

BIOGRAPHICAL SKETCH

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NAME: Hui Zheng

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

POSITION TITLE: Assistant Professor of Medicine

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
Beijing University, Beijing, China	B.S.	07/94	Applied Mathematics
Texas A&M University, College Station, TX	M.S.	05/98	Applied Mathematics
University of Michigan, Ann Arbor, MI	M.S.	12/02	Biostatistics
University of Michigan, Ann Arbor, MI	Ph.D.	04/03	Biostatistics
Harvard Medical School, Boston, MA	Postdoctoral Fellow	01/03	Biostatistics

A. Personal Statement

I am a faculty member in Harvard Medical School and Massachusetts General Hospital. I have over 16 years of research experience in biostatistics, with specific training and expertise in medical research. I am co-investigator in a number of clinical trials. My interest in biostatistical research lead to multiple online software applications. I have made important and well-cited contributions to cancer and diabetes research studies particularly related to the analysis of blood glucose data.

As a faculty member in Harvard Medical School, I further expanded my statistical research to in clinical trials and applied statistics. As co-Investigator on institution- and NIH-funded grants, I provided statistical expertise in the design of clinical trials and developed statistical methodologies that lead to publications in top medical and statistical journals including NEJM, Lancet and JAMA. My recent research interests are focused on machine learning and artificial intelligence.

In summary, I have a demonstrated record of successful and productive contributions to the proposed area of study to serve as a co-investigator in this research project.

B. Positions and Honors**Positions and Employment**

1995–1998	Teaching Assistant, Texas A&M University, Department of Mathematics
1998–2003	Research Assistant, University of Michigan, Department of Biostatistics
2000–2001	Leslie Kish Founders Research Assistant, University of Michigan, Institute of Social Research, Survey Research Center
2003–2004	Postdoctoral Fellow, Harvard Medical School, Department of Health Care Policy
2004–2007	Instructor in Medicine, Harvard Medical School, Massachusetts General Hospital
2007–	Assistant Professor in Medicine, Harvard Medical School, Massachusetts General Hospital

Other Experience and Professional Memberships

2000–	Member, American Statistical Association
2000–	Member, International Biometric Society, Eastern North American Region
2006–	Member, Society for Medical Decision Making

Honors

2000	Leslie Kish Founders GSRA Award, Survey Research Center, Institute of Social Research, University of Michigan
2002	University of Michigan Rackham Graduate School Travel Grant
2010	Partners in Excellence Award(team), Massachusetts General Hospital

C. Contributions to Science

1. Bayesian Nonparametric Models

I developed statistical methods using smoothing splines, including penalized splines and B-splines in hierarchical models. The methods assume flexible mean using splines while accounting for correlations due to clustering or repeated measurements. I apply these models in a number of fields, including survey sampling and diabetes research.

- a. Little, R.J.A. and Zheng, H. (2006), "The Bayesian Approach to the Analysis of Finite Population Surveys", *Bayesian Statistics 8*, J.M. Bernardo, M.J. Bayarri, J.O. Berger, A.P. Dawid, D. Heckerman, A.F.M. Smith and M. West(Eds.), 283-302 (with discussion and rejoinder) Oxford: Oxford University Press.
- b. Zheng, H. and Little, R.J.A. (2005), "Inference for the Population Total from Probability-Proportional-to-Size Samples Based on Predictions from a Penalized Spline Nonparametric Model", *Journal of Official Statistics*, 21-1, 1-20.
- c. Zheng, H. and Little, R.J.A. (2004), "Penalized-spline Nonparametric Mixed Models for Inference about a Finite Population Mean from Two-stage Samples", *Survey Methodology*, 30-2, 209-218.
- d. Schoenfeld, D, Zheng, H, and Finkelstein, D, (2009), "Bayesian Design Using Adult Data to Augment Pediatric Trials", *Clinical Trials* 2009 6(4):297-304

2. Cancer

I have been involved in gastrointestinal cancer research through my collaborations with clinical investigators at Harvard Cancer Center (HCC) and Dana Farber Cancer Institute (DFCI).

