Research

FOURTH EDITION

Successful Approaches in Nutrition and Dietetics

Linda Van Horn, PhD, RDN
and Judith Beto, PhD, RDN
Editors

eat right® Academy of Nutrition and Dietetics

Academy of Nutrition and Dietetics
120 S. Riverside Plaza, Suite 2190
Chicago, IL 60606-6995

Research: Successful Approaches in Nutrition and Dietetics, Fourth Edition
ISBN 978-0-88091-946-3 (print)
ISBN 978-0-88091-947-0 (eBook)
Catalog Number 199919 (print)
Catalog Number 199919e (eBook)

10 9 8 7 6 5 4 3 2 1

For more information on the Academy of Nutrition and Dietetics, visit www.eatright.org.

Library of Congress Cataloging-in-Publication Data
Names: Van Horn, Linda, editor. | Beto, Judith A., editor. | Academy of Nutrition and Dietetics, issuing body.
Title: Research : successful approaches in nutrition and dietetics / [edited by] Linda Van Horn and Judith Beto.
Other titles: Research (Van Horn)
Description: 4th edition. | Chicago, IL : Academy of Nutrition and Dietetics, [2019] | Includes bibliographical references and index.
Identifiers: LCCN 2018060019 (print) | LCCN 2018061669 (ebook) | ISBN 9780880919470 (eBook) | ISBN 9780880919463 (print : alk. paper)
Subjects: | MESH: Nutritional Physiological Phenomena | Research Design | Data Collection | Dietetics--methods | Epidemiologic Methods
Classification: LCC TX367 (ebook) | LCC TX367 (print) | NLM QU 145 | DDC 613.2072--dc23
LC record available at https://lccn.loc.gov/2018060019

Contents

Section 4: Observational and Experimental Research

Section 5: Integrative and Translational Research

Section 6: Evaluation and Assessment Methods in Research

Section 9: Presentation of Research Data

Section 10: Applications of Research to Practice

List of Boxes, Tables, and Figures

Boxes

Tables

Figures

Editors

Linda Van Horn, PhD, RDN, earned her bachelor's degree from Purdue University in Nutrition and Dietetics, her master's degree from the University of Pittsburgh in Exercise Physiology, and her doctorate from the University of Illinois at Chicago in Public Health. She completed her dietetic internship at Indiana University in Indianapolis. She began her career as a hospital dietitian I at the University of Illinois Hospitals and Clinics and eventually joined the faculty at Northwestern University Feinberg School of Medicine, where she is currently a tenured professor in the Department of Preventive Medicine and Associate Dean for Faculty Development. She served as Editor-in-Chief of the *Journal of the Academy of Nutrition and Dietetics* for the ten-year term limit and chaired the 2010 US Dietary Guidelines Advisory Committee.

Judith Beto, PhD, RDN, earned her bachelor's degree from Dominican University in Nutrition and Dietetics, her master's degree in Health Professions Education from the University of Illinois at Chicago, and her doctorate from the University of Chicago in Measurement, Evaluation, and Statistical Analysis. She completed her dietetic internship at the Hines Veterans Administration Hospital where she continued as a renal dietitian. She was the department chair and tenured professor of Nutrition Sciences at Dominican University until 2012. She still collaborates as a Research Associate in Nephrology and Hypertension at Loyola University Chicago, Health Sciences Division. She serves as a Research Editor for the *Journal of the Academy of Nutrition and Dietetics* and as an elected public member of the National Board of Podiatric Medical Examiners.

Contributors

Regan L. Bailey, PhD, MPH, RD
Associate Professor, Purdue University
West Lafayette, IN

Judith Beto, PhD, RDN
Research Associate, Loyola University Healthcare System
Maywood, IL

Carol J. Boushey, PhD, MPH, RDN
Associate Research Professor, Epidemiology Program, University of Hawaii Cancer Center
Honolulu, HI

Maureen Brady Moran, MPH
Assistant Professor of Preventive Medicine, Northwestern University, Feinberg School of Medicine,
Chicago, IL

Laura D. Byham-Gray, PhD, RDN, FNKF
Professor and Vice Chair of Research, Rutgers University , Department of Clinical and Preventive Nutrition Sciences
New Brunswick, NJ

Catherine M. Champagne PhD, RDN, LDN, FTOS, FAHA, FADA, FAND
Professor and Chief, Nutritional Epidemiology/Dietary Assessment & Nutrition Counseling , Pennington Biomedical Research Center, Part of Louisiana State University
Baton Rouge, LA

Feon Cheng, PhD, MPH, RDN, CHTS-CP
Nutrition Researcher, Academy of Nutrition and Dietetics
Los Angeles, CA

Marilyn C. Cornelis, PhD
Assistant Professor, Northwestern University Feinberg School of Medicine
Chicago, IL

Sharon M. Donovan, PhD, RD
Professor and Melissa M. Noel Endowed Chair in Diet and Health, University of Illinois at Urbana-Champaign
Urbana, IL

Judith A. Gilbride, PhD, RDN, FAND
Professor Emerita, Department of Nutrition and Food Studies, New York University Steinhardt
New York, NY

