BIOGRAPHICAL SKETCH

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NAME: Lee-Jen Wei

eRA COMMONS USER NAME (credential, e.g., agency login): LWEI112

POSITION TITLE: Professor of Biostatistics, Harvard T.H. Chan School of Public Health

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
Fu-Jen University, Taipei, Taiwan	BS	06/1970	Mathematics
University of Wisconsin, Madison, WI	PhD	06/1975	Biostatistics

A. Personal Statement

For over 40 years, I have developed various statistical procedures for the design, monitoring and analysis of clinical trials, especially for studies with multiple outcomes. Quite a few procedures have been utilized routinely, for example, the Wei-Lachin, Wei-Johnson and Wei-Lin-Weissfeld methods. In the past ten years, I have been working on the personalized medicine and have developed statistical procedures to identify subset of patients systematically, which would benefit the most from the new treatment from a risk benefit perspective. Those procedures are mostly applicable to the clinical trial data so there is a causal interpretation for the treatment difference. I am also doing research on “translational statistics,” that is, translate basic statistical science research into decision makings for real world problems. The present proposal is one of the examples in translational statistics.

B. Positions and Honors

Positions and Employment

1975–1979 Assistant Professor of Statistics, University of South Carolina
1979–1980 Associate Professor of Statistics, University of South Carolina
1980–1981 Cancer Expert, National Cancer Institute
1981–1986 Professor of Statistics, George Washington University
1986–1988 Professor of Biostatistics and Statistics, U. of Michigan; Director, Biostatistics Unit, University of Michigan Cancer Center
1988–1991 Professor of Statistics and Human Oncology, University of Wisconsin
1991– Professor of Biostatistics, Harvard University
1994–1999 Associate Director, Statistical Center for AIDS Research, Harvard University
1997– Prof. of Biostatistics, Department of Biostatistical Science, Dana-Farber Cancer Inst.

Honors

1986 Fellow, American Statistical Association
1987 Spiegelman Award for Outstanding Statistical Research in Public Health
1988 Elected Member for the International Statistical Association
1993 Fellow, Institute of Mathematical Statistics
2001 Greenberg Distinguished Lectureship, U. of North Carolina at Chapel Hill
2009 Wilks Award by American Statistical Association

C. Contributions to Science

1. I have developed numerous quantitative procedures for designing, monitoring and analyzing clinical studies. I proposed the urn design for clinical trials, which provides a restricted randomization scheme for allocating patients to the treatment groups. This design has been used for several large clinical trials. I also proposed the randomized play the winner rule, which tends to place more study patients on the better arm. This response adaptive design has been extensively discussed in the clinical trial and statistical literature and has been utilized in the ECMO and anti-depression drug studies. My colleagues and I were first introducing the concept of the allocation of the Type I error rate in the group sequential trials. We also developed the well-known procedure called WLW (Wei-Lin-Weissfeld), which has been extensively used in analyzing multiple outcomes in survival analysis. I am responsible for developing the robust variance estimate for the parametric estimate for the group contrast in survival analysis and is well known as the sandwich estimate. My colleagues and I developed several methods for model checking techniques in survival analysis, for example, the cumulative martingale residues. I developed the procedure for meta analysis for the case that the event rate is small. This method has been extensively utilized in drug development for safety studies.
   a. Lin, D.Y., Wei, L.J., Yang, I. and Ying, Z. (2000) “Robust inferences for counting processes under Andersen-Gill model,” Journal of the Royal Statistical Society. Series B, 62(4)711–730.
   b. Lin, D.Y., Wei, L.J. and Ying, Z. (2002) “Model-checking techniques based on cumulative residuals,” Biometrics, 58(1):1-12.
   c. Jin, Z., Lin, DY, Wei, L.J. and Ying, Z. (2003) “Rank-based inference for the accelerated failure time model,” Biometrika, 90(2):341–353.
   d. Tian, L., Zucker, D. and Wei, L.J. (2005) “On the Cox model with time-varying regression coefficients,” Journal of the American Statistical Association, 100(469):172–183.

2. In the past ten years, I have been working on the personalized medicine and have developed statistical procedures to identify subset of patients systematically, which would benefit the most from the new treatment from a risk benefit perspective. We are one of the leading group for personalize (or stratified) medicine.
   a. Zhao L, Tian L, Cai T, Claggett B, Wei LJ. Effectively selecting a target population for a future comparative study. J Am Stat Assoc. 2013 Jan 1;108(502):527-539. PubMed PMID: 24058223; PubMed Central PMCID: PMC3775385.
   b. Cai T, Tian L, Wong PH, Wei LJ. Analysis of randomized comparative clinical trial data for personalized treatment selections. Biostatistics. 2011 Apr;12(2):270-82. Epub 2010 Sep 28. PubMed PMID: 20876663; PubMed Central PMCID: PMC3062150.
   c. Claggett B, Tian L, Castagno D, Wei LJ. Treatment selections using risk-benefit profiles based on data from comparative randomized clinical trials with multiple endpoints. Biostatistics. 2015 Jan;16(1):60-72. Epub 2014 Aug 12. PubMed PMID: 25122189; PubMed Central PMCID: PMC4263228.