- a. Ng K, Nimeiri HS, McCleary NJ, Abrams TA, Yurgelun MB, Cleary JM, Rubinson DA, Schrag D, Miksad R, Bullock AJ, Allen J, Zuckerman D, Chan E, Chan JA, Wolpin BM, Constantine M, Weckstein DJ, Faggen MA, Thomas CA, Kournioti C, Yuan C, Ganzer C, Wilkinson B, Mackintosh C, Zheng H, Hollis BW, Meyerhardt JA, Fuchs CS (2019), "Effect of High-Dose vs Standard-Dose Vitamin D3 Supplementation on Progression-Free Survival Among Patients With Advanced or Metastatic Colorectal Cancer: The SUNSHINE Randomized Clinical Trial", *JAMA* 2019 Apr 9;321(14):1370-1379
- b. Zhu, AX, Meyerhardt, JA, Blaszkowsky, LS, Kambadakone, AR, Muzikansky, A, Zheng, H, Clark, JW, Abrams, TA, Chan, JA, Enzinger, PC, Bhargava, P, Kwak, EL, Allen, JN, Jain, SR, Stuart, K, Horgan, K, Sheehan, S, Fuchs, CS, Ryan, DP, Sahani, DV, "Efficacy and safety of gemcitabine, oxaliplatin, and bevacizumab in patients with advanced biliary tract cancers and correlation of fluorodeoxyglucose positron emission tomography changes with clinical outcome: a phase II study", *Lancet Oncology*, 2010 Jan;11(1):48-54(PMID: 19932054)
- c. Chan JA, Blaszkowsky L, Stuart K, Zhu AX, Allen J, Wadlow R, Ryan DP, Meyerhardt J, Gonzalez M, Regan E, Zheng H, Kulke MH, 2013, "A Prospective, Phase I/II Study of Everolimus and Temozolomide in Patients with Advanced Pancreatic Neuroendocrine Tumor", *Cancer*, 2013, 119(17):3212-8
- d. Goyal L, Zheng H, Yurgelun M, Abrams TA, Allen JN, Cleary JM, Knowles M, Regan E, Reardon A, Khachatryan A, Jain RK, Nardi V, Borger DR, Duda GD, Zhu AX 2017, "A Phase II and Biomarker Study of Cabozantinib in Patients with Advanced Cholangiocarcinoma", *Cancer*, 2017 Feb 13. Jun 1;123(11):1979-1988

3. Diabetes

I developed B-spline based approaches for assessing blood glucose patterns in individuals and patient group using continuous glucose monitoring (CGM) data. These methods summarize multiple days of CGM data into an average blood glucose pattern over a 24-hour period. They make it possible to make statistical comparisons of glucose patterns in different patients or patient groups. They can also help physicians estimate and predict risks of hyperglycemia or hypoglycemia.

- a. I also participated in a multi-center clinical trials studying the relationship between HbA1c and blood glucose, and several trials studying the safety and efficacy of bionic pancreas.
- b. Zheng, H, Nathan, DM, Schoenfeld, DA (2011), "Using A Multi-Level B-Spline Model to Analyze and Compare Patient Glucose Profiles Based on Continuous Monitoring Data", Diabetes Technology and Therapeutics, June 2011, 13(6): 675-682, PMID: 21488799
- c. Nathan, DM., Kuenen, J, Borg, R, Zheng, H, Schoenfeld, D, Heine, RJ, The A1c-Derived Average Glucose (ADAG) Study Group, (2008), "Translating the A1c Assay into Estimated Average Glucose Values", Diabetes Care, 31(8) 1473-1478, PMID:18540046
- d. Crane PK, Walker R, Hubbard RA, Li G, Nathan DM, Zheng H, Haneuse S, Craft S, Montine TJ, Kahn S, McCormick W, McCurry S, Bowen JD, Larson EB (2013), "Glucose Levels and Risk of Dementia", New England Journal of Medicine, 2013, 369:540-548
- e. El-Khatib, FH, Balliro C, Hillard MA, Magyar KL, Ehklaspour L, Sinha M, Mondesir D, Esmaeili A, Hartigan C, Thompson MJ, Malkani S, Lock JP, Harlan DM, Clinton P, Frank E, Wilson D, DeSalvo D, Norlander L, Ly T, Buckingham B, Diner J, Dezube M, Young LA, Goley A, Kirkman S, Buse JB, Zheng H, Selagamsetty RR, Damiano ER, Russell SJ (2016), "Home use of a bihormonal bionic pancreas vs insulin pump therapy in adults with type 1 diabetes: A multicenter randomized clinical trial", Lancet, 2016, Published online December 19, 2016 [http://dx.doi.org/10.1016/S0140-6736\(16\)32567-3](http://dx.doi.org/10.1016/S0140-6736(16)32567-3)

4. Anesthesia

I have been involved in anesthesia research through my collaborations with clinical investigators at Harvard Medical School and Massachusetts General Hospital.

