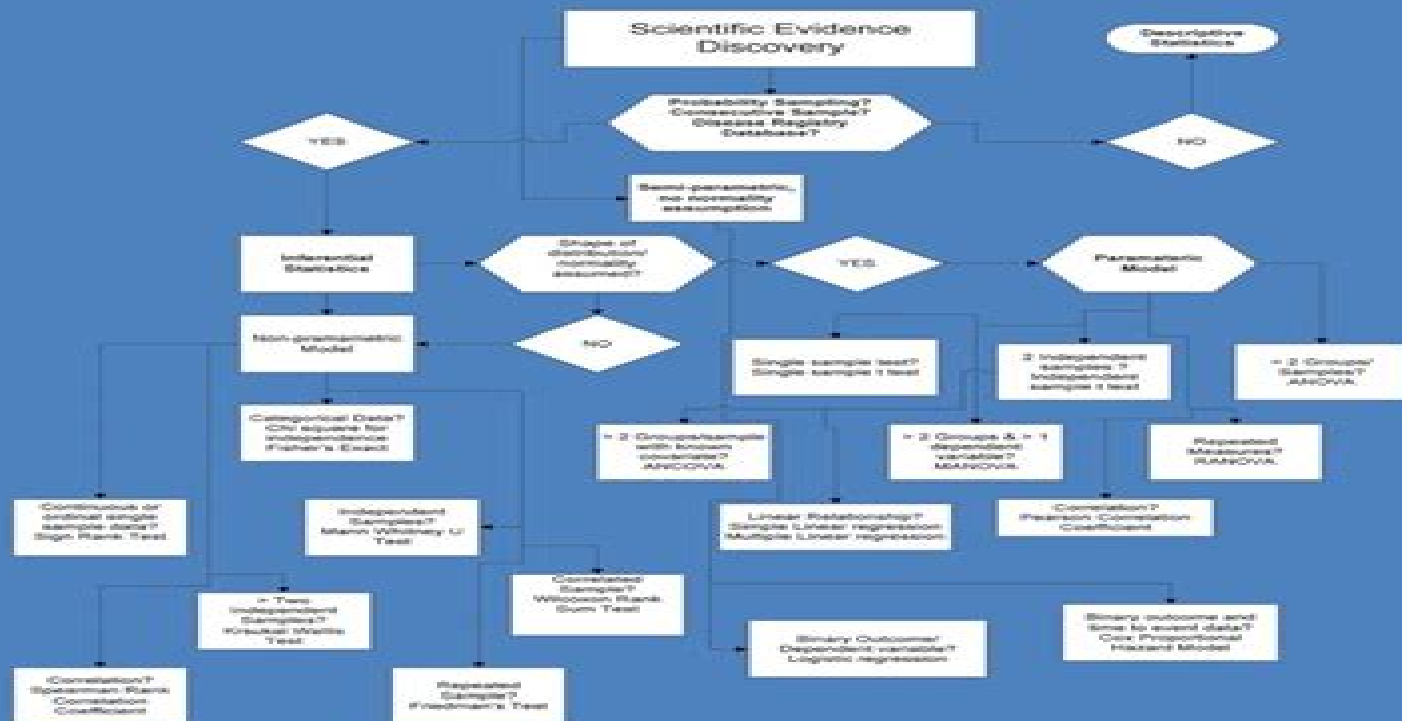


# Concise Biostatistical Principles & Concepts

Guidelines for Clinical and Biomedical Researchers



Laurens Holmes, Jr.  
and Franklin Opara

# Concise Biostatistical Principles Concepts Guidelines For Clinical And Biomedical Researchers

**Marco Lorenzi, Maria A Zuluaga**



## **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 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 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. 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 patients' care through scientific research initiatives.

**Concise Epidemiologic Principles and Concepts** Laurens Holmes, Franklin Opara, 2013-09

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 error 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 conduct, hence 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 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 *Clinical Trials* Steven Piantadosi, 2024-04-03 Comprehensive resource presenting methods essential in planning designing conducting analyzing and interpreting clinical trials The Fourth Edition of Clinical Trials builds on the text's reputation as a straightforward detailed and authoritative presentation of quantitative methods for clinical trials discussing principles of design for various types of clinical trials and elements of planning the experiment assembling a study cohort assessing data and reporting results Each chapter contains an introduction and summary to reinforce key points Discussion questions stimulate critical thinking and help readers understand how they can apply their newfound knowledge Written by a highly qualified author with significant experience in the field the Fourth Edition of Clinical Trials approaches the topic with Problems that may arise during a trial and accompanying common sense solutions Design alternatives for addressing many questions in therapeutic development Statistical principles with new and provocative topics such as generalizing results operating characteristics trial issues during the COVID 19 pandemic and more Alternative medicine ethics middle development comparative studies adaptive designs and clinical trials using point of care data Revamped exercise sets updated and extensive references new material on endpoints and the developmental pipeline and revisions of numerous sections tables and figures Standing out due to its accessible and broad coverage of statistical design methods which are the building blocks of clinical trials and medical research Clinical Trials is an essential learning aid on the subject for undergraduate and graduate clinical trials courses

**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 including 70% new to this edition present the latest challenges in the field and emphasize the adolescent and post operative outcomes for management Now in full color this leading reference offers you everything you need to treat and manage pediatric heart conditions A comprehensive and exhaustive reference of fundamental and clinical aspects of heart disease in infancy and childhood The contributors are well known experts in the field and the editors are a world class group who have published extensively in the field Emphasizes the treatment of corrected congenital heart disease for coverage of the clinical management of cardiac problems in the adolescent and young adult Integrates development in chapters on lesions to make physiology clinically relevant for the specific cardiac lesions Provides the latest clinical perspectives on neonate cardiac development management issues so you can offer the best long term care Presents the contributions of 70% new authors from all over the world in a consistent format to make referencing global perspectives quick and easy Captures the nuances of the anatomical structure of lesions through full color illustrations depicting morphologic congenital and surgically corrected examples for exceptional visual guidance

**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



*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 Expanded coverage of data visualization including content on visual perception and discussion of tools such as Tableau Qlik and MS Power BI Sampling and power calculations imbedded with discussion of the statistical model Updated content examples and data sets throughout **Undersea Biomedical Research**, 1991

**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 *Choice*,2008     **Directory of Research Grants, 1995** Lynn E. Miner,1994     **Biostatistics** Gerald van Belle,2004-07-26 This versatile reference provides a wide ranging look at basic and advanced biostatistical concepts and methods in a format calibrated to individual interests and levels of proficiency Written with an eye toward the use of computer applications the book examines the design of medical studies descriptive statistics and introductory ideas of probability theory and statistical inference explores more advanced statistical methods and illustrates important current uses of biostatistics Miwest

Announcement University of California, Los Angeles. School of Medicine,1990     **Biostatistics and Epidemiology** Sylvia Wassertheil-Smoller,2004-02-11 For the new edition of Biostatistics and Epidemiology Dr Wassertheil Smoller has included several new chapters genetic statistics molecular epidemiology scientific integrity and research ethics and a new appendix on the basic concepts of genetics and a glossary of genetic terminology She has also expanded the coverage of multi center trials an important aspect of implementation of the standards of evidence based medicine controversies in screening for prostate colon breast and other cancers     Directory of Biomedical and Health Care Grants ,1989     *Stanford Bulletin* ,2003     **Graduate School** Indiana University. Graduate School,1972     **Bulletin of the Medical Library Association** Medical Library Association,1990

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