3. My colleagues and I have developed new procedures for comparing two groups with survival data without any model assumption basing the restricted mean survival time. Recently, my colleagues and I published papers in clinical journals, which provide a robust, clinically interpretable way to analyze survival data instead of using the routine hazard ratio estimate.
   a. Tian L, Zhao L, Wei LJ. Predicting the restricted mean event time with the subject’s baseline covariates in survival analysis. Biostatistics. 2014 Apr;15(2):222-33. Epub 2013 Nov 29. PubMed PMID: 24292992; PubMed Central PMCID: PMC3944973.
   b. Uno H, Claggett B, Tian L, Inoue E, Gallo P, Miyata T, Schrag D, Takeuchi M, Uyama Y, Zhao L, Skali H, Solomon S, Jacobus S, Hughes M, Packer M, Wei LJ. Moving beyond the hazard ratio in quantifying the between-group difference in survival analysis. J Clin Oncol. 2014 Aug 1;32(22):2380-5. Epub 2014 Jun 30. PubMed PMID: 24982461; PubMed Central PMCID: PMC4105489.
   c. Kim DH, Uno H, Wei LJ. Restricted Mean Survival Time as a Measure to Interpret Clinical Trial Results. JAMA Cardiol. 2017 Sep 6. PMCID: PMC Journal - In process
   d. Pak K, Uno H, Kim DH, Tian L, Kane RC, Takeuchi M, Fu H, Claggett B, Wei L. Interpretability of Cancer Clinical Trial Results Using Restricted Mean Survival Time as an Alternative to the Hazard Ratio. JAMA Oncol. 2017 Sep 21. PMCID: PMC5824272

Complete List of Published Work in MyBibliography: http://www.ncbi.nlm.nih.gov/sites/myncbi/lee-jen.wei.1/bibliography/40810955/public/?sort=date&direction=ascending

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

Ongoing Research Support

U01 AI068616 (Shapiro) 06/29/06–11/30/20
NIH/NIAID
Statistical and Data Management Center–Impact Leadership Group
Provides statistical and data management expertise and support to the IMPAACT Group to conduct studies on the treatment of HIV- infected children and of the prevention of mother to child transmission.
Role: Senior Statistician

U01 AI068634 (Hughes) 06/29/06–11/30/20 NIH/NIAID
Statistical and Data Management Center–AIDS Clinical Trials Group
Provides statistical and data management expertise and support to the AIDS Clinical Trials Group (ACTG) to conduct studies on the treatment of HIV-infected adults.
Role: Senior Statistician

R35 CA197449 (Lin) 08/05/15–07/31/22 NIH/NINDS
Statistical Methods for Analysis of Massive Genetic and Genomic Data in Cancer Research
Our ultimate goal is to use rich data sources to understand cancer etiology, risk and prognosis, and discover new effective strategies for cancer prevention, intervention and treatment. It has become increasingly evident that limited methods suitable for analyzing massive data have emerged as a bottleneck to effectively translate rich information into meaningful knowledge.
Role: Statistician

36C24E18D0048 (Cai) 08/31/18–08/30/23
Department of Veteran Affairs
Aim is to develop and apply bioinformatics approaches for phenotyping and analysis of high dimensional datasets directly translatable to clinical research studies. Role: Statistician

Completed Research Support

R01 AI024643 (Hughes) 07/15/11-06/30/16
NIH/NIAID
Statistical Methods in AIDS Research
The main goal of this project are to develop statistical models and methods to analyze various types of AIDS data and to better understand the natural history and future spread of the epidemic. Role: Co-Investigator

R01 GM079330 (Cai) 07/01/11-06/30/16
NIH/NIGMS
Robust Approaches to the Development and Evaluation of Prognostic Classifiers
The major aims of this project are applicable to event time endpoints as essential measures for monitoring disease progression or assessing the effects of a treatment.
Role: Senior Statistician

U01 HL121518 (Abman) 07/01/14–04/30/18
NIH/NHLBI

Data Fusion-A Self-Scaling, Open Source Registry Advancing Pediatric Pulmonary Vascular Disease Research
This proposal will compare the ability of two data sources, electronic health records (HER) and traditional prospective patient-based clinical and research data, to answer research questions regarding the natural history, longitudinal outcomes, and phenotypes of therapeutic response for pediatric PVD.
Role: Statistician

R01 HS022193 (Wang) 03/01/15-02/28/18
NIH/AHRQ

Methods for Studying Treatment Heterogeneity Using Large Observational Databases
The research propose a multi-phase program of research to develop, validate, apply and disseminate Methods for estimating and communicating individual level heterogeneity in effectiveness and safety (for a range of patient/clinician identified outcomes of interest) for non-randomized comparative effectiveness research.
Role: Consortium Investigator

R21 AG049385 (Zhao) 08/01/15-05/31/17
NIH/NIA

Optimal Older Donor and Recipient Matching to Enhance Liver Transplant Outcomes
The objective of this application is to improve donor-recipient matching for optimizing liver utilization and transplant outcomes of elderly donors and recipients. The proposed research is relevant to public health because the prevalence of end stage liver disease patients is increasing, and liver transplantation is the only definitive treatment option for these patients. These investigations will help to improve access to transplantation, organ allocation and utilization, graft survival, and short- and long-term outcomes of LT, especially for older donors and recipients.
Role: Consortium Investigator

No Number (Wei) 12/22/15-12/31/17

Pharmaceutical Research and Manufacturers of America
Making Inferences of the Treatment Effectiveness for a Specific Subpopulation in a Comparative Clinical Trial
The major aims is the development of new methods for dealing with statistical inference issues for small subgroups from clinical study data, and the application of these new methods to an existing database for illustration/validation.
Role: Principal Investigator

R01 GM085047 (Zheng) 09/04/09–04/30/19 NIH/NIGMS

Statistical Methods for Prospective Evaluation of Biomarkers
The project aim is to develop all the statistical tools for constructing and evaluating biomarkers based prediction rules in aiding medical decisions on disease surveillance and treatment plan. This includes 1) statistical tools for developing and validating biomarker based risk prediction algorithm for predicting outcome among a heterogeneous population; (2) prediction with serially measured biomarkers and the validation of predictive accuracy of such biomarkers; (3) quantitative tools for quantifying the incremental values of cancer markers over existing models under cost-effective designs. Role: Statistician