- a. Peng M, Zhang C, Dong Y, Zhang Y, Nakazawa H, Kaneki M, Zheng H, Shen Y, Marcantonio ER, and Xie Z, "Battery of behavioral tests in mice to study postoperative delirium", 2016, Nature Scientific Reports, 6:29874 | DOI: 10.1038/srep29874
- b. Yuan J, Cui G, Li W, Zhang X, Wang X, Zheng H, Zhang J, Xiang S, Xie Z, "Propofol Enhances Hemoglobin-Induced Cytotoxicity in Neurons", 2016, Apr;122(4):1024-30 Anesthesia & Analgesia. PMID: 26771264, PMCID:PMC5123442
- c. Xie Z, Swain CA, Ward SAP, Zheng H, Dong Y, Sunder N, Burke DW, Escobar D, Zhang Y, Marcantonio ER "Preoperative cerebrospinal fluid b-Amyloid/Tau ratio and postoperative delirium", Annals of Clinical and Translational Neurology, 2014 May 1;1(5):319-328, PMID: 24860840; PMCID: PMC4029597

5. Other clinical research

I also have experiences in research in health policy and surgery.

My Bibliography public URL: http://www.ncbi.nlm.nih.gov/sites/myncbi/1Z33GM_T2T-QO/bibliography/49902557/public/?sort=date&direction=ascending

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

Ongoing Research Support

5P30 CA06516-51

(PI:Nathan)

12/01/16-11/30/21

NIH-NCI

Cancer Center Support Grant (Biostatistics CORE)

The major goals of this project are to support CORE activities that represent shared resources used by a variety of investigators in different labs throughout the DF/HCC. This is a subcontract through the Dana-Farber Cancer Institute.

1R01CA205406-01A1

(PI:Ng)

03/15/17-02/28/22

NIH

Novel randomized controlled trials of vitamin D supplementation in patients with colorectal cancer: Impact on survival and biology

The major goals to test the hypothesis that vitamin D supplementation to achieve sufficient levels of 25(OH)D leads to improved survival in colorectal cancer patients and influences several neoplastic pathways that can be exploited as biomarkers of efficacy and targets for novel treatment strategies.

1R01DK119699-01 (Putman) 01/16/19 - 12/31/23

NIH/NIDDK

Clinical studies of a bionic pancreas for automated glucose management in cystic fibrosis-related diabetes mellitus

The goal of this clinical trial is to evaluate the safety and efficacy of fully automated artificial pancreas technology, the bionic pancreas, in the management of CF-related diabetes in both the inpatient and outpatient setting.

5R35HL135816-02 (Rowe) 01/15/17-12/31/23

UAB/NHLBI/NIH

Translation Program in CFTR-Related Airway Disease

Goals of project: to provide technical support to the existing uOCT technology located in the Rowe laboratory at UAB, assistance in data analysis.

(Kabrhel) 04/15/15-09/30/23

Janssen Scientific Affairs

Outpatient Treatment of Pulmonary Embolism and Deep Vein Thrombosis with Rivaroxaban – Impact of a New Protocol on Emergency Department Efficiency and Patient Safety

The major goals of this project: Multicenter study to identify the effect of a novel outpatient management strategy for patients with deep vein thrombosis and low risk pulmonary embolism on emergency department operational metrics and patient safety.

1U01CA233360-01 (Lee, Hakho) 09/01/18 - 07/31/23

NIH-NCI National Cancer Institute

Early Detection through Novel OCEAN Technology – Ovarian Cancer Exosomal Analysis with Nanoplasmonics (MPIs)

The major goals are to translate a novel liquid biopsy platform for early cancer detection. Specifically, we will advance a forward-thinking nano-plasmonic platform for comprehensive, high-throughput molecular analyses of extracellular vesicles (EVs). As a targeted cancer application, the patient-oriented study will rigorously address EVs' clinical utility for early detection of ovarian cancer.