Philip Gleason, PhD
Senior Fellow, Mathematica Policy Research
Geneva, NY

Geoffrey W. Greene, PhD, RD, LDN
Professor and Dietetic Internship Director, University of Rhode Island
Kingston, RI

Mary B. Gregoire, PhD, RD, FADA, FAND
Executive Director, Accreditation Council for Education in Nutrition and Dietetics
Chicago, IL

Rosa K. Hand, PhD, RDN, LD, FAND
Instructor and Director, Combined Dietetic Internship/Master's Degree Program, Case Western Reserve University
Cleveland, OH

Deepa Handu, PhD, RDN
Senior Scientific Director, Evidence Analysis Center, Academy of Nutrition and Dietetics
Chicago, IL

Jeffrey Harris, DrPH, MPH, RDN, LDN, FAND
Professor, Department of Nutrition, West Chester University of Pennsylvania
West Chester, PA

David Haytowitz, MSc
Nutritionist, USDA-ARS-BHNRC Nutrient Data Laboratory
Beltsville, MD

James H. Hollis, PhD, BSc(Hons),
Associate Professor Food Science and Human Nutrition, Iowa State University
Ames, IA

Sharon I. Kirkpatrick, PhD, RD
Associate Professor, University of Waterloo
Waterloo, ON, Canada

Carol Koprowski, PhD, RDN
Clinical Assistant Professor of Preventative Medicine, Keck School of Medicine at the University of Southern California
Los Angeles, CA

Joanne Kouba, PhD, RDN
Associate Professor, Loyola University of Chicago, Health Science Campus
Maywood, IL

Nicole Larson, PhD, MPH, RDN
Senior Research Associate, University of Minnesota School of Public Health
Minneapolis, MN

JoAnn E. Manson, MD, DrPH
Chief, Division of Preventive Medicine, Brigham and Women's Hospital, and Professor of Medicine and the Michael and Lee Bell Professor of Women's Health, Harvard Medical School
Boston, MA

Kelsey Mangano, PhD, RD
Assistant Professor, Zuckerberg College of Health Sciences, University of Massachusetts Lowell
Lowell, MA

Shortie McKinney, PhD, RD, FADA
Dean, Zuckerberg College of Health Sciences, University of Massachusetts Lowell
Lowell, MA

Veronica McLymont, PhD, RD, CDN
Director, Food and Nutrition Services, Memorial Sloan Kettering Cancer Center
New York, NY

Jade McNamara, PhD
Assistant Professor of Human Nutrition, University of Maine
Orono, ME

Barbara Millen, DrPH, RD, FADA
President of Millennium Prevention, Inc. and Chairman of Boston Nutrition Foundation, Inc
Boston, MA

Lisa Moloney, MS, RDN
Nutrition Researcher, Academy of Nutrition and Dietetics
Chicago, IL

Yasmin Mossavar-Rahmani, PhD, RD
Associate Professor, Department of Epidemiology and Population Health, Albert Einstein College of Medicine,
Bronx, NY

Suzanne P. Murphy, PhD
Professor Emeritus, University of Hawaii Cancer Center
Honolulu, HI

William Murphy, MS, RDN
Chief Technology Officer, 3 Data, Inc
Austin, TX

Mary C. Naglak, PhD, RD
Clinical Research Director, Abington-Jefferson Health Memorial Hospital
Abington, PA

Dianne Neumark-Sztainer, PhD, MPH, RD
Mayo Professor and Division Head, Division of Epidemiology and Community Health, School of Public Health, University of Minnesota
Minneapolis, MN

Angela Odoms-Young, PhD
Associate Professor, University of Illinois at Chicago
Chicago, IL

Constantina Papoutsakis, PhD, RDN
Senior Director, Nutrition and Dietetics Data Science Center, Academy of Nutrition and Dietetics
Chicago, IL

Pamela R. Pehrsson, PhD
Research Leader, USDA-ARS-BHNRC Nutrient Data Laboratory
Beltsville, MD

Colleen A. Redding, PhD
Research Professor, University of Rhode Island
Kingston, RI

Mary Rozga, PhD, RDN
Nutrition Researcher, Academy of Nutrition and Dietetics
Chicago, IL

Lianne Russo, MS, RDN, CDN
Clinical Dietician and Nutritionist, Memorial Sloan Kettering Cancer Center
New York, NY

Kevin Sauer, PhD, RDN, LD, FAND
Associate Professor, Kansas State University
Manhattan, KS

Maria O. Scott, MPH
Academic/Scientific Editorial Manager, University of Iowa College of Public Health
Iowa City, IA

Madeleine Sigman-Grant, PhD, RD
Professor Emerita, University of Nevada, Reno
Las Vegas, NV

Linda Snetselaar, PhD, RDN, LD, FAND
Professor in Epidemiology, College of Public Health, University of Iowa
Iowa City, IA

Lyn M. Steffen, PhD, MPH, RDN, FAHA
Associate Professor of Epidemiology, University of Minnesota School of Public Health
Minneapolis, MN

