BIOGRAPHICAL SKETCH

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NAME: Roger B. Davis

eRA COMMONS USER NAME (credential, e.g., agency login): ROGERDAVIS

POSITION TITLE: Associate Professor of Medicine (Biostatistics)

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Rochester, Rochester, NY	BA	06/1975	Statistics/Math
University of Rochester, Rochester, NY	MA	06/1978	Statistics
Harvard School of Public Health, Boston, MA	ScD	05/1988	Biostatistics

A. Personal Statement

I am Associate Professor of Medicine at Harvard Medical School and Principal Biostatistician in the Division of General Medicine & Primary Care at Beth Israel Deaconess Medical Center (BIDMC). As a biostatistician, I have over thirty-five years of experience collaborating in the design and analysis of NIH-funded clinical trials and other clinical research. I have extensive experience in the design, conduct, analysis and publication of pilot clinical trials of integrative medicine interventions. I have over 350 peer-reviewed publications. I am responsible for all statistical aspects of the project.

a. Dossett ML, Mu L, **Davis RB**, Bell IR, Lembo AJ, Kaptchuk TJ, Yeh GY. Patient-provider interactions affect symptoms in gastroesophageal reflux disease: a pilot randomized double-blind, placebo-controlled trial. PLoS One 2015, Sep 30;10(9):e0136855. Doi:101371/journal.pone.0136855. eCollection 2015. PMC: PMCID4589338
b. Chacko SA, Yeh GY, **Davis RB**, Wee CC. A mindfulness-based intervention to control weight after bariatric sugery: preliminary results from a randomized controlled pilot trial. Complement Ther Med 2016; 28:13-21. PMC: PMCID5043638
c. Jacobson EE, Meleger AL, Bonato P, Wayne PM, Langevin HM, Kaptchuk TJ, **Davis RB**. Structural Integration as an adjunct to outpatient rehabilitation for chronic nonspecific low back pain: a randomized pilot clinical trial. Evid Based Complement Alternat Med 2015;2015:813418. Doi:10.1155/2015/813418. Epub 2015 Apr 7. PMC: PMCID4405211
d. Holden SC. Manor B, Zhou J, Zera C, **Davis RB**, Yeh GY. Prenatal yoga for back pain, balance, and maternal wellness: a randomized controlled pilot study. Glob Adv Health Med 2019 Aug 26;8:2164956119870984. doi: 10.1177/2164956119870984. eCollection 2019. PMC: PMCID6710668

B. Positions and Honors

Positions and Employment

1979–1988 Statistician, Dept. of Biostatistics, Harvard School of Public Health and Dana-Farber Cancer Institute, Boston, MA
1988–1990 Lecturer on Biostatistics, Harvard School of Public Health, Boston, MA
1990–1998 Assistant Professor of Biostatistics, Harvard School of Public Health, Boston, MA
1992–1998 Assistant Professor of Medicine, Harvard Medical School, Boston, MA
1992– Principal Biostatistician, Division of General Medicine and Primary Care, Beth Israel Deaconess Medical Center, Boston, MA
1998–2018 Assoc. Professor of Biostatistics, Harvard School of Public Health, Boston, MA
1998– Assoc. Prof. of Medicine, Dept. of Medicine, Harvard Medical School, Boston, MA

Other Experience and Professional Memberships

1995-2001 Editorial Board, MD Computing
2000-2002 NIH Peer Review Committee: NIMH AIDS Centers Core, ad hoc reviewer
2000-2003 NIH Peer Review Committee: Cancer Epidemiology, Prevention and Control, Site Visit Panel ad hoc reviewer
2009-2016 Editorial Board, Circulation
2009-2017 Editorial Board, Circulation: Arrhythmia and Electrophysiology
2009-2016 Editorial Board, Circulation: Cardiovascular Genetics
2009-2016 Editorial Board, Circulation: Cardiovascular Imaging
2009-2016 Editorial Board, Circulation: Cardiovascular Interventions
2009-2016 Editorial Board, Circulation: Heart Failure