1R01CA229777-01 (Lee, Hakho) 07/01/18 - 06/30/23

NIH-NCI National Cancer Institute

Clinical platform for high-throughput analyses of extracellular vesicles

The goal of this proposal is i) to address such technical challenges by advancing a robust platform for EV protein analyses, and ii) to rigorously evaluate EVs' clinical value as cancer biomarkers.

R01 AGO62509 (Xie, Zhongcong) 04/15/19 - 03/31/24

NIH

Postoperative Delirium and Alzheimer's Disease Related Dementias

The major goals for the project are to provide statistical support.

1R01DK118509-01 (Tearney) 07/01/18-06/30/22

NIH

Less invasive assessment of inflammation and subepithelial remodeling in eosinophilic esophagitis patients
The major goal of this project is to develop and validate a less invasive swallowable capsule that quantifies both eosinophils and subsurface remodeling

Completed Research Support

K24 K24DK078772-06

(PI: Raymond Chung)

09/01/12-08/31/17

NIH
Patient-Oriented Research on Hepatitis in Special Populations
Mid-Career Investigator Award in Patient-Oriented Research to allow PI to mentor fellows and junior faculty in initiation of patient-oriented research careers in the study of HCV-related disease in special populations, predominantly in (a) HCV and HIV coinfection and (b) the relationship between HCV and insulin resistance and initiate innovative pilot clinical trials in difficult to treat HCV-related liver disease based on key observations from our mechanistic work.
Co-investigator

4P50CA127003-09

(PI: Finkelstein)

09/23/13-6/30/18

NIH-NCI
DF/HCC SPORE in Gastrointestinal Cancer
This application represents the competitive renewal of a Specialized Program of Research Excellence (SPORE) in Gastrointestinal Cancer originating from the Gastrointestinal (GI) Malignancies Program of the Dana-Farber/Harvard Cancer Center (DF/HCC). Five major projects are proposed including: 1) Molecular imaging for detection of high grade dysplasia in Barrett's Esophagus; 2) Defining the role of vitamin D in colorectal carcinogenesis and cancer survival; 3) Identifying novel therapeutic strategies for KRAS-mutant colorectal cancer; 4) Overcoming resistance to RAF inhibition in BRAF-mutant colorectal cancer; and 5) Overcoming Resistance to KIT/PDGFR Inhibition in GIST. These projects will be integrated by three cores: 1) Administration, Evaluation & Planning; 2) Tissue & Pathology; and 3) Biostatistics & Bioinformatics.
Co-investigator

4K23 DK099422-04

(PI: Corey)

07/01/13-6/30/18

NIH/NIDDK
The Impact of Obstructive Sleep Apnea on Non-Alcoholic Fatty Liver Disease
The major goals of this project are to: 1) determine the prevalence of NAFLD in patients with OSA and to define clinical predictors of NAFLD in those patients, 2) evaluate oxidized lipids as mediators linking OSA and NAFLD, 3) evaluate the efficacy of CPAP therapy for the treatment of NAFLD
Co-investigator

P50CA127003

(PI: Charlie Fuchs)

02/01/13-11/30/18

NIH
GI Specialized Programs of Research Excellence program
The main goal of the DF/HCC SPORE in GI Cancer is the translation of biological and technological advances into improvements in prevention, diagnostics, predictors of outcome, and advances in the treatment of gastrointestinal malignancies.
Co-investigator

5R01CA184102-03

(Tearney)

06/04/14 - 05/31/19

NIH
Natural History of Barrett's Esophagus Using Capsule Endomicroscopy
The major goals of this project are: To develop TCE technology for screening the entire esophagus at the microscopic level and Determine the natural history of BE.

PUTMAN16A0

(PI: Putman)

09/01/16-08/31/19

NIH
Cystic Fibrosis Related Diabetes Glycemic Measurements Project. The major goals are the project are to provide statistical support.

5R01EB022077-03

(Tearney)

02/01/2016 - 01/31/20

NIBIB/NIH

In Vivo Laser Capture Microdissection

The major goal of this project is to develop a new biopsy technology that obtains microscopic images of entire organs, identifies specific sites of diseased tissue based on tissue microstructure, and isolates these tissues by adhering them to the device in vivo.