Alison L. Steiber, PhD, RDN
Chief Scientific Officer, Research, International, and Scientific Affairs, Academy of Nutrition and Dietetics
Chicago, IL

Cynthia Thomson, PhD, RDN
Professor, Health Promotion Sciences, and Director, Canyon Ranch Center for Prevention & Health Promotion, Mel & Enid Zuckerman College of Public Health, University of Arizona
Tuscon, AZ

Linda Van Horn, PhD, RDN
Professor, Preventive Medicine and Chief, Nutrition Division, Northwestern University
Chicago, IL

Jacqueline A. Vernarelli, PhD
Assistant Professor of Public Health, Sacred Heart University
Fairfield, CT

Connie Weaver, PhD
Distinguished Professor, Nutrition Science, Purdue University
West Lafayette, IN

Miryam Yusufov, PhD
Research Fellow, Dana-Farber Cancer Institute, Harvard Medical School
Boston, MA

Reviewers

Melinda Anderson, PhD, RDN, LDN
DPD Director, School of Human Ecology, Tennessee Technological University
Cookeville, TN

Shanna Beth Bernstein, MPH, RD, CDE
Metabolic Research Dietitian, National Institutes of Health, Clinical Center
Bethesda, MD

Catherine M. Champagne, PhD, RDN, LDN, FTOS, FAHA, FADA, FAND
Professor and Chief, Nutritional Epidemiology/Dietary Assessment & Nutrition Counseling Pennington Biomedical Research Center, Louisiana State University
Baton Rouge, LA

Natasha Chong Cole, PhD, MPH, RD
Postdoctoral Research Fellow
Baylor College of Medicine/Children's Nutrition Research Center
Houston, TX

Brenda M. Davy, PhD, RD
Professor, Department of Human Nutrition, Foods and Exercise, Virginia Polytechnic Institute and State University
Blacksburg, VA

Phillip Gleason, PhD
Senior Fellow, Mathematica Policy Research
Geneva, NY

Amanda Goldman, MS, RD, LD, FAND
System Director of Quality and Wellness; Director of Diabetes and Nutrition Care, Catholic Health Initiatives
Lexington, KY

Rosa K. Hand, PhD, RDN, LD, FAND
Instructor and Director, Combined Dietetic Internship/Master's Degree Program, Case Western Reserve University
Cleveland, OH

Kristen Heitman, MS, RDN, LD
Clinical Research Dietitian,
The Ohio State University Wexner Medical Center
Columbus, OH

Carrie King, PhD, RDN, LD, CDE
Professor, Dietetics and Nutrition, University of Alaska Anchorage
Anchorage, AK

Nicole M. Moore, MS, RDN, LD
Assistant Professor, Augusta University
Augusta, GA

Mary Rozga, PhD, RDN
Nutrition Researcher, Academy of Nutrition and Dietetics
Chicago, IL

Shey Schnell, MHA, RD
Director of Food and Nutrition Services
The University of Vermont Health Network-Champlain Valley Physicians Hospital
Plattsburgh,NY

Kim S. Stote, PhD, MPH, RDN
Associate Dean, Health Professions State University of New York, Empire State College
Albany, NY

Ashley Vargas, PhD, MPH, RDN, FAND
Health Scientist, Office of Disease Prevention, Office of the Director, National Institutes of Health
North Bethesda, MD

Foreword

Research: Successful Approaches in Nutrition and Dietetics, now in its fourth edition, remains a touchstone for all nutrition and dietetics researchers. This text contains the collective knowledge of our field, with each chapter authored by a distinguished nutrition and dietetics researcher. This newest edition will continue to serve as a reference and educational foundation for our profession.

While the scientific method underpinning research has not changed in hundreds of years, the complexity of our research questions and research tools have increased appreciably. Professors Van Horn and Beto do an excellent job orienting readers to the full-spectrum of nutrition and dietetics research throughout this text, including clear indications of pros and cons for different tools and methodological approaches. Chapters 1 though 4 orient the reader, walk through the scientific method, describe how to obtain monetary support for research, and explain the ethical responsibility of researchers, respectively. The remaining chapters largely dive deeper into the array of different approaches, methods, and tools used in nutrition and dietetic research. This format easily allows the reader to simply choose topics of interest or to read through all topics for a more global understanding.

In 2017, the Academy of Nutrition and Dietetics celebrated its centennial, and, on behalf of the Research Dietetic Practice Group, I am beyond pleased to see the prominence of research within the Academy of Nutrition and Dietetics strategic plan. This is especially vital right now because research is more complex than ever and is being communicated to the public in smaller and smaller sound bites. Indeed, the Academy of Nutrition and Dietetics designated research as the first of four strategies to fulfill their mission to "Accelerate improvements in global health and well-being through food and nutrition." For over 25 years the Academy of Nutrition and Dietetics has committed to publishing this text, which demonstrates the long-standing dedication of the Academy of Nutrition and Dietetics, and its membership, to quality research.