C. Contributions to Science

1. I have been a principal biostatistical contributor to several important trials and other studies examining the impact of placebo. The innovative and provocative work on the placebo effect led by Professor Ted Kaptchuk have required highly imaginative study designs. I have contributed critical methodological expertise to these efforts, including a highly innovative design for a study that met ethical standards while allowing head-to-head comparison of different placebos by utilizing the run-in periods of two separate randomized controlled trials. We have also investigated whether the placebo effect is enhanced by direct physician interaction with the patient.
   a. Kaptchuk TJ, Stason WB, **Davis RB**, Legedza ATR, Schnyer RN, Kerr CE, Stone DA, Nam BH, Kirsch I, Goldman RH. Sham device versus inert pill: a randomized controlled trial comparing two placebo treatments for arm pain due to repetitive strain injury. BMJ 2006; 332:391-7. PMCID: PMC 1370970
   b. Kaptchuk TJ, Kelley JM, Conboy LA, **Davis RB**, Kerr CE, Jacobson EE, Kirsch I, Schnyer RN, Nam BH, Nguyen LT, Park M, Rivers AL, McManus C, Kokkotou E, Drossman DA, Goldman P, Lembo AJ. Components of the placebo effect: a randomized controlled trial of irritable bowel syndrome patients. BMJ 2008; 336:999-1003. PMCID: PMC2364862
   c. Hall KT, Nelson CP, **Davis RB**, Buring JE, Kirsch I, Mittleman MA, Loscalzo J, Samani NJ, Ridker PM, Kaptchuk TJ, Chasman DI. Polymorphisms in catechol-o-methyltransferase modify treatment effects of aspirin on risk of cardiovascular disease. Arterioscler Thromb Vasc Biol 2014; 34:2160-7. PMCID:PMC4148908
   d. Ballou S, Kaptchuk TJ, Hirsch W, Nee J, Iturrino-Moreda J, Hall KT, Kelley J, Cheng V, Kirsch I, Jacobson E, Conboy L Lembo A, **Davis RB**. Open-label versus double-blind placebo treatment in irritable bowel syndrome: study protocol for a randomized controlled trial. Trials 2017 May 25; 18(1):234. doi: 10.1186/s13063-017-1964-x. PMCID: PMC5445390
2. Survival analysis has been a major focus of my career. I developed an algorithm to extend the Classification and Regression Tree (CART) methodology to survival data. The method has been applied to clinical problems and other researchers have extended the method to include time-dependent covariates and to incorporate a frailty term to allow for correlated outcomes. The second reference is a novel application of survival analysis. I was the first to recognize that the outcomes in studies of computer reminders involve a time-to-event outcome and proper analysis requires survival analysis, an approach that has been adopted by other researchers. The third paper applied discrete time survival analysis to cross sectional survey data to obtain estimates of long-term trends in the use of complementary and alternative medicine in the U.S. The last paper reports the development and validation of a score to predict 6-month survival in nursing home residents with advanced dementia.
   a. **Davis RB**, Anderson JR. Exponential survival trees. Stat Med 1989; 8:947-61.
   b. Safran C, Rind DM, **Davis RB**, Ives D, Sands DZ, Currier J, Slack WV, Makadon HJ, Cotton DJ. Guidelines for management of HIV infection with computer-based patient's record. Lancet 1995; 346:341-6.
   c. Kessler RC, **Davis RB**, Foster DF, Van Rompay MI, Walters EE, Wilkey SA, Kaptchuk TJ, Eisenberg DM. Long-term trends in the use of complementary and alternative medical therapies in the United States. Ann Intern Med 2001; 135:262-8.
   d. Mitchell SL, Miller SC, Teno JM, Kiely DK, **Davis RB**, Shaffer ML. Prediction of 6-month survival of nursing home residents with advanced dementia using ADEPT vs hospice eligibility guidelines. JAMA 2010; 304:1929-35. PMCID: PMC3017367