Ashley J. Vargas, PhD, MPH, RDN, FAND
Health Scientist, Office of Disease Prevention, Office of the Director, National Institutes of Health;
Chair, Academy of Nutrition and Dietetics Research Dietetic Practice Group, 2018–2019

Acknowledgments

We are grateful to each of our talented authors. Their expertise is evident in these chapters, which provide the most current and credible information available in their respective areas of concentration. We highly respect these individuals for their hard work and creativity in presenting complex concepts in new and novel ways. We want to further give our appreciation to past authors whose contributions in earlier editions modelled certain topic areas.

We sincerely thank the Academy of Nutrition and Dietetics for supporting the development of this new edition. Specifically, the Publications, Resources, and Products team is recognized for its commitment to excellence, ongoing involvement, and dedication. Without them, this book could not have been produced.

We also wish to remember our former colleague and past editor of the *Journal of the Academy of Nutrition and Dietetics*, Elaine Monsen, PhD, RD, whose initiative launched the first edition of this book. Her commitment to teaching and training nutrition researchers has inspired countless investigators to take the tools and tips provided to design, implement, and publish remarkable findings and new discoveries.

Finally, we thank you, the readers, for your interest, scientific curiosity, and ambition. We encourage each of you to discover "successful approaches" to developing high impact nutrition research of your own!

Linda Van Horn, PhD, RDN
Judith Beto, PhD, RDN

About the Fourth Edition

The fourth edition of *Research: Successful Approaches in Nutrition and Dietetics* is a timely and comprehensive update on designing, conducting, and evaluating nutrition research. This text strategically targets nutrition students, their professors, and practitioners who seek a deeper understanding of the evidence base that forms nutrition policy and practical applications. There is an emphasis on the modern integration of nutrition science, epidemiology, clinical translational relevance and food-based practices. Advances in biostatistical analyses, biological mechanisms, and newly emerging biomarkers are encompassed throughout.

The book's ten sections capture the excitement of research discovery, the importance of establishing a supportive research environment, and details specific to conducting observational, integrative, and translational research in the modern era.

Section 1 follows in the footsteps of the previous edition, laying a general foundation for the importance of discovery through research. Examples have been updated to give readers a glimpse of current research models to illustrate the main points.

Section 2 brings to the reader the most up-to-date information on advancing science through ethical research. Detailed information on writing proposals has been revised to feature the most current resources in grant writing and proposal funding resources.

Section 3 explores, in depth, the unique attributes of descriptive research with a new focus on efficiency in data collection.

Section 4 has been expanded to introduce the topic of consistency in study findings and includes new figures and illustrations to elaborate on clinical nutrition studies. Chapter 9 has been augmented to offer the latest in nutrition monitoring.

Section 5 includes a brand new chapter on bridging disciplinary boundaries and working on teams with members from varied backgrounds.

Section 6 incorporates key components relevant to evaluation and assessment methods in research, ranging from surveys to assessment methodology, as well as the importance of the food composition databases and dietary reference intakes that are essential to all aspects of nutrition research. A detailed and up-to-date review of existing biomarkers and how to apply them is included, as well as a specific focus on research involving appetite assessment.

Section 7 includes six chapters that are fundamental to the food, nutrition, and dietetics arena. New to this section is the subject of diet and human genetics, which is rapidly evolving. This topic is an essential component of understanding nutrition research in the modern era.

Section 8 concentrates on statistical applications that are vital to nutrition research and an invaluable component of understanding as well as writing nutrition research papers that merit publication in high impact journals.

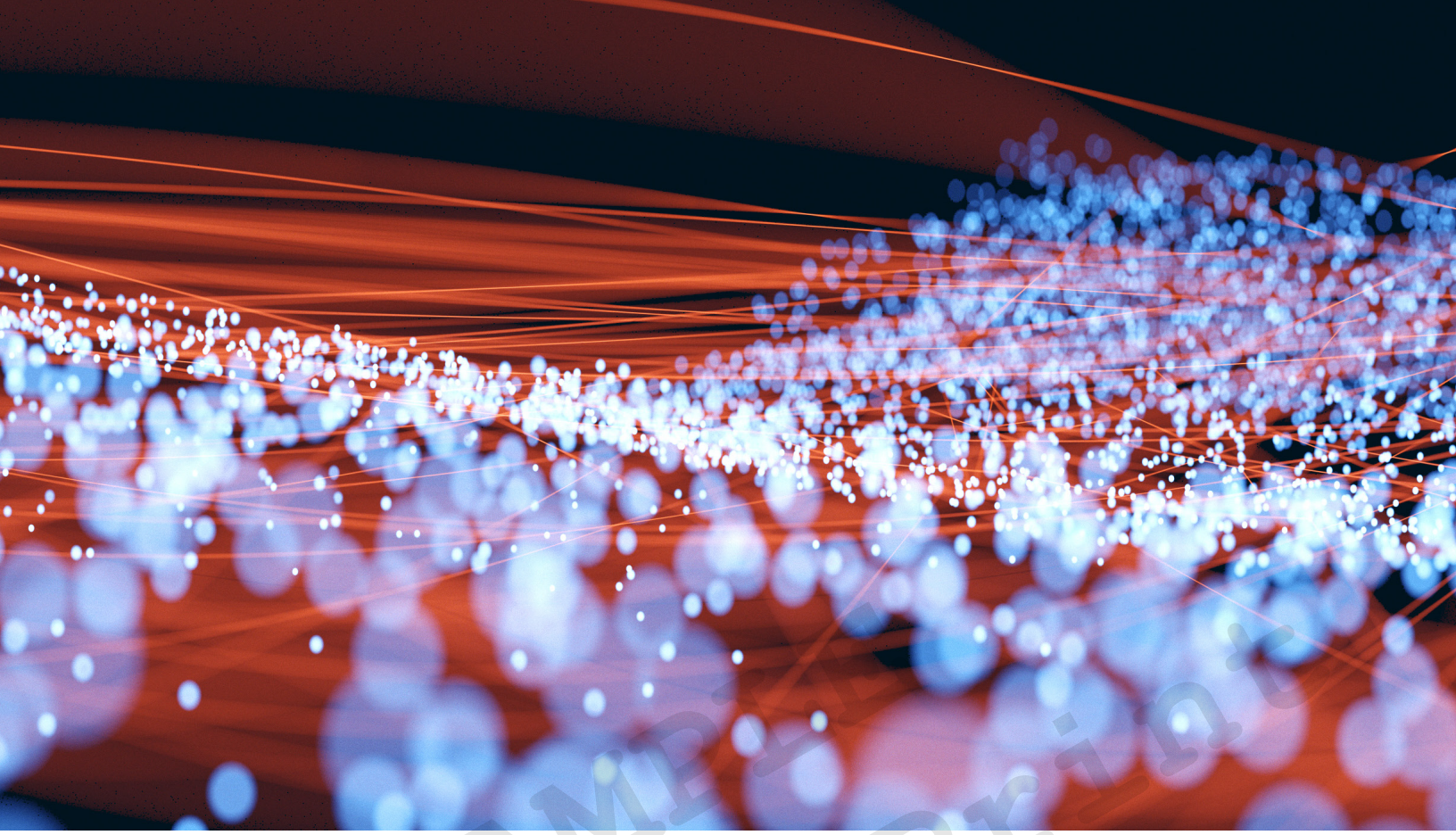
Section 9 further describes best approaches to illustrate, evaluate, and integrate nutrition research data within the development of subsequent studies and their interpretation.

Finally, **Section 10** brings it all together in the process of applying research in practice. The importance of community–based research in implementing public health benefits is the new culminating chapter to further emphasize applied-side nutrition and dietetics.

Authors who have contributed their time and talents to the fourth edition are uniquely qualified to address each topic, and their individual areas of expertise are well recognized and respected in the published literature. This text aims to enhance, expand, and energize readers to embrace the excitement of nutrition research, ignite new ideas and approaches, and achieve a better understanding of the importance of diet and nutrition in health throughout the life course.

SECTION 1

An Introduction to Discovery Through Research in Nutrition and Dietetics



Chapter 1

Advancing the Research Continuum

Linda Van Horn, PhD, RDN

LEARNING OBJECTIVES

1. Introduce the overall premise of this book.
2. Highlight key topics and research elements addressed.
3. Encourage readers, whether novice or experienced, to apply these principles and strategies to their own research as they move forward with their careers.

Nutrition research is fundamental to the evidence-based practice of nutrition and dietetics. Well-designed, carefully executed, quality-controlled studies offer insights and breakthroughs that drive the field forward. Research fosters objective measurement of complex environments and demands rigorous evaluation of procedures, treatments and outcomes. Through research, associations can be identified, hypotheses tested, programs compared, and protocols validated. Research documents practice, monitors approaches, ensures credibility, and assesses cost-effectiveness. The strength of a discipline, whether in health sciences or management, is characterized by the quality and quantity of evidence in its research base. Strong and consistent research is essential to a vibrant profession, pending active involvement of professionals in keeping abreast of the dynamic findings.

FORCES FOR RESEARCH

Monsen[1] identified driving forces that continue to influence nutrition research today. These include recognizing unexpected findings, extending existing data, posing point-counterpoint comparisons, and responding to socioeconomic, political, and behavioral influences of a culturally diverse environment. Included in modern applications of research are the numerous influences conferred by social media and the rapid-fire communication of results that can undermine careful consideration of unintended consequences.

Recognizing the Unexpected

An exciting by-product of a research study is sometimes the hidden finding that launches new topic areas of study. This is more commonly known as the "Aha!" moment. Discovery of the first vitamin is a clear example. In the 1700s, a British naval surgeon, James Lind, gave a great deal of thought to the vast occurrence of scurvy among English sailors. The disease was particularly rampant on long voyages. In 1747, Lind completed the first controlled dietary study where he proved that citrus fruits cured scurvy. Six years later Lind[2] published his treatise, and in 1796, 43 years after his publication, the British navy officially introduced lemon juice as a prophylactic against scurvy.

More than a century later, in 1906, the concept of developing accessory food factors was introduced. In 1932, 185 years after Lind's first controlled study, crystalline vitamin C was prepared from lemon juice. While no one can plan for a breakthrough (such as the dietary importance of citrus fruit), investigators should always be alert for the unexpected. For example, the findings from the Women's Health Initiative reported completely unexpected results regarding the use of progestin-containing hormone therapy, which was long considered protective; the report found that progestin was adversely associated with increased risk of postmenopausal breast cancer.[3-5] These results changed the course of clinical postmenopausal management almost overnight. From 1988 through 1994, 44% of American women reported using hormone therapy, but this was reduced to 4.7% by 2010, with ongoing recommendations against its use in 2017 by the US Preventive Services Task Force.[6]

Extending Existing Data

Going beyond what is known to discover what is not known remains a compelling force of research. Another classic example is discovery of the second vitamin. When the idea of accessory food factors was introduced to the scientific community, researchers eagerly devoted attention to ascertaining whether other important food factors existed and their sources and functions. From 1913 to 1916, research teams led by McCullum et al[7,8] observed and isolated components from foods that they termed Fat Soluble A and Water Soluble B. Shortly thereafter, Fat Soluble A was partitioned into vitamins A, D, E, and K, and Water Soluble B developed into the long series of B vitamins.[9] This search for accessory food factors was a highly productive extension of the earlier discovery of vitamin C.

A more current example is the study of glycemic index and glycemic load. While the relevance and practical application of these two factors in regards to development of insulin resistance or type 2 diabetes remains somewhat mixed,[10,11] awareness of the potential role of these factors in impacting postprandial glucose/insulin response opened a new and compelling area for nutrition research.[12-14] The epidemiologic relevance of a topic like this and its importance in setting the stage for next generation research are addressed more extensively in Chapters 5 and 7.

One of the trending topics of today centers on the growing awareness of biomarkers, which can help provide objective measures of nutrient intake and help to identify biological pathways and processes related to digestion, absorption, and metabolism. Chapters 16 and 21 are particularly relevant to this topic and offer insights into how best to cross-check diet intake with metabolic outcomes.

Also, with the increasing interest in precision medicine and now precision nutrition, nutrigenomics and the myriad of diet-gene interactions are likely to become even more important to the understanding of prevention and diet therapy to meet the

needs of the individual, including questions regarding weight control.[15] Chapter 19 is devoted to this topic and raises many hypothesis-generating research questions.

Point-Counterpoint Comparisons

The point-counterpoint concept involves actions and reactions. A current example is the explosion of "functional foods," including prebiotics and probiotics that have been developed by the food industry, presumably to conveniently meet nutrient needs of busy people without imposing the hassle of buying and preparing raw ingredients. Whether these foods and products prove helpful or harmful (perhaps due to extra calories, sugar, salt, or other factors) remains controversial,[16,17] but the presence of these products continues to have a growing influence on the modern diet.[18] The knowledge gap associated with their risk-benefit ratios—especially the gap based on age, sex, health status, and pharmacological influences—requires future study.

Responding to the Socioeconomic, Political, and Culturally Diverse Environment

The Special Supplemental Food Program for Women, Infants and Children (WIC) represents an outstanding response to the socioeconomic and political environment.[19] Evaluation and documentation of the WIC program and innovative new approaches are among the prime reasons that the program has been so successful.[20] Increasing cultural diversity and the accompanying increase in rates of homelessness raise challenges related to economic opportunity and adequate nutrition for underserved pregnant women. Qualitative research on these and associated topics is addressed in Chapter 6. Applied research on these topics offers promise for ameliorating these difficult problems.[21]

Research Now

Nutrition research has never been more exciting or more challenging. The forces of research are ever influencing new studies and their findings. Registered Dietitian Nutritionists (RDNs) are encouraged to take an active role in designing studies, both basic science and clinical, to document the benefits of nutrition in prevention and treatment of disease. Applied translational research is especially valued; it takes results from bench to bedside and even curbside, offering timely community health benefits derived from well executed experimental and clinical designs. Chapters 11, 18, 29, and 30 are especially relevant in this area. This book offers a wealth of tools and techniques for designing nutrition research studies of your own. Here are a few of the basics to get you started.

Prepare the Research Protocol

A research protocol is essential to direct the study in a manner that ensures meaningful results. The research protocol includes (1) specific aims and hypotheses that pose focused and concisely stated research questions, (2) a comprehensive literature review, (3) the merit and potential value or innovations of the research, and (4) the appropriate research design to adequately test the questions. Research design includes the study methods, data collection, and decisive statistical analyses to be used to test the hypotheses. See Chapters 8 through 10.

Research proposals must conform to a funding agency's requirements, as stated in its guidelines. Chapter 4 provides detailed guidance on securing funding. Many private and public agencies model their guidelines after those of the National Institutes of Health (NIH). Proposals are typically submitted electronically, requiring the authors to pay careful attention to all details, including the due date and time.

Conduct the Pilot Study to Produce Preliminary Data

A pilot study to generate preliminary results is essential in most NIH studies to demonstrate the feasibility and merit of the proposed study design and methodology. Testing instruments and validated methods permits researchers to make adjustments before launching the study, thereby assuring that data collection is efficient and accurate. All data collection needs justification. Providing preliminary data and demonstrating experience gained from the

pilot study are crucial to successful review and funding for the proposed project. See Chapters 2, 8, 9, 12, and 13.