3. For nearly a decade while I was at Dana-Farber Cancer Institute, I collaborated with the Leukemia Committee of Cancer and Leukemia Group B, an NCI-sponsored national cooperative clinical trials group. I was the statistician for numerous multicenter clinical trials evaluating treatments for acute myeloctic leukemia and was responsible for the design, monitoring and analysis of AML trials. The culmination of this work was the trial of post-remission intensification with cytosine arabinoside (Mayer et al, below). This trial randomized 596 patients in complete remission to one of 3 post-remission regimens. The trial clearly demonstrated that the high-dose treatments resulted in longer disease-free survival than standard maintenance and established the superiority of post-remission intensification for AML, and this treatment remains the standard of care.
    a. Preisler HD, **Davis RB**, Kirshner J, Dupre E, Richards F, Hoagland HC, Kopel S, Levy RN, Carey R, Schulman P, Gottlieb AJ, McIntyre OR. Comparison of three remission induction regimens and two post-induction strategies for the treatment of acute nonlymphocytic leukemia: a Cancer and Leukemia Group B study. Blood 1987; 69:1441-9.
    b. Capizzi RL, **Davis R**, Powell B, Cuttner J, Ellison RR, Cooper MR, Dillman R, Major WB, Dupre E, McIntyre OR. Synergy between high-dose ara-C and asparaginase in the treatment of adults with refractory and relapsed acute myelogenous leukemia: a study from the CALGB. J Clin Oncol 1988; 6:499-508.
    c. Dillman RO, **Davis RB**, Green MR, Weiss RB, Gottlieb AJ, Caplan S, Kopel S, Preisler H, McIntyre OR, Schiffer C. A comparative study of two different doses of cytarabine for acute myeloid leukemia: a phase III trial of Cancer and Leukemia Group B. Blood 1991; 78:2520-6.
    d. Mayer RJ, **Davis RB**, Schiffer CA, Berg DT, Powell BL, Schulman P, Omura GA, Moore JO, McIntyre OR, Frei E. Intensive postremission chemotherapy in adults with acute myeloid leukemia. N Engl J Med 1994; 331:896-903.
4. While at Harvard School of Public Health, I collaborated with the NIAID AIDS Clinical Trials Group. Within the Statistical and Data Analysis Center, I was Section Head for Opportunistic Infections studies, the Co-Chair of the Study Design Review Committee and a member of the Analysis Review Committee. I was the statistician for numerous clinical trials for treatment of cytomegalovirus infections, pneumocystis carinii pneumonia and herpes simplex infections, with responsibility for design, monitoring, analysis and reporting of results.
    a. Safrin S, Crumpacker C, Chatis P, **Davis R**, Hafner R, Rush J, Landry B, Mills J. A controlled trial comparing foscarnet with vidarabine for acyclovir-resistant mucocutaneous herpes simplex infection in the acquired immunodeficiency syndrome. N Engl J Med 1991; 325:551-5.
    b. Sattler FR, Frame P, **Davis R**, Nichols L, Shelton B, Akil B, Baughman R, Hughlett C, Weiss W, Boylen CT, van der Horst C, Black J, Powderly W, Steigbigel RT, Leedom JM, Masur H, Feinberg J. Trimetrexate with leucovorin versus trimethoprim-sulfamethoxazole for moderate to severe episodes of pneumocystis carinii pneumonia in patients with AIDS: a prospective, controlled multicenter investigation of the AIDS Clinical Trials Group protocol 029/031. J Infect Dis 1994; 170:165-72.
    c. Jacobson MA, Wulfsohn M, Feinberg JE, **Davis R**, Power M, Owens S, Causey D, Heath-Chiozzi ME, Murphy RL, Cheung TW, Dieterich DT, Spector SA, McKinley GF, Parenti DM, Crumpacker C. Phase II dose-ranging trial of foscarnet salvage therapy for cytomegalovirus retinitis in AIDS patients intolerant of or resistant to ganciclovir (ACTG protocol 093). AIDS 1994; 8:451-9.
    d. Ives DV, **Davis RB**, Currier JS. Impact of the introduction of clarithromycin and azithromycin on patterns of treatment and survival among AIDS patients with disseminated mycobacterium avium complex. AIDS 1995; 9:261-6.
5. Since coming to Beth Israel Deaconess Medical Center, I have participated extensively in clinical and health services research projects. I was the lead author on an innovative project to evaluate nursing assessments of functional status as an independent predictor of in-hospital mortality. This project leveraged our medical center's vanguard clinical informatics system to merge patient data from a variety of sources within the hospital. The study demonstrated that the nursing assessments were the best predictors of patient outcomes. The other 3 papers are from a project to validate the Complications Screening Program (CSP), an algorithm to identify potentially preventable complications of hospital care based on claims data. I was responsible for all statistical aspects of the project including the development and implementation of the analytic plan, interpretation of study results and drafting portions of the manuscript. On the strength of these validation studies, several of the CSP screens form the basis of AHRQ's patient safety indicators (PSIs).

a. **Davis RB**, Iezzoni LI, Phillips RS, Reiley P, Coffman GA, Safran C. Predicting in-hospital mortality: the importance of functional status information. Med Care 1995; 33:906-21.
b. Lawthers AG, McCarthy EP, **Davis RB**, Peterson LE, Palmer RH, Iezzoni LI. Identifying in-hospital complications from claims data: is it valid? Med Care 2000; 38:785-795.
c. Weingart SN, Iezzoni LI, **Davis RB**, Palmer RH, Cahalane M, Hamel MB, Mukamal K, Phillips RS, Davies DT, Banks NJ. Use of administrative data to find substandard care: validation of the Complications Screening Program. Med Care 2000; 38:796-806.
d. McCarthy EP, Iezzoni LI, **Davis RB**, Palmer RH, Cahalane M, Hamel MB, Mukamal K, RS, Davies DT. Does clinical evidence support ICD-9-CM coding of complications? Med Care 2000; 38:868-76.