Ensure Ethical Research

Institutional Review Board (IRB) approval is required prior to initiating all research studies. Researchers must follow ethical procedures in all aspects of the design and conduct of their research. Everything, ranging from the choice of topic, to the samples collected, to the interventions designed, to the data collected, to—perhaps most important of all—gaining informed consent, must be considered ethical as judged by IRB approval. Data analyses and reporting of data are likewise subject to scrutiny. Chapter 3 provides a more detailed discussion.

These investigations must meet ethical guidelines to protect the rights, privacy, and welfare of the individuals. The Declaration of Helsinki, drafted in 1964 by the World Medical Association, serves as the basis for the ethical guidelines that are now detailed regulations issued by governmental agencies, such as the NIH. The local IRB is required to review all investigations using human subjects to ensure ethical conduct and evaluate potential risks and benefits.

As part of informed consent, the investigator must explain to potential participants the nature of the study, including the possible risks and discomforts they may experience. Confidentiality of all data is mandated by all review boards. Specific elements to be included in the informed consent procedure, including written and verbal descriptions, are designated by the local IRB. See Chapters 3 and 9.

Validity, Accuracy, Reliability, and Precision

Qualities critical to all research are validity, accuracy, and precision. Use of validated instruments is essential to ensuring accuracy, reliability, and precision of the data and the results.[22] The National Cancer Institute has developed a highly comprehensive Dietary Assessment Primer (https://dietassessmentprimer.cancer.gov) that provides detailed definitions and examples of these and other aspects of nutrition research as follows:

- **Validity:** The degree to which a tool measures what it claims to measure.
- **Accuracy:** The degree of closeness of measurements of a quantity to that quantity's true value.
- **Precision:** The degree to which repeated measurements under unchanged conditions show the same results.

Sensitivity and Specificity

The choice of a single cut point to categorize individuals may not always be clear when the test yields a continuous scale of values. A cut point selected to maximize sensitivity will unavoidably cause the test to be less specific. The selection of an appropriate cut point is aided by use of graph plotting true-positive against false-positive ratios, known as the receiver operating characteristic (ROC) curve. The ROC curve graphically displays the reciprocal relationship between sensitivity and specificity for values of a test measured on a continuous scale, and it allows investigators to choose a cut-point that maximizes the performance of the test for the needed levels of sensitivity, specificity, or both. See Chapters 17, 25, 28, for more detailed explanations.

National Health and Nutrition Examination Survey (NHANES) I, II, and III provide countless examples of valid survey testing. The mean intakes of certain vitamins by age and gender are useful for determining areas of weakness in the population's diet and indicating possible policies to apply. Limitations in survey results often include low response rate and cross-sectional design.[23] Randomized clinical trials and longitudinal cohort studies are considered more robust, but these also have limitations that require further considerations. Chapters 8, 9, 12, 13, and 14 offer further discussion and insights regarding these issues.

Researchers must also use discretion in applying inferential statistical tests to data from survey research. Because survey studies are designed to be descriptive rather than analytic, formal tests of hypotheses are undertaken after the data are viewed,

and the test result is likely to be biased toward a spurious statistically significant result. Such inferential tests should be regarded as exploratory and useful in generating questions for future analytic studies. Chapters 21 and 25 offer further explanation of this topic.

ADVANCING YOUR OWN RESEARCH

The topics listed in this chapter represent only a few of the key aspects of nutrition research that are addressed in this book. The possibilities are endless, but the competitive nature of grant reviews and funding constraints often steer research proposals towards filling high priority knowledge gaps identified by the funding agencies.[24] A newly convened Dietary Guidelines for Americans Advisory Committee, with the assistance of the Nutrition Evidence Library, conducts systematic reviews of newly published nutrition research every 5 years as part of the process for developing the next edition of the Dietary Guidelines for Americans. Savvy researchers can begin with the end in mind by reviewing these priority areas and carefully developing testable hypotheses that will address them. Consider the population, intervention, comparator, and outcome (PICO) that form the criteria used in systematic reviews. Formulation of study questions, specific aims, and validated outcome measures that are consistent with these criteria can often make or break an investigator's chances of achieving a fundable score.

CONCLUSION

In this era, massive use of social media, blogs, tweets, and crowdsourcing to derive answers to countless questions has influenced public perception of what to believe and how to behave. The importance of evidence-based science to provide sound answers and guide public policy, including what to eat, is paramount. Take these tools and **go for it!**

REFERENCES

1. Monsen E. Forces for research. *J Am Diet Assoc.* 1993; 93:981-985.
2. Lind J. *A treatise of the Scurvy. In three parts. Containing an inquiry into the nature, causes, and cure, of that disease. Together with a critical and chronological view of what has been published on the subject*. Edinburgh, Scotland: Sands, Murray, and Cochran for A Kincaid & A Donaldson; 1753.
3. Modugno F, Kip KE, Cochrane B, et al. Obesity, hormone therapy, estrogen metabolism and risk of postmenopausal breast cancer. *Int J Cancer*. 2006;118(5):1292-1301.
4. Collaborative Group on Hormonal Factors in Breast Cancer. Breast cancer and hormone replacement therapy: collaborative reanalysis of data from 51 epidemiological studies of 52,705 women with breast cancer and 108,411 women without breast cancer. *Lancet*. 1997;350(9084): 1047-1059.
5. Chlebowski RT, Hendrix SL, Langer RD, et al. Influence of estrogen plus progestin on breast cancer and mammography in healthy postmenopausal women: the Women's Health Initiative randomized trial. *JAMA*. 2003;289:3243-3253.
6. Osborne T, Mendell, L. *Feeding experiments with isolated food substances*. Washington DC: Carnegie Institute; 1911:156.
7. Osborne T, Mendell L. Amino acids in nutrition and growth. *J Biol Chem*. 1914;17:325-349.
8. Stipanuk M. The vitamins. In: *Biochemical, Physiological and Molecular Aspects of Human Nutrition*. 2nd ed. St. Louis, MO: Saunders; 2006:661-663.
9. Campfield LA, Smith FJ, Rosenbaum M, Hirsch J. Human eating: evidence for a physiological basis using a modified paradigm. *Neurosci Biobehav Rev.* 1996;20:133-137.
10. Sacks FM, Carey VJ, Anderson CAM, et al. Effects of high vs low glycemic index of dietary carbohydrate on cardiovascular disease risk factors and insulin sensitivity: the OmniCarb randomized clinical trial. *JAMA*. 2014; 312(23):2531-2541. doi:10.1001/jama.2014.
11. Tay J, Luscombe-Marsh ND, Thompson CH, et al, Comparison of low- and high-carbohydrate diets for type 2 diabetes management: a randomized trial. *Am J Clin Nutr*. 2015;102(4):780-790. doi: 10.3945/ajcn.115.112581.
12. Shukla AP, Andono J, Touhamy SH, et al. Carbohydrate-last meal pattern lowers postprandial glucose and insulin excursions in type 2 diabetes. *BMJ Open Diabetes Res Care*. 2017;5(1):e000440. doi:10.1136/bmjdrc-2017-000440.

13. Le T, Flatt SW, Natarajan L, et al. Effects of diet composition and insulin resistance status on plasma lipid levels in a weight loss intervention in women. *J Am Heart Assoc*. 2016;5(1):e002771. doi:10.1161/JAHA.115.002771.

14. Shikany JM, Margolis KL, Pettinger M, et al. Effects of a low-fat dietary intervention on glucose, insulin, and insulin resistance in the Women's Health Initiative (WHI) dietary modification trial. *Am J Clin Nut*r. 2011;94(1):75-85. doi.org/10.3945/ajcn.110.010843.

15. Celis-Morales C, Marsaux CF, Livingstone KM, et al. Can genetic-based advice help you lose weight? Findings from the Food4Me European randomized controlled trial. *Am J Clin Nutr*. 2017;105(5):1204-1213.

16. Pandey KR, Naik SR, Vakil BV. Probiotics, prebiotics and synbiotics–a review. *J Food Sci Technol*. 2015;52(12):7577-7587. doi:10.1007/s13197-015-1921-1.

17. Hu FB. Do functional foods have a role in the prevention of cardiovascular disease? *Circulation*. 2011;124(5):538-540.

18. De Filippis F, Vitaglione P, Cuomo R, Canani RB, Ercolini D. Dietary interventions to modulate the gut microbiome—how far away are we from precision medicine. *Inflamm Bowel Dis*. 2018;24(10):2142-2154. doi:10.1093/ibd/izy080.

19. Phelan S, Hagobian T, Brannen A, et al. Effect of an internet-based program on weight loss for low-income postpartum women: a randomized clinical trial. *JAMA*. 2017;317(23):2381-2391. doi:10.1001/jama.2017.7119.

20. Walker L, Freeland-Graves JH, Milani T, et al. Weight and behavioral and psychosocial factors among ethnically diverse, low-income women after childbirth: II. Trends and correlates. *Women Health*. 2004;40(2):19-34.

21. May L, Borger C, McNutt S, et al. *WIC ITFPS-2 infant report: Intention to breastfeed*. Rockville, MD: Westat; 2015.

22. Walker JL, Ardouin S, Burrows T. The validity of dietary assessment methods to accurately measure energy intake in children and adolescents who are overweight or obese: a systematic review. *Eur J Clin Nutr*. 2018;72(2):185-197. doi:10.1038/s41430-017-0029-2.

23. Briefel RR, Johnson, CL. Secular trends in dietary intake in the United States. *Annu Rev Nutr*. 2004;24:401-31.

24. Dwyer JT, Rubin KH, Fritsche KL, et al. Creating the future of evidence-based nutrition recommendations: case studies from lipid research. *Adv Nutr*. 2016;7(4):747-755. doi:10.3945/an.115.010926.

Index

Page numbers followed by *b*, *f*, or *t* refer to boxes, figures or tables.

B

C

D

E

F

G

H

I

J

K

L

M

N

O

P

Q

R

T

U

V

W

Y

Z