A complete list of my 300+ published manuscripts may be found at:
https://www.ncbi.nlm.nih.gov/sites/myncbi/roger.davis.2/bibliography/51199579/public/?sort=date&direction=ascending

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

R01 HL125379 (Mullington, PI) 08/19/2016 – 06/30/2021
Mechanisms Underlying the Blood Pressure Lowering Effect of Sleep Extension
We will conduct a randomized clinical trial to test the efficacy of an individualized sleep extension intervention in the treatment of pre-hypertension and stage 1 hypertension.
Role: Biostatistician

R01 CA181357 (Schonberg, PI) 06/12/2014 – 05/31/2020
NIH NCI
Randomized Trial of a Mammography Decision Aid for Women Aged 75 and Older
The aim of this grant is to test the efficacy of a previously developed decision aid on mammography screening for women ≥75 years in a large cluster randomized controlled trial. This study will be conducted at an academic primary care clinic in Boston, three community clinics in Boston, and an academic internal medicine and family practice clinic affiliated with the University of North Carolina.
Role: Co-Investigator

UL1 TR002541 (Nadler, PI) 05/01/2018 - 04/30/2023
NIH NCATS
Harvard Clinical and Translational Science Center
This grant project in conjunction with funding from Harvard institutions catalyzes and transforms clinical / translational research throughout Harvard.
Role: Biostatistician

R01 AT008573 (Lembo/Kaptchuk, PI) 07/01/2015 - 06/30/2020
NIH NCCIH
Efficacy of Open-label and Double-blind Placebo and Peppermint Oil in IBS
We propose to conduct a randomized controlled clinical trial comparing peppermint oil to placebo and comparing blinded treatment to open-label treatment in patients with irritable bowel syndrome.
Role: Co-Investigator

R01 AG065554 (Subramaniam) 09/30/2019 – 05/31/2024
NIH NIA
Scheduled Prophylactic 6-Hourly IV Acetaminophen to Prevent Postoperative Delirium in older Cardiac Surgery Patients
To conduct a multicenter randomized controlled clinical trial of IV acetaminophen versus placebo in patients age 60 or older to study the impact on: the incidence, duration and severity of postoperative delirium; the use

of opioids and other rescue analgesics in the first 48 hours after surgery; pain scores and length of stay in the ICU and overall hospital length of stay; and longer-term cognitive, physical and self-care functional recovery after surgery.
Role: Co-Investigator

K24 AT009465 (Yeh, PI) 05/01/2017 – 04/30/2022

NCCIH
Mentoring and Patient-Oriented Research in Mind-Body Exercise
To conduct rigorous research evaluating the clinical efficacy and mechanisms of mind-body therapies, apply innovative methodology and investigate the complex array of patient factors that impactengagement and adherence. Provide a diverse, creative and supportive research environment to mentor and train junior investigators in integrative medicine research.
Role: Biostatistician

R01 GM104987 (Goldberger, PI) 07/01/2015 – 06/30/2020

NIH NIGMS
Research Resource for Complex Physiologic Signals
The goals of this study are 1. Accelerate PhysioNet's growth with new technology and data; 2. Drive relevant innovation through a vigorous research program on complex physiologic signals; and 3. Stimulate and challenge a growing community of investigators.
Role: Biostatistician

R56 AR075964 (Alkalay, PI) 09/25/2019 – 08/31/2020

NIH NIAMS
Predicting Fracture Risk in Patients Treated with Radiotherapy for Spinal Metastatic Disease
The goals are to test the performance of computed tomography-based structural analysis (CT-SAP) to predict the risk of vertebral fractures in patients with metastatic spinal disease undergoing radiotherapy and evaluate whether addition of CT-SAP improves prediction of fracture in existing models.
Role: Biostatistician

Completed Research Support

R01 AT006358 (Yeh, PI) 09/29/2012 – 07/31/2019

NIH NCCAM
Tai Chi After Pulmonary Rehabilitation in Patients with COPD
This study examines Tai Chi, a low-moderate intensity mind-body exercise that may be helpful in maintaining the benefits of exercise after pulmonary rehabilitation in persons with COPD.
Role: Co-